

TÜRKİYE ODALAR VE BORSALAR BİRLİĞİ



Dumlupınar Bulvarı No:252 (Eskişehir Yolu 9. Km.) 06530 /ANKARA

www.tobb.org.tr - tobb@hs01.kep.tr

: E-34221550-720-11524 Savi

Tarih: 21.10.2024

Konu : Sri Lanka Devlet İlaç Kurumu Tarafından Yayımlanan İhale Duyurusu

# **TÜM ODA VE BORSALARA** (Genel Sekreterlik)

İlgi : Sri Lanka Ankara Büyükelçiliği'nin 15.10.2024 tarihli e-postası

İlgide kayıtlı e-postada, Sri Lanka Devlet İlaç Kurumu tarafından yayınlanan ihale duyuruları iletilmekte ve bahse konu ihalelerin kapanış tarihlerinin 12 Kasım 2024 olduğu bildirilmektedir.

Bilgilerinizi ve söz konusu ihalelerin ilgili üyelerinize duyurulmasını rica ederim.

Saygılarımla,

#### e-imza

Ali Emre YURDAKUL Genel Sekreter Yardımcısı

# EK:

- 1- DHS P M WW 06 24 (7 sayfa)
- 2- DHS-SA-WW-31-23\_5854072 (9 sayfa)
- 3- DHS-SA-WW-32-23\_5854073 (10 sayfa)
- 4- DHS-SA-WW-128-24\_5854075 (9 sayfa)
- 5- DHS-SA-WW-33-23\_5854074 (9 sayfa)
- 6- DHS-SA-WW-129-24\_5854076 (10 sayfa)
- 7- DHS-SA-WW-130-24\_5854077 (8 sayfa)
- 8- DHS-SA-WW-142-25\_5854080 (9 sayfa)
- 9- DHS-SA-WW-143-25\_5854081 (10 sayfa)
- 10-SKM\_458e24100114580\_5854082 (4 sayfa)
- 11-DHS-SA-WW-141-25\_5854079 (10 sayfa)

Bu belge, 5070 sayılı Elektronik İmza Kanununa göre Güvenli Elektronik İmza ile imzalanmıştır.





# **PROCUREMENT NOTICE - GLOBAL**

# MINISTRY PROCUREMENT COMMITTEE, MINISTRY OF HEALTH

The Chairman, Ministry Procurement Committee of The Ministry of Health will receive sealed bids for supply of following items to the Ministry of Health for year 2024.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/M/WW/06/24	12.11.2024 at 11.00 a.m.	20,000 vials of Dried Factor VIII fraction 200IU-350IU vial.	01.10.2024	Rs. 60,000/= + Taxes

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

Wherever necessary 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", 16<sup>th</sup> 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 authorized 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 – MINISTRY PROCUREMENT COMMITTEE MINISTRY OF HEALTH C/O STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 16<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

 FAX
 : 00 94-11- 2582496

 TELEPHONE
 : 00 94-11- 2326227

 E-MAIL
 : pharma.manager@spc.lk

# BID NO.: DHS/P/M/WW/06/24DATE OF ISSUE: 01<sup>st</sup> October 2024CLOSING DATE & TIME: 12<sup>th</sup> November 2024 AT 1100 HOURS SRI LANKA TIME

