

Note No: EA/145/2021 Ref: EA/GEN/560/Vol.xiii

The Foreign Ministry of the Democratic Socialist Republic of Sri Lanka presents its compliments to all Diplomatic Missions and Honorary Consulates in Sri Lanka and has the honor to inform that the State Pharmaceuticals Corporation of Sri Lanka has invited bids for Supply of Surgical, Pharmaceutical and relevant Laboratory items.

Copies of relevant Procurement Notices are enclosed.

The Foreign Ministry of the Democratic Socialist Republic of Sri Lanka avails itself of this opportunity to renew to all Diplomatic Missions and Honorary Consulates in Sri Lanka the assurances of its highest consideration.

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All Diplomatic Missions and Honorary Consulates in Colombo

- CC: 1. General Manager / State Pharmaceuticals Corporation of Sri Lanka
 - 2. Mr. Saman Munasinghe (Manager Imports DHS /Pharma) / State Pharmaceuticals Corporation of Sri Lanka



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/131/22	29.06.2021 at 9.00 a.m.	37,000 Capsules of Acitretin Capsule 10mg	18.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/131/22

DATE OF ISSUE : 18TH MAY 2021

CLOSING DATE & TIME : 29TH JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00010

SR No.	Item Description/ Specification	<u>Quantity</u>	<u>Delivery</u>
01106601	Acitretin capsule 10mg Acitretin capsule 10mg	37,000 Capsules	37,000 Capsules – October 2022
	Packing; 10 Capsules in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 117,061.00 or USD 587.00.

Bid Bond should be submitted with valid up to 25.01.2022 together with the bid Bid should be valid till 26.12.2021.

Non refundable Bid Fee Rs. 3,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
 - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted.
 - document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Terms and Conditions of Bid/Instructions to Bidders

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per Annex III encashable on first written demand to the value stated against each item in the Annex 1 of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

DID NO /DID DEED	-1105		ANNE
BID NO./BID REFERE (TENDER NO.)	ENCE :		
DATE OF ISSUE	:		
CLOSING DATE & TI (SRI LANKAN TIME)	ME : :		
ORDER LIST NO. :			
	tem Specifications	Quantity	Delivery Schedule
Nos of Repre evaluation as tende		nples for th	ne item to be submitted for
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> **BID FOR THE SUPPLY OF** BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX – II(B)** to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 TERMS OF DELIVERY

- 8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/132/22	29.06.2021 at 9.00 a.m.	135,000g of Sulphur Precipitated Powder	18.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/132/22

DATE OF ISSUE : 18TH MAY 2021

CLOSING DATE & TIME : 29TH JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00010

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01104901	Sulphur Precipitated Powder	135,000 g	135,000 g
	Precipitated Sulphur BP or Precipitated Sulphur USP (As very fine, amorphours powder)		– June 2022
	Packing: 500g should be packed in well closed container		
	Note: 01. The shelf life of the product should be minimum of 24 months		

Representative Tender samples to be submitted for the evaluation.

Bid should be valid till 26.12.2021.

Non refundable Bid Fee Rs. 3,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be

extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

rejected.

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of $30\,^{\circ}\text{C}$ +/- $2\,^{\circ}\text{C}$ temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms

(L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
 - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Terms and Conditions of Bid/Instructions to Bidders

- Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;
- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

			ANIN	EX – 1
BID NO (TENDE	./BID REFERENCE :		ANN	<u> </u>
DATE C	F ISSUE :			
	IG DATE & TIME : NKAN TIME) :			
ORDER L	IST NO. :			
SR No.	Item Description/Specifications	Quantity	Delivery Schedule	
evalua	tion as tender samples.	-	ne item to be submitted for to be submitted along with	
Bid				
Bid Bor	nd valid till(date)		
Bid vali	dity period: Bid should be	valid till	(date)	
Bid Doo	cument Fee :			
(should	be paid in cash to SPC for eacl	h set of Bid Do	ocuments).	
MSD COI	NDITIONS OF SUPPLY			
1.				
		PLIES) ANNEX	- IIA Content of the cage to be a	<u>mende</u>
ad as follo	<u>ows;</u>			

> **BID FOR THE SUPPLY OF** BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX – II(B)** to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 TERMS OF DELIVERY

- 8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/133/22	29.06.2021 at 9.00 a.m.	8,000,000ml of Ortho- phthaladehyde Disinfectant Solution 0.55% w/v	18.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/133/22
DATE OF ISSUE : 18TH MAY 2021
CLOSING DATE & TIME : 29TH JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00010

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01105501	Ortho-Phthaladehyde disinfectant solution 0.55% w/v,	8,000,000ml	4,000,000ml - March
	Ortho-Phthaladehyde 0.55%w/v, disinfectant solution for reprocessing heat sensitive reusable and other suitable medical devices only as a high level disinfectant and not as a chemical sterilant.		2022 4,000,000ml – September 2022
	The product should have a valid registration certificate from NMRA.		
	2. The supplier should provide a certificate endorsing good manufacturing practice at the production facility (GMP) certification.		
	3. The strength of the solution should be 0.55% w/v.		
	4. The product should be virucidal, bactericidal (including mycobacteria), fungicidal and sporicidal.		
	5. The efficacy and suitability of the product as a high level disinfectant reprocessing should have been approved by the FDA, EU, WHO approved laboratory or a comparable approving authority.		
	6. Time for achieving high level disinfection should be within12 minutes when used for manual disinfection.		
	7. The product should be patient and user safe.		
	8. The product should produce negligible changes in either appearance or function of processed items, even after repeated re-cycling.		
	9. The product should not corrode instruments or cause deterioration of rubber, plastics, metals or other construction materials.		
	10. Adequate test strips should be provided to monitor minimum effective concentration.		
	11. An appropriate neutralizing agent should be provided with the product to be used before disposal after use.		
	12. The shelf life of the product should be minimum of 24 months.13. There should be a leaflet with each container giving relevant information such as chemical composition, instructions for use etc.		

14.	The strength of the solution should clearly be	
	indicated in the label. Label should have letters of	
	readable size. 15. Container size should be 1 litre	
	and should be screw capped.	
Pac	cking: 1000 ml	

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 97,600.00 or USD 489.00.

Bid Bond should be submitted with valid up to 25.01.2022 together with the bid Bid should be valid till 26.12.2021.

Non refundable Bid Fee Rs. 3,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items. The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

Format shall be according to Code 128 or 2D standards.

- Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

- 22. Maintenance of Cold Chain;
 - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
 - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
 - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
 - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
 - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.

- (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
 - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

with the performance bond.

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace

period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers

- on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Terms and Conditions of Bid/Instructions to Bidders

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance

& Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX – 1 to be amended to read as follows;

_	D./BID REFERENCE ER NO.)	:		ANNEX -
DATE (OF ISSUE	:		
CLOSII	NG DATE & TIME	:		
(SRI LA	ANKAN TIME)	:		
ORDER	LIST NO. :			
SR No.	Item		Quantity	Delivery Schedule
	D			
	Description/Specific Nos of Representat tion as tender samp	ive sar		ne item to be submitted for the
evalua Amoun Bid	Nos of Representat tion as tender samp	ive sar les.	nples for th	ne item to be submitted for the
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Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX – II(B)** to be amended to read as follows;

Heading of 2nd Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 TERMS OF DELIVERY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their

- Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/134/22	01.07.2021 at 9.00 a.m.	1,500,000 Tablets of Levetiracetam Tablets 250mg	19.05.2021	Rs. 12,500/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/134/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00305902	Levetiracetam tablets 250mg	1,500,000	1,500,000
	Levetiracetam tablets 250mg	Tablets	Tablets – June 2022
	Each coated tablet to contain 250mg of Levetiracetam		
	Note: 01.The shelf life of the product should be minimum of 24 months		
	Packing: 100 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 441,600.00 or USD 2,213.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 12,500.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.
 - When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.
- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.

5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

rejected.

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.
 Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)

If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.

- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.
 - Format shall be according to Code 128 or 2D standards.
 - Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges,

labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of $30\,^{\circ}\text{C}$ +/- $2\,^{\circ}\text{C}$ temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
 - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.

- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
 - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists).

The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.

- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eq. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.

- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Terms and Conditions of Bid/Instructions to Bidders

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.

- O8.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost, within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX -1 to be amended to read as follows;

				ANN	IEX – 1
)./BID REFERENCE ER NO.)	:			
DATE (OF ISSUE	:			
	NG DATE & TIME ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item Description/Specific	ations	Quantity	Delivery Schedule	
Amoun	der samples. It of Bid Bond : LKR Ind valid till	(or USD date)	n to be submitted for the evalu	
Bid val	idity period : Bid sho	uld be v	valid till	(date)	
Bid Do	cument Fee :		•••		
(should	be paid in cash to SPC	for eacl	h set of Bid Do	ocuments).	
MSD CO	NDITIONS OF SUPPLY				
1. 2.					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX – II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)
 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/135/22	01.07.2021 at 9.00 a.m.	2,240,000 Tablets of Levetiracetam Tablets 500mg	19.05.2021	Rs. 12,500/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/135/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00305901	Levetiracetam tablets 500mg	2,240,000	2,240,000
		Tablets	Tablets
	Levetiracetam tablets 500mg		June 2022
	Each coated tablet to contain 500mg of Levetiracetam		
	Note:		
	01. The shelf life of the product should be minimum of 24 months		
	Packing: 100 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 909,888.00 or USD 4,559.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 12,500.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the

information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)

If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.

- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

			<u>ANNEX – 1</u>			
_	D./BID REFERENCE : ER NO.)					
DATE	OF ISSUE :					
	NG DATE & TIME : ANKAN TIME) :					
ORDER	LIST NO. :					
SR No.	Item Description/Specification	Quantity	Delivery Schedule			
	Nos of Representative samples for the item to be submitted for the evaluation as tender samples.					
Amour	nt of Bid Bond : LKR	or USD	to be submitted along with the			
Bid						
Bid Bo	nd valid till	(date)				
Bid validity period : Bid should be valid till (date)						
Bid Document Fee :						
(should	be paid in cash to SPC for e	each set of Bid D	ocuments).			
MSD CO	NDITIONS OF SUPPLY					
1.						

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/136/22	01.07.2021 at 9.00 a.m.	7,500 Vials of Dexmedetomidine Hydrochloride Injection 200mcg/2ml vial	19.05.2021	Rs. 12,500/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5

TENDER NO. : DHS/P/WW/136/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00308101	Dexmedetomidine Hydrochloride injection	7,500	4,000 Vials
	200mcg/2ml vial	Vials	January
			2022
	Dexmedetomidine Hydrochloride injection 200mcg/2ml vial		3,500 Vials - June 2022
	Packing: 10 Vials in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 330,000.00 or USD 1,654.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid

Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 12,500.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the

information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)

If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.

- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.
 - Format shall be according to Code 128 or 2D standards.
 - Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
 - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
 - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
 - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
 - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

			ANNEX	<u>(– 1</u>		
_	D./BID REFERENCE : ER NO.)					
DATE (OF ISSUE :					
	NG DATE & TIME : ANKAN TIME) :					
ORDER	LIST NO. :					
SR No.	Item	Quantity	Delivery Schedule			
	Description/Specifications)				
	Nos of Representative samples for the item to be submitted for the evaluation as tender samples.					
Amour	nt of Bid Bond : LKR	or USD	to be submitted along with	the		
Bid						
Bid Bo	nd valid till	. (date)				
Bid validity period : Bid should be valid till (date)						
Bid Document Fee :						
(should be paid in cash to SPC for each set of Bid Documents).						
MSD CO	NDITIONS OF SUPPLY					
1.						

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/137/22	01.07.2021 at 9.00 a.m.	760,000 Tablets of Ropinirole Tablets 0.5mg	19.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/137/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00307301	Ropinirole tablets 0.5mg	760,000	380,000
		Tablets	Tablets
	Ropinirole tablets 0.5mg		February
	Each coated tablet to contain Ropinirole hydrochloride		2022
	equivalent to 0.5mg of Ropinirole base.		
			380,000
	Note:		Tablets
	01. The shelf life of the product should be		– July 2022
	minimum of 24 months		
	Packing: 100 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 3,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the

information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)

If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.

- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

	/DID DEEEDENGE		ANNEX -
	./BID REFERENCE ER NO.)	:	
DATE (OF ISSUE	:	
	NG DATE & TIME NKAN TIME)	: :	
ORDER I	LIST NO. :		
SR No.	Item	Quantity	
	Description/Specificati	-	Delivery Schedule
	Description/Specificati	samples for	
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<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 TERMS OF DELIVERY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted

- in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/138/22	01.07.2021 at 9.00 a.m.	180,000 Capsules of Amantadine Capsule 100mg	19.05.2021	Rs. 12,500/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. TENDER NO. : DHS/P/WW/138/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00307201	Amantadine Capsules 100mg Amantadine Capsules 100mg Each capsule to contain 100mg of Amantadine BP or	180,000 Tablets	90,000 Tablets – January 2022
	Amantadine Hydrochloride USP Note: 01.The shelf life of the product should be minimum of 24 months when stored at a temperature range of 28'C-32'C		90,000 Tablets – June 2022
	02.The product should be kept in an airtight container and protected from light.03.Each pack should be labeled accordingly.Packing: 100 Capsules in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 541,080.00 or USD 2,711.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 12,500.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local

suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.

- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
 - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted
 - for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

 As an alternative, supplier can request MSD to take over the consignment on the same day, subject
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Terms and Conditions of Bid/Instructions to Bidders

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX – 1 to be amended to read as follows;

				ANNEX –
_	D./BID REFERENCE ER NO.)	:		
DATE	OF ISSUE	:		
	NG DATE & TIME ANKAN TIME)	:		
ORDER	LIST NO. :			
SR No.	Item Description/Specification	ations	Quantity	Delivery Schedule
evalua	tion as tender sampl	es.		ne item to be submitted for the
	nd valid till	('date)	
	lidity period : Bid sho			(date)
Bid Do	cument Fee :			
(should	be paid in cash to SPC	for eac	h set of Bid Do	ocuments).
MSD CO	NDITIONS OF SUPPLY			
1.				

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/139/22	01.07.2021 at 9.00 a.m.	700,000 Tablets of Quetiapine Tablets 100mg	19.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/139/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00306703	Quetiapine tablet 100mg	700,000	350,000
		Tablets	Tablets
	Quetiapine tablet 100mg		– March 2022
	Each tablet to contain 100mg of Quetiapine		
			350,000
	Note:		Tablets
	01. The shelf life of the product should be minimum of 24 months		– August 2022
	Packing: 100 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 42,000.00 or USD 211.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 3,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

 Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

			<u>ANNEX – 1</u>		
_	D./BID REFERENCE : ER NO.)				
DATE	OF ISSUE :				
	NG DATE & TIME : ANKAN TIME) :				
ORDER	LIST NO. :				
SR No.	Item Description/Specification	Quantity	Delivery Schedule		
	Nos of Representative stion as tender samples.	samples for t	ne item to be submitted for the		
Amour	nt of Bid Bond : LKR	or USD	to be submitted along with the		
Bid					
Bid Bo	nd valid till	(date)			
Bid val	lidity period: Bid should b	e valid till	(date)		
Bid Document Fee :					
(should	be paid in cash to SPC for e	each set of Bid D	ocuments).		
MSD CO	NDITIONS OF SUPPLY				
1.					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/140/22	01.07.2021 at 9.00 a.m.	125,000 Tablets of Quetiapine modified release	19.05.2021	Rs. 12,500/= + Taxes
		Tablets 200mg		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/140/22

DATE OF ISSUE : 19[™] MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00306702	Quetiapine Modified Release tablets 200mg	125,000	125,000
		Tablets	Tablets
	Quetiapine Modified Release tablets 200mg		 August 2022
	Each prolonged-release tablet to contains 200mg of		
	Quetiapine		
	Note: 01.The shelf life of the product should be minimum of 24 months		
	Packing: 100 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 577,875.00 or USD 2,896.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 12,500.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.
 - When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the

information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)

If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.

- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

				ANI	<u>NEX – 1</u>		
BID NO./BID REFERENCE : (TENDER NO.)							
DATE	OF ISSUE	:					
CLOSING DATE & TIME : (SRI LANKAN TIME) :		:					
ORDER	LIST NO. :						
SR No.	Item Description/Specificat	tions	Quantity	Delivery Schedule			
	Nos of Representative tion as tender sample		nples for th	ne item to be submitted fo	r the		
Amour	nt of Bid Bond : LKR		. or USD	to be submitted along wi	th the		
Bid							
Bid Bo	nd valid till	(date)				
Bid validity period : Bid should be valid till (date)							
Bid Do	cument Fee :						
(should	be paid in cash to SPC f	or eac	h set of Bid Do	ocuments).			
MSD CO	NDITIONS OF SUPPLY						
1.	1.						

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/141/22	01.07.2021 at 9.00 a.m.	1,400,000 Tablets of Quetiapine Tablets 25mg	19.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/141/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00306701	Quetiapine tablets 25mg	1,400,000	700,000 Tablets
		Tablets	February
	Quetiapine tablets 25mg		2022
	Each tablet to contain 25mg of Quetiapine		
			700,000 Tablets
	Note:		– July 2022
	01. The shelf life of the product should be minimum of 24 months		
	Packing: 100 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 169,400.00 or USD 849.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 3,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be

extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
 - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Terms and Conditions of Bid/Instructions to Bidders

- Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;
- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

			<u>ANNEX – 1</u>				
BID NO./BID REFERENCE : (TENDER NO.)							
DATE	OF ISSUE :						
	NG DATE & TIME : ANKAN TIME) :						
ORDER	LIST NO. :						
SR No.	Item Description/Specification	Quantity	Delivery Schedule				
	Nos of Representative stion as tender samples.	samples for t	ne item to be submitted for the				
Amour	nt of Bid Bond : LKR	or USD	to be submitted along with the				
Bid							
Bid Bo	nd valid till	(date)					
Bid validity period : Bid should be valid till (date)							
Bid Do	cument Fee :						
(should	be paid in cash to SPC for e	each set of Bid D	ocuments).				
MSD CO	NDITIONS OF SUPPLY						
1.	1.						

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/142/22	01.07.2021 at 9.00 a.m.	3,000,000 Capsules of Pregabalin Capsule 75mg	19.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/142/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00306601	Pregabalin capsule 75 mg	3,000,000	3,000,000
		Capsules	Capsules
	Pregabalin capsule 75 mg		– April 2022
	Each capsule to contain 75 mg of pregabalin.		
	Note:		
	01. The shelf life of the product should be minimum of 24 months.		
	Packing: 100 Capsules in a bottle		

Representative Tender samples to be submitted for the evaluation.

Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 3,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the

information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)

If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.

- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.
 - Format shall be according to Code 128 or 2D standards.
 - Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
 - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
 - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
 - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
 - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

				ANNE	X – 1
BID NO./BID REFERENCE (TENDER NO.)		:			
DATE	OF ISSUE	:			
CLOSING DATE & TIME (SRI LANKAN TIME)		:			
ORDER	LIST NO. :				
SR No.	R No. Item Quantity Delivery Schedule Description/Specifications				
evalua	tion as tender sampl	es.		ne item to be submitted for to be submitted along with	
	nd valid till	1	data)		
		_	-		
Bid val	lidity period : Bid sho	uld be \	alid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC	for each	n set of Bid Do	ocuments).	
MSD CO	NDITIONS OF SUPPLY				
1.					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/143/22	01.07.2021 at 9.00 a.m.	9,000,000 Capsules of Gabapentin Capsule 100mg	19.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5.