# Order List No. 2024/SPC/A/C/P/00071

SR no.	Item Description/Specifications	Quantity	Delivery
00206101	Dried, Factor VIII Fraction 200IU-350IU vial	20,000	20,000 vials/
		Vials	As early as
	Dried factor VIII Fraction BP (Dried Human		possible
	Antihaemophilic Fraction) OR		
	Human Coagulation Factor VIII Ph Eur. OR		
	Antihemophilic Factor USP OR Dried Human		
	Antihaemophilic Fraction IP		
	Each vial to contain 200 - 350 IU of concentrated,		
	monoclonal purified and detergent treated dried factor VIII		
	Fraction BP,Ph Eur,USP or IP.		
	Note:		
	1. The item should be stable at temperature 2'C - 8'C.		
	2. The product should have minimum 24 months shelf life		
	at the time of delivery to MSD.		
	3. Tenderer should submit detailed specifications of the		
	product offered.		
	4. The product should ensure, at least two steps on virus		
	inactivation as recommended by WHO/US.FDA		
	5. The donor selection process should be specified by the		
	manufacturer.		
	6. Each batch should be certified as free from HIV and		
	hepatitis viruses.		
	7. Anti viral test methods used for screening for HIV and		
	Hepatitis viruses should be declared by the manufacturer.		
	The test methods used should be approved by		
	WHO/US.FDA.		
	8. Each vial to be supplied with suitable diluent.		
	9. The product should be protected from light.		

Four (04) Nos of Representative tender sample with catalogue & Literature to be submitted for the Bid evaluations.

The amount of Bid Bond: LKR 9,837,640.00 or USD 32,709.00.

Bid Bond should be submitted with valid up to 09.06.2025 together with the bid

Bid should be valid till 10.05.2025.

Non refundable Bid Fee Rs. 60,000.00 + Taxes.

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

# **CONDITIONS OF SUPPLY**

- 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 bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by State Pharmaceuticals Corporation.
- 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 National Medicines Regulatory Authority (NMRA).
- 3. Maintaining the validity of the product registration during the period of supply (delivery schedule), obtaining import license / manufacture licensing at NMRA, is a pre-requisite for the supply of pharmaceutical 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. If MSD decides to accept a part f full consignment, with deviations from certain tender conditions (eg. with regard 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 th 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) x 0.25) or 2% of the invoiced value, whichever is the highest.
- 5. 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 will not be entertained.

# Shelf life & Warrantees

6. 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 in case of local supplies) of the product , shall be 85% of the shelf life requested (specified in order/Indent/PO) In respect of the items with requested shelf life equals or more than 24 months, any deficit between the residual shelf life and requested shelf , shall not be more that 04 months.

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

When the shelf life is not specified in the Indent/PO/item spec; the requested shelf life shall be considered as , 24 months for pharmaceuticals.

# Standards & Quality

and will subject to application of a penalty (as clause No. 30)

- 7. <u>Standards</u>; In addition to Pharmacopoeial Standards that are indicated in the item specifications other Pharmacopoeial Standards that are registered a National Medicines Regulatory Authority in Sri Lanka are also acceptable when no bidders have quoted for the standard specified in the item specification.
- 8. 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.

- 9. 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 charge of the same.
- 10. 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.20)

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.

11. 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/semigovernment/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.

12. 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. 9).

# Pack size, Labeling & Packaging

- 13. 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.
- 14. 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)

- 15. 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.
- 16. 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.

17. 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

- 18. 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.
- 19. 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.
- 20. 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.10)

#### **Delivery Requirements**

21. 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. 23 on delayed deliveries, shall be applied.

22. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed.

- 23. 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.
- 24. 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. 23 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 25. 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. 23, 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**

- 26. 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.
- 27. 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.
- 28. 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 23 will not be applicable.

#### Common conditions

- 29. 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.
- 30. 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. 08,05,10,13)

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

In case of an offer of product not registered with NMRA, bidders should submit documents annexure ` (Checklist for WOR) along with the offer to consider under exceptional circumstances.

#### Checklist for Waver of Registration,

- Certificate of Analysis (COA) of the relevant product
- Certificate of Pharmaceutical Product
- Label of the Product
- Product Information Leaflet (PIL)
- Pro-forma Invoice.

In the event of an award of an un registered product, SPC will apply for a WOR from NMRA and the supplier shall submit corresponding samples of the product; upon the demand of SPC; for onward submission to NMRA.

However, NMRA may request for additional information/documentation to consider allowing the WOR and the suppliers may refer the official website of NMRA (<u>www.nmra.gov.lk</u>) for more details on the documentation required.

The payment due to NMRA for issuance of WOR: shall be borne by the supplier/Local agent.