TENDER NO. : DHS/P/WW/143/22 DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00304302	Gabapentin Capsule 100mg	9,000,000	4,500,000
		Capsules	Capsules –
	Gabapentin Capsule 100mg		February 2022
	Each capsule to contain 100mg of Gabapentin USP		
			4,500,000
	Note:		Capsules – July
	01. The shelf life of the product should be minimum of 24 months.		2022
	Packing: 100 Capsules in a box		

Representative Tender samples to be submitted for the evaluation.

Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 3,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be

extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product,
 - document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Terms and Conditions of Bid/Instructions to Bidders

- Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;
- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

				ANNE	X – 1
BID NO./BID REFERENCE (TENDER NO.)		:			
DATE	OF ISSUE	:			
CLOSING DATE & TIME (SRI LANKAN TIME)		:			
ORDER	LIST NO. :				
SR No.	R No. Item Quantity Delivery Schedule Description/Specifications				
evalua	tion as tender sampl	es.		ne item to be submitted for to be submitted along with	
	nd valid till	1	data)		
		_	-		
Bid val	lidity period : Bid sho	uld be \	alid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC	for each	n set of Bid Do	ocuments).	
MSD CO	NDITIONS OF SUPPLY				
1.					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/144/22	01.07.2021 at 9.00 a.m.	3,500,000 Tablets of Sodium Valproate modified release Tablets 300mg	19.05.2021	Rs. 12,500/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/144/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00304005	Sodium Valproate modified release tablet	3,500,000	1,750,000
	300mg.	Tablets	Tablets
			- January 2022
	Sodium Valproate Prolonged-release tablet BP		
	300mg.		1,750,000
	Each prolonged-release tablet to contain 300mg of		Tablets
	Sodium Valproate BP		– June 2022
	OR		
	Sodium Valproate controlled -release tablet 300mg.		
	Each tablet to contain 300mg of Sodium Valproate,		
	Note:		
	1.The product should be stable for a minimum of 24		
	months when stored at a temperature range of 28'C-32'C.		
	2.The product should be packed in moisture proof		
	Strip pack.		
	Packing: 100 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 346,900.00 or USD 3,743.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 12,500.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-

requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

 Format shall be according to Code 128 or 2D standards.

 Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
 - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
 - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
 - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
 - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

23. In respect of the products requiring controlled temperature storage (Eg. $< 25 \, ^{\circ}\text{C}$, 2-25 $^{\circ}\text{C}$, 15-20 $^{\circ}\text{C}$ /30 $^{\circ}\text{C}$, 2-8 $^{\circ}\text{C}$ etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 $^{\circ}\text{C}$ +/- 2 $^{\circ}\text{C}$ & 75% +/- 5% RH for AC stored items and at 25 $^{\circ}\text{C}$ +/- 2 $^{\circ}\text{C}$ & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
 - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
 - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding

- defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.

- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.
 - Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.
 - Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.
- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15.Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available

for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.

17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Terms and Conditions of Bid/Instructions to Bidders

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

				ANNEX	<u>(– 1</u>
_	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
	NG DATE & TIME ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item Description/Specification	ations	Quantity	Delivery Schedule	
evalua	tion as tender sampl	es.		ne item to be submitted for t	
	nd valid till		(data)		
			-		
Bid val	idity period : Bid sho	uld be	valid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC	for eac	h set of Bid Do	ocuments).	
MSD CO	NDITIONS OF SUPPLY				
1.					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 TERMS OF DELIVERY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/145/22	01.07.2021 at 9.00 a.m.	9,000,000 Tablets of Paracetamol 500mg+ Codein 8mg (Co-codamol 8mg/500mg) tablet	19.05.2021	Rs. 12,500/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/145/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00305701	Paracetamol 500mg + Codein 8mg	9,000,000	9,000,000
	(Co-codamol 8mg/500mg) tablet	Tablets	Tablets
	Paracetamol 500mg + Codein phosphate 8mg tablet (Co-codamol tablet 8mg/500mg) Each tablet to contain 500mg of Paracetamol and 8mg of Codein phosphate		– April 2022
	Note: 01.The shelf life of the product should be minimum of 24 months.		
	02.Product should be protected from light		
	Packing: 100 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 842,400.00 or USD 4,221.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 12,500.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be

extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.

- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b), printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < $25 \,^{\circ}$ C, $2-25 \,^{\circ}$ C, $15-20 \,^{\circ}$ C /30 $\,^{\circ}$ C, $2-8 \,^{\circ}$ C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at $30 \,^{\circ}$ C +/- $2 \,^{\circ}$ C & 75% +/- 5% RH for AC stored items and at $25 \,^{\circ}$ C +/- $2 \,^{\circ}$ C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
 - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace

period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B – Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

<u>Sufficient quantity of Samples should be forwarded for evaluation</u>

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15.Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Terms and Conditions of Bid/Instructions to Bidders

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- O8.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

			ANNEX	<u>(– 1</u>		
_	D./BID REFERENCE : ER NO.)					
DATE (OF ISSUE :					
	NG DATE & TIME : ANKAN TIME) :					
ORDER	LIST NO. :					
SR No.	Item	Quantity	Delivery Schedule			
	Description/Specifications)				
	Nos of Representative setion as tender samples.	amples for t	ne item to be submitted for	the		
Amour	nt of Bid Bond : LKR	or USD	to be submitted along with	the		
Bid						
Bid Bo	nd valid till	. (date)				
Bid validity period : Bid should be valid till (date)						
Bid Document Fee :						
(should	be paid in cash to SPC for ea	ach set of Bid D	ocuments).			
MSD CO	NDITIONS OF SUPPLY					
1.						

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/146/22	01.07.2021 at 9.00 a.m.	50,000 Capsules of Atomoxetine HCl Capsule 10mg	19.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/146/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00305501	Atomoxetine HCl capsule 10mg	50,000	50,000
		Capsules	Capsules
	Atomoxetine hydrochloride capsule 10mg		– July 2022
	Each capsule to contain Atomoxetine hydrochloride		
	equivalent to 10mg of		
	Atomoxetine		
	Note:		
	01. The shelf life of the product should be minimum of 24 months.		
	Packing: 100 Capsules in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 32,420.00 or USD 163.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 3,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.
 - When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

 Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

				ANNE	X – 1
_	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
	NG DATE & TIME ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item Description/Specification	ations	Quantity	Delivery Schedule	
evalua	tion as tender sampl	es.		ne item to be submitted for to be submitted along with	
	nd valid till	1	data)		
		_	-		
Bid val	lidity period : Bid sho	uld be \	alid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC	for each	n set of Bid Do	ocuments).	
MSD CO	NDITIONS OF SUPPLY				
1.					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/147/22	01.07.2021 at 9.00 a.m.	3,000,000 Tablets of Topiramate Tablet 50mg	19.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/147/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00304502	Topiramate Tablet 50mg	3,000,000	3,000,000
		Tablets	Tablets
	Topiramate Tablet 50mg		– July 2022
	Each coated tablet to contain Topiramate 50mg		
	Note:		
	01. The shelf life of the product should be minimum of 24 months.		
	Packing: 100 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 103,200.00 or USD 518.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 3,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the

information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)

If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.

- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.
 - Format shall be according to Code 128 or 2D standards.
 - Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

				ANI	<u>NEX – 1</u>
BID NO./BID REFERENCE : (TENDER NO.)					
DATE	OF ISSUE	:			
CLOSING DATE & TIME (SRI LANKAN TIME)		:			
ORDER	LIST NO. :				
SR No.	Item Description/Specificat	tions	Quantity	Delivery Schedule	
Nos of Representative samples for the item to be submitted for the evaluation as tender samples.					
Amour	nt of Bid Bond : LKR		. or USD	to be submitted along wi	th the
Bid					
Bid Bo	nd valid till	(date)		
Bid validity period : Bid should be valid till (date)					
Bid Document Fee :					
(should	be paid in cash to SPC f	or eac	h set of Bid Do	ocuments).	
MSD CO	NDITIONS OF SUPPLY				
1.					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/148/22	01.07.2021 at 9.00 a.m.	2,000,000 Tablets of Topiramate Tablet 25mg	19.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/148/22

DATE OF ISSUE : 19[™] MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00304501	Topiramate Tablet 25mg	2,000,000	2,000,000
		Tablets	Tablets
	Topiramate Tablet 25mg		 August 2022
	Each coated tablet to contain Topiramate 25mg		
	Note: 01.The shelf life of the product should be minimum of 24 months.		
	Packing: 100 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 68,000.00 or USD 341.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 3,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.
 - All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).
- 6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

 Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

			<u>ANNEX – 1</u>			
BID NO./BID REFERENCE : (TENDER NO.)						
DATE	OF ISSUE :					
	NG DATE & TIME : ANKAN TIME) :					
ORDER	LIST NO. :					
SR No.	Item Description/Specification	Quantity	Delivery Schedule			
	Nos of Representative samples for the item to be submitted for the evaluation as tender samples.					
Amour	nt of Bid Bond : LKR	or USD	to be submitted along with the			
Bid						
Bid Bo	nd valid till	(date)				
Bid validity period : Bid should be valid till (date)						
Bid Document Fee :						
(should be paid in cash to SPC for each set of Bid Documents).						
MSD CO	NDITIONS OF SUPPLY					
1.						

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/149/22	01.07.2021 at 9.00 a.m.	800,000 Tablets of Lamotrigine Tablet 100mg	19.05.2021	Rs. 12,500/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5.

TENDER NO. : DHS/P/WW/149/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00304403	Lamotrigine tablet 100mg	800,000	400,000 Tablets
		Tablets	- January 2022
	Lamotrigine tablets BP 100mg		
	Each tablet to contain 100mg of Lamotrigine BP		400,000 Tablets
			– May 2022
	Note:		
	01. The shelf life of the product should be minimum		
	of 24 months		
	Packing: 50 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 489,120.00 or USD 2,451.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 12,500.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

 Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

			<u>ANNEX – 1</u>			
BID NO./BID REFERENCE : (TENDER NO.)						
DATE	OF ISSUE :					
	NG DATE & TIME : ANKAN TIME) :					
ORDER	LIST NO. :					
SR No.	Item Description/Specification	Quantity	Delivery Schedule			
	Nos of Representative samples for the item to be submitted for the evaluation as tender samples.					
Amour	nt of Bid Bond : LKR	or USD	to be submitted along with the			
Bid						
Bid Bo	nd valid till	(date)				
Bid validity period : Bid should be valid till (date)						
Bid Document Fee :						
(should be paid in cash to SPC for each set of Bid Documents).						
MSD CO	NDITIONS OF SUPPLY					
1.						

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/150/22	01.07.2021 at 9.00 a.m.	1,000,000 Tablets of Lamotrigine Tablet 50mg	19.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/150/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00304402	Lamotrigine tablet 50mg	1,000,000	1,000,000
		Tablets	Tablets
	Lamotrigine tablets BP 50mg		– June 2022
	Each tablet to contain 50mg of Lamotrigine BP		
	Note:		
	01.The shelf life of the product should be minimum of 24 months.		
	Packing: 30 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 104,400.00 or USD 524.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 3,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the

information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)

If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.

- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.
 - Format shall be according to Code 128 or 2D standards.
 - Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

			ANNEX -	<u>- 1</u>	
_	D./BID REFERENCE : ER NO.)				
DATE	DATE OF ISSUE :				
	NG DATE & TIME : ANKAN TIME) :				
ORDER	LIST NO. :				
SR No.	Item Description/Specification	Quantity ons	Delivery Schedule		
	Nos of Representative tion as tender samples.		ne item to be submitted for th	ıe	
Amour	nt of Bid Bond : LKR	or USD	to be submitted along with the	1e	
Bid					
Bid Bo	nd valid till	(date)			
Bid val	idity period : Bid should	be valid till	(date)		
Bid Do	cument Fee :				
(should	be paid in cash to SPC for	each set of Bid Do	ocuments).		
MSD CO	NDITIONS OF SUPPLY				
1.					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 TERMS OF DELIVERY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/151/22	01.07.2021 at 9.00 a.m.	1,000,000 Tablets of Lamotrigine Tablet 25mg	19.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5.

TENDER NO. : DHS/P/WW/151/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00304401	Lamotrigine tablet 25mg	1,000,000	1,000,000
		Tablets	Tablets
	Lamotrigine tablet 25mg		 August 2022
	Each tablet to contain Lamotrigine 25mg		
	Note: 01.The shelf life of the product should be minimum of 24 months.		
	Packing: 50 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 112,400.00 or 564.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 3,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the

information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)

If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.

- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.
 - Format shall be according to Code 128 or 2D standards.
 - Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

				ANNE	X – 1
_	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
	NG DATE & TIME ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item Description/Specification	ations	Quantity	Delivery Schedule	
evalua	tion as tender sampl	es.		ne item to be submitted for to be submitted along with	
	nd valid till	1	data)		
		_	-		
Bid val	lidity period : Bid sho	uld be \	alid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC	for each	n set of Bid Do	ocuments).	
MSD CO	NDITIONS OF SUPPLY				
1.					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/152/22	01.07.2021 at 9.00 a.m.	170,000 Tablets of Melatonin Tablet 2mg	19.05.2021	Rs. 12,500/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/152/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00306101	Melatonin tablets 2mg	170,000	170,000 Tablets
		Tablets	– June 2022
	Melatonin tablets 2mg		
	Each tablet to contains 2mg of Melatonin		
	Note:		
	01. The shelf life of the product should be minimum of 24 months		
	Packing: 100 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 300,560.00 or USD 1,506.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 12,500.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

 Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

				ANNE	X – 1
_	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
	NG DATE & TIME ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item Description/Specification	ations	Quantity	Delivery Schedule	
evalua	tion as tender sampl	es.		ne item to be submitted for to be submitted along with	
	nd valid till	1	data)		
		_	-		
Bid val	lidity period : Bid sho	uld be \	alid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC	for each	n set of Bid Do	ocuments).	
MSD CO	NDITIONS OF SUPPLY				
1.					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/153/22	01.07.2021 at 9.00 a.m.	180 Bottles of Haloperidol Syrup 2mg/1ml, 100ml	19.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/153/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00300804	Haloperidol Syrup 2mg/1ml, 100ml	180 Bottles	90 Bottles – January 2022
	Haloperidol Oral solution Bp/USP, 2mg/ml in 100ml Bottle. Each 1ml to contain 2mg of Haloeridol BP/USP in a suitable vehicle (free from sugar)		90 Bottles - May 2022
	Note: 1. This solution should be stable for a minimum of 24 months when stored under normal room temperature and protected from light Packing: 10 bottles in a box		
	Packing: 10 bottles in a box		

Representative Tender samples to be submitted for the evaluation.

Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 3,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.
 - All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).
- 6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

 Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

			ANNEX – 1
_	D./BID REFERENCE : ER NO.)		
DATE	OF ISSUE :		
	NG DATE & TIME : ANKAN TIME) :		
ORDER	LIST NO. :		
SR No.	Item Description/Specification	Quantity	Delivery Schedule
evalua	tion as tender samples.		ne item to be submitted for the
Bid			
Bid Bo	nd valid till	(date)	
Bid val	idity period : Bid should b	oe valid till	(date)
Bid Do	cument Fee :		
(should	be paid in cash to SPC for e	each set of Bid Do	ocuments).
MSD CO	NDITIONS OF SUPPLY		
1.			

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/154/22	01.07.2021 at 9.00 a.m.	440,000 Tablets of AmisulprideTablet 100mg	19.05.2021	Rs. 12,500/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/154/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00301302	Amisulpride tablet 100mg	440,000	220,000 Tablets
		Tablets	- January 2022
	Amisulpride tablet 100mg		000 000 Tableta
	Each tablet to contain 100mg of Amisulpride		220,000 Tablets
	BP/USP		– May 2022
	Note:		
	01. The shelf life of the product should be minimum		
	of 24 months.		
	Packing: 100 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 259,072.00 or USD 1,299.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 12,500.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.
 - When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.
 - All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).
- 6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

 Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

				ANNE	X – 1
_	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
	NG DATE & TIME ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item Description/Specification	ations	Quantity	Delivery Schedule	
evalua	tion as tender sampl	es.		ne item to be submitted for to be submitted along with	
	nd valid till	1	data)		
		_	-		
Bid val	lidity period : Bid sho	uld be \	alid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC	for each	n set of Bid Do	ocuments).	
MSD CO	NDITIONS OF SUPPLY				
1.					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/155/22	01.07.2021 at 9.00 a.m.	320,000 Tablets of AmisulprideTablet 200mg	19.05.2021	Rs. 12,500/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/155/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00301303	Amisulpride tablet 200mg	320,000	320,000 Tablets
		Tablets	– April 2022
	Amisulpride tablet 200mg		
	Each tablet to contain 200mg of Amisulpride		
	BP/USP		
	Note:		
	01.The shelf life of the product should be minimum		
	of 24 months.		
	Pooking: 10 Toblete in a hov		
	Packing: 10 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 313,984.00 or USD 1,574.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 12,500.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.
 - When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the

information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)

If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.

- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

			<u>ANNEX – 1</u>				
_	D./BID REFERENCE : ER NO.)						
DATE	OF ISSUE :						
	NG DATE & TIME : ANKAN TIME) :						
ORDER	LIST NO. :						
SR No.	Item Description/Specification	Quantity	Delivery Schedule				
	Nos of Representative stion as tender samples.	samples for t	ne item to be submitted for the				
Amour	nt of Bid Bond : LKR	or USD	to be submitted along with the				
Bid							
Bid Bo	nd valid till	(date)					
Bid validity period : Bid should be valid till (date)							
Bid Document Fee :							
(should	be paid in cash to SPC for e	each set of Bid D	ocuments).				
MSD CO	NDITIONS OF SUPPLY						
1.	1.						

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/156/22	01.07.2021 at 9.00 a.m.	10,000 Tablets of Sumatriptan Tablet 50mg	19.05.2021	Rs. 12,500/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/156/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00303501	Sumatriptan Tablet 50mg	10,000	5,000 Tablets
		Tablets	February
	Sumatriptan Tablet 50mg		2022
	Each tablet to contain 50mg of Sumatriptan		
	Succinate BP.		5,000 Tablets
			– July 2022
	Note:		
	01. The shelf life of the product should be minimum		
	of 24 months.		
	Packing: 100 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 625,082.00 or USD 3,132.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 12,500.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.
 - When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.
 - All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).
- 6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

 Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

			<u>ANNEX – 1</u>				
_	D./BID REFERENCE : ER NO.)						
DATE	OF ISSUE :						
	NG DATE & TIME : ANKAN TIME) :						
ORDER	LIST NO. :						
SR No.	Item Description/Specification	Quantity	Delivery Schedule				
	Nos of Representative stion as tender samples.	samples for t	ne item to be submitted for the				
Amour	nt of Bid Bond : LKR	or USD	to be submitted along with the				
Bid							
Bid Bo	nd valid till	(date)					
Bid validity period : Bid should be valid till (date)							
Bid Document Fee :							
(should	be paid in cash to SPC for e	each set of Bid D	ocuments).				
MSD CO	NDITIONS OF SUPPLY						
1.	1.						