Please refer Global Bid Document

A: Global Tender - MPC Bidding Document for Procurement of Pharmaceuticals (Pink Book)

# <u>ANNEX – 1</u>

# BID NO. : DHS/SA/WW/31/23 DATE OF ISSUE : 01/10/2024 CLOSING DATE & TIME : 12/11/2024 AT 09.00 HOURS SRI LANKA TIME

#### Special Conditions for tendering :

- 1. Offers should be accompanied with the original of valid registration certificate/any **Subsequent renewal** certificates where applicable or a copy certified by an Attorney at law, of aforesaid document issued by the National Medicine Regulatory Authority in Sri Lanka.
- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. **A break-up of** FOB and Freight charges should be quoted separately against each item in addition to quoted C&F price.
- 4. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>)
- 5. Foreign offers should be on C&F {CPT/CFR (into FOB and freight]} Colombo basis. Only 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 in LKR for the total delivery price to MSD stores.
- **6.** 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 Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere 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.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.

#### 10. The offer should be valid up to 11/05/2025

#### CONDITIONS FOR SUPPLY FOR SPC ORDERS – APPLICABLE FOR SURGICAL & LAB ITEMS

#### (a) Part A-General Order Conditions (GOC) of Supply

- 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 & 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 surcharge (as clause No. 37).

6. The specifications of the product offered by the suppliers in the tender, 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. In respect of Non consumables; laboratory items and surgical items: Manufacturer or supplier or local agent shall provide a warranty for a period, not less than as specified in the specification of the item and /or it's sub components/articles supplied (eg: Special Instrument sets), unless otherwise agreed upon prior to awarding the tender.

The supplier's invoice shall indicate, the validity period of the warrantee from the date of receiving goods at MSD and a warrantee card with all details, including the local contact details of warrantee services provider, shall also be inserted in each individual pack.

Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repair and spares, when necessary (**This clause No. 07 is not applicable for all Pharmaceuticals and all Consumable Surgical & Laboratory items**)

- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in 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 of 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.

(b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37)

#### **Standards & Quality**

- **9.** <u>Standards</u>: In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals 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.

- 11. 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative surcharge of the same.
- **12.** 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.24)

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.

**13.** 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 and 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 and testing charges, etc, will be recovered from the supplier.

14. 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.11).

#### Pack size, Labeling & Packaging

- **15.** 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.
- 16. In respect of bulk packs of all pharmaceuticals (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 purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots <u>or</u> when an exemption is notified in the special order conditions of the relevant MSD order list (**This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items**)

**17.** Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Product Reference/Catalogue No.s of Surgical items), Date of Manufacture, Date of Expiry (of consumables only) and "STATE LOGO" of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (not applicable for Surgical Nonconsumables) & date of Manufacture (in any form as "Year & Month" or "No Exp."), in the innermost pack and supplier's invoice.

- 18. 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.
- **19.** 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.
- 20. 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).
- **21.** 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**

- 22. 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  $30^{\circ}c$  +/-  $2^{\circ}c$  temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. 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 coldchain 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.
- **24.** 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.12)

#### **Delivery Requirements**

**25.** 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. 27 on delayed deliveries, shall be applied.

- 26. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- **27.** 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 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.

**28.** (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.

**29.** 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. 27 (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 other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** 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. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** 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. 27, 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**

**32.** 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.

**33.** 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 laboratory regular items except when specified in respective order lists).

The product artwork or dimensional detail diagrams, product Catalogues and Catalog No's, as necessary for the surgical items (**not relevant to pharmaceutical & Laboratory items**) shall be provided with the bid document, for reference in the; tender evaluation by SPC, ascertaining (before awarding) user acceptance of deviations from the spec by MSD and inspecting the consignments delivered to MSD.

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

- 34 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 <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. 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 <u>www.msd.gov.lk</u>)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 condition No. 27 will not be applicable.

#### **Common conditions**

- 36. 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.
- 37. 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. 08,05,10,13)
- **Abbreviations :***NMRA ; National Medicines Regulatory Authority/Sri Lanka,* SPC ; State *Pharmaceuticals Corporation, MSD; Medical Supplies Division,*

#### (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. and SR No. s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### Sufficient quantity of samples should be forwarded for evaluation.

#### **Special Conditions**

(I) Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.

Demurrage / additional charges if any which

requirement will be claimed from the supplier.

- (II) In the event of an award made to you on this tender, SPC reserve 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.
- (III) 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.

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- (IV) Where a purchase for a particular item is being made for the first time from a supplier, or where there are previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.
- (V) 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.
- (VI) 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 submit 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.
- (VII) In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- (VIII) All Shipment 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 vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely 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.
- (IX) 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.
- (X) 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.
- (XI) a)For products which are imported to Sri Lanka, the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE).

b)For products which are manufactured in Sri Lanka, the registration shall be valid until the last delivery of the products to be procured is received by the PE.

# (XII) Supplier shall submit the signed contract within 14 days of receiving of the contract agreement from SPC.

(XIII) The below mentioned documents (the original or copies certified by the attorney at law) should be submitted along with copy documents to SPC.

this

- 1. A certified copy of the Certificate of Analysis/warranty
- 2. A certified copy of the Customs declaration
- 3. Original of the Import License
- 4. Original of the Customs Assessment Notice
- 5. Certificate copy of NMRA or WOR.

<u>Note</u>: A certified copy of Business registration Certificate (by an Attorney at low) should be submitted with the offer

# BID NO: DHS/SA/WW/31/23 CLOSING ON : 12/11/2024 at 9.00 a.m.

#### ORDER LIST NUMBER: 2023/SPC/N/R/S/0002

<u> </u>		С	D	E	F
ITEM NO	SR NO	ITEM	QTY	DELIVERY	Bid Bond value (LKR)
1	12604319	Threaded Guide pin 2.0mm for 6.5/7.0 mm Cannulated screw System, stainless steel, unsterile.	350 nos	100% Immediately	

All tenderers should furnish an unconditional Bid Bond for each SR No. encashable on demand to the value mentioned in the Column F.

Amount of Bid Bond should be 2% of the bid value of each item to be submitted along with the bid, when the tendered value of each item exceeds LKR 01 million. (when not indicated in the Column F).

Bid Bond should be submitted with valid up to 10/06/2025 together with the tender

Bidding Document Fee- As per the guideline 6.1.1 (a) of the Government Procurement Guidelines 2006.

A non refundable fee of Rs. 3,000/=+ taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

#### NOTE

Amemndments to Global tender Book,

(I) Clause No 27 (Page 18) To be deleted 27.4 & 27.5

#### (II) Clause No 19 [REGISTRATION - Page 13] To be include to read as

(c) For products which are imported to Sri Lanka the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE).

(d) For products which are manufactured in Sri Lanka the registration shall be valid until the last delivery of the products to be procured is received by the Procuring Entity (PE).

(III) To replace the clause No 17.4 & 17.5 in contract document on page No 44 as above (c) & (d).

# <u>ANNEX – 1</u>

# BID NO. : DHS/SA/WW/32/23 DATE OF ISSUE : 01/10/2024 CLOSING DATE & TIME : 12/11/2024 AT 09.00 HOURS SRI LANKA TIME

#### Special Conditions for tendering :

- 1. Offers should be accompanied with the original of valid registration certificate/any **Subsequent renewal** certificates where applicable or a copy certified by an Attorney at law, of aforesaid document issued by the National Medicine Regulatory Authority in Sri Lanka.
- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. **A break-up of** FOB and Freight charges should be quoted separately against each item in addition to quoted C&F price.
- 4. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>)
- Foreign offers should be on C&F {CPT/CFR (into FOB and freight]} Colombo basis. Only 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 in LKR for the total delivery price to MSD stores.
- **6.** 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 Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere 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.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.

#### 10. The offer should be valid up to 10/05