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/157/22	01.07.2021 at 9.00 a.m.	15,000 Vials of Paracetamol 10mg/ml solution for infusion 100ml vial	19.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/157/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00004

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00303307	Paracetamol 10mg/ml solution for infusion	15,000	15,000 vials –
	100ml vial	vials	June 2022
	Paracetamol 10mg/ml solution for infusion Each 100ml glass vial to contain 10mg/1ml of Paracetamol BP or Acetaminophen USP, solution for infusion.		
	Note:		
	01. Each vial should be labeled accordingly.		
	02. The shelf life of the product should be minimum of 24 months		
	Packing: 10 vials in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 164,736.00 or USD 826.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 3,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.
 - When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

 Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

					ANNEX – 1
_	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
CLOSING DATE & TIME (SRI LANKAN TIME)		:			
ORDER	LIST NO. :				
SR No.	Item Description/Specifica		Quantity	Delivery Schedule	
evalua Amour	tion as tender sample	es.		ne item to be submitte	
Bid		(.1.	4		
RIG RO	nd valid till	(da	te)		
Bid val	lidity period : Bid sho	uld be val	id till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC	for each s	et of Bid Do	ocuments).	
MSD CO	NDITIONS OF SUPPLY				
1.					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/158/22	01.07.2021 at 9.00 a.m.	225,000 PF Syringes of Epoetin Injection 2,000 IU PF Syringe	19.05.2021	Rs. 12,500/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/158/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00021

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00404001	Epoetin injection 2,000 IU PF syringe	225,000	75,000 PF
		PF	Syringes
	Epoetin injection 2,000 IU Pre-filled syringe	Syringes	– March 2022
	Each pre-filled syringe to contain 2,000 IU of		75,000 PF
	Epoetin (Recombinant Human		Syringes
	Erythropoietin) in water for injection BP/USP for subcutaneous or intravenous injection.		– June 2022
			75,000 PF
	Note:		Syringes
	1. The product should be stable for minimum of 02 years when stored under 2'C-8'C.		– October 2022
	Each Pre-filled syringe should be labeled accordingly.		
	Packing: 10 PF Syringes in a box	_	

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 824,400.00 or USD 4,131.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 12,500.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.

- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
 - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of

supply.

- As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Terms and Conditions of Bid/Instructions to Bidders

- Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;
- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- O8.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX – 1 to be amended to read as follows;

			ANNEX – 1		
_	D./BID REFERENCE : ER NO.)				
DATE	DATE OF ISSUE :				
	NG DATE & TIME : ANKAN TIME) :				
ORDER	LIST NO. :				
SR No.	Item Description/Specification	Quantity	Delivery Schedule		
evalua	tion as tender samples.		ne item to be submitted for the		
Bid					
Bid Bo	nd valid till	(date)			
Bid val	idity period : Bid should b	oe valid till	(date)		
Bid Do	cument Fee :				
(should	be paid in cash to SPC for e	each set of Bid Do	ocuments).		
MSD CO	NDITIONS OF SUPPLY				
1.					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/159/22	01.07.2021 at 9.00 a.m.	6,800 Bottles of Protein Hydrolysate Injection 100ml	19.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5.

TENDER NO. : DHS/P/WW/159/22 TENDER NO. : DHS/P/WW/15 DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00021

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00402201	Protein Hydrolysate injection 100 ml	6,800	3,400 Bottles –
	Protein Hydrolysate injection USP in 100ml Bottle.	Bottles	May 2022
	Each 100ml solution to contain Amino Acids and short chain peptides which represents the approximate nutritive equivalent to the casein, Lactalbumin, plasma fibrin or other suitable protein which derived by the acid, enzymatic or other methods of hydrolysis. It may contain alcohol, Dextrose or other carbohydrate suitable for intravenous infusion not less than 50% of the total nitrogen present is in the form of L-amino Nitrogen for intravenous infusion for infants and children.		3,400 Bottles – September 2022
	Note: 1. The bottle should be graduated to 100ml and be made of medicinal grade Polyethylene or Polypropylene. PVC is not acceptable.		
	2. The bottle should have a device for hanging.		
	3. To prevent leakage of fluid with insertion or withdrawal of spike or continuous use the site of the insertion of piercing spike should be covered with a sterile rubber disk or bung and the plastic cover of the disk or bung should be fused to neck of the bottle right round.		
	4. Each bottle should be packed individually in a protective polyethylene cover.		
	5. The product should be sterile and stable for a minimum of 24 months within a temperature range of 30 C- 35 C.6. The bottle should be labelled accordingly.		
	Packing: 10 Bottles in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 113,091.00 or USD 567.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 3,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.

- (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth)
 - The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
- (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger

quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.

- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
 - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item,

quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
 - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

with the performance bond.

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)
 - If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.

36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.

Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.

- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Terms and Conditions of Bid/Instructions to Bidders

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per Annex III encashable on first written demand to the value stated against each item in the Annex 1 of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional

25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX -1 to be amended to read as follows;

ANNEX – 1 BID NO./BID REFERENCE (TENDER NO.) DATE OF ISSUE **CLOSING DATE & TIME** (SRI LANKAN TIME) **ORDER LIST NO. :** SR No. Item Quantity **Delivery Schedule Description/Specifications** Nos of Representative samples for the item to be submitted for the evaluation as tender samples. Amount of Bid Bond: LKR or USD to be submitted along with the Bid Bid Bond valid till(date) Bid validity period: Bid should be valid till (date) Bid Document Fee: (should be paid in cash to SPC for each set of Bid Documents). **MSD CONDITIONS OF SUPPLY** 1.

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX – II(B)** to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 TERMS OF DELIVERY

- 8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be

- borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/160/22	01.07.2021 at 9.00 a.m.	650 Vials of Botulinum Toxin 50 IU vial	19.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/160/22 DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00021

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00305302	Botulinum Toxin 50 IU vial	650 Vials	350 Vials – May 2022
	Botulinum A Toxin Each vial to contain 50IU of Botulinum A toxin haemaglutinin complex as sterile powder for reconstitution.		300 Vials – September 2022
	Note: 1.This injection should be stable for minimum of 24 months when stored at a temperature of 2'C-8'C		
	2.Each vial should be labelled accordingly.		
	Packing: 10 Vials in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 169,000.00 or USD 847.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 3,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all

suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

 Format shall be according to Code 128 or 2D standards.

 Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
 - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
 - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
 - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
 - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
 - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
 - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and

other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B – Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.

4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.

17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Terms and Conditions of Bid/Instructions to Bidders

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

				ANNEX	<u>(– 1</u>
BID NO./BID REFERENCE (TENDER NO.)		:			
DATE	OF ISSUE	:			
CLOSING DATE & TIME (SRI LANKAN TIME)		:			
ORDER	LIST NO. :				
SR No.	R No. Item Operation Description/Specifications			Delivery Schedule	
evalua	tion as tender sampl	es.		ne item to be submitted for t	
	nd valid till		(data)		
			-		
Bid val	idity period : Bid sho	uld be	valid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC	for eac	h set of Bid Do	ocuments).	
MSD CO	NDITIONS OF SUPPLY				
1.					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 TERMS OF DELIVERY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/161/22	01.07.2021 at 9.00 a.m.	4,700 Vials of Botulinum Toxin 100 IU vial	19.05.2021	Rs. 20,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5.

TENDER NO. : DHS/P/WW/161/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00021

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00305301	Botulinum Toxin 100 IU vial	4,700	2,500 Vials -
		Vials	March 2022
	Botulinum A Toxin		
	Each vial to contain 100 IU of Botulinum A toxin		2,200 Vials –
	haemaglutinin complex as sterile powder for reconstitution.		August 2022
	Note:		
	1. This injection should be stable for minimum of 24 months when stored at a temperature of 2'C-8'C		
	2.Each vial should be labelled accordingly.		
	Packing: 10 Vials in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 1,865,158.00 or USD 9,345.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 20,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.

- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
 - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of

supply.

- As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B – Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15.Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Terms and Conditions of Bid/Instructions to Bidders

- Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;
- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX – 1 to be amended to read as follows;

				ANN	EX – 1
BID NO./BID REFERENCE (TENDER NO.)		:			
DATE	OF ISSUE	:			
CLOSING DATE & TIME (SRI LANKAN TIME)		:			
ORDER	LIST NO. :				
SR No.	R No. Item Quantity Description/Specifications		Quantity	Delivery Schedule	
evalua	tion as tender sampl	es.		ne item to be submitted for	
	nd valid till	(date)		
Bid val	idity period : Bid sho	uld be v	valid till	(date)	
Bid Do	cument Fee :		···		
(should	be paid in cash to SPC	for eac	h set of Bid Do	ocuments).	
MSD CO	NDITIONS OF SUPPLY				
1.					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 **TERMS OF DELIVERY**

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/162/22	01.07.2021 at 9.00 a.m.	600 Vials of Activated Prothrombin Complex Concentrate Injection 500 IU	19.05.2021	Rs. 20,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE "MEHEWARA PIYASA", 26^{TH} FLOOR NO. 41, KIRULA ROAD COLOMBO 5.

TENDER NO. : DHS/P/WW/162/22 DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00021

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00206301	Activated Prothrombine Complex Concentrate Injection 500IU	600 Vials	600 Vials – October 2022
	Activated Prothrombine Complex Concentrate Injection 500IU vial (Activated concentrates: By passing agents) Each vial to contain Human plasma fraction with a factor Eight inhibitor by passing activity and it should contain Factors II,IX,X, mainly in inactive form as factor VII mainly in the activated form. The product should contain approximately equal units of factor eight by passing activity and prothrombin complex factors.		
	 Note: The item should be stable at temperature 2'C - 8'C. The product should have minimum 24 months shelf life at the time of delivery to MSD. Tender should submit detail specifications of the product offered including a product leaflet. The product should ensure, at least two steps on virus inactivation as recommended by WHO/US.FDA The donor selection process should be specified by the manufacturer. Each batch should be certified as free from HIV and hepatitis viruses. Anti viral test methods used for screening for HIV and Hepatitis viruses should be declared by the manufacturer. This test methods used should be approved by WHO/US.FDA. 		
	8. Each vial to be submitted with suitable diluent.		
	9. The product should be protected from light.		
	10. Product content should be printed in the label of the vial as well as in the box.		
	11. The product should have the CDDA registration.		
	Packing: 10 Vials in a box		

Representative Tender samples to be submitted for the evaluation. The amount of Bid Bond: LKR 1,643,341.00 or USD 8,234.00.

Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 20,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

- The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
- (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.

- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

 Format shall be according to Code 128 or 2D standards.

 Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

consignment 100%, by MSD.

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
 - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
 - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total

- rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
 - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
 - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

with the performance bond.

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the **closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.

- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Terms and Conditions of Bid/Instructions to Bidders

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance

& Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX – 1 to be amended to read as follows;

ERENCE : : : : : : : : : : : : : : : : : : :			
Item ion/Specifications	Quantity s	Delivery Schedule	
	namelas far tha	itom to be submitted for	
<u>-</u>	amples for the	item to be submitted for	·
Rond : LKP	or USD	to be submitted along wit	h th
John LKK	01 03D	to be submitted along wit	(.
ш	(data)		
	. (uate)		
od: Bid should b	e valid till	(date)	
ee :	,		
	 ach set of Bid Doc	uments).	
		uments).	
	epresentative sender samples. Bond: LKR	epresentative samples for the ender samples. Bond : LKR or USD	epresentative samples for the item to be submitted for the samples. Bond: LKR

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX – II(B)** to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

<u>Amendment to Bidding Document under 'Conditions of Contract'</u>

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 TERMS OF DELIVERY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.

- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/163/22	01.07.2021 at 9.00 a.m.	235,000 Tablets of Oxybutynine Hydrochloride Tablet 2.5mg	19.05.2021	Rs. 12,500/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/163/22

DATE OF ISSUE : 19TH MAY 2021

CLOSING DATE & TIME : 1ST JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00052

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01302001	Oxybutynine Hydrocloride Tablet 2.5mg	235,000	120,000 Tablets
		Tablets	– April 2022
	Oxybutynine tablet BP 2.5mg		
	Each tablet to contain Oxybutynine Hydrocloride BP		115,000 Tablets
	2.5mg		 August 2022
	OR		
	Oxybutynine Chloride tablets USP 2.5mg		
	Each tablet to contain Oxybutynine Chloride USP		
	2.5mg		
	Note:		
	01. The shelf life of the product should be minimum of 24 months.		
	Packing: 10 Tablets in a strip 10 strips in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 834,250.00 or USD 4,180.00.

Bid Bond should be submitted with valid up to 27.01.2022 together with the bid Bid should be valid till 28.12.2021.

Non refundable Bid Fee Rs. 12,500.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS OF SUPPLY

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

 The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.

- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
 - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
 - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
 - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules
 - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
 - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

 Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

Delivery Requirements

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
 - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
 - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
 - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

 In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of

supply.

- As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

(b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions for Bidding:

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
 - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

Terms and Conditions of Bid/Instructions to Bidders

- Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;
- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
 - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- O8.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX – 1 to be amended to read as follows;

				ANNEX	<u>(– 1</u>
BID NO./BID REFERENCE (TENDER NO.)		:			
DATE	OF ISSUE	:			
CLOSING DATE & TIME (SRI LANKAN TIME)		:			
ORDER	LIST NO. :				
SR No.	R No. Item Operation Description/Specifications			Delivery Schedule	
evalua	tion as tender sampl	es.		ne item to be submitted for t	
	nd valid till		(data)		
			-		
Bid val	idity period : Bid sho	uld be	valid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC	for eac	h set of Bid Do	ocuments).	
MSD CO	NDITIONS OF SUPPLY				
1.					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows;

Heading of 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

08 TERMS OF DELIVERY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

 May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
 - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
 - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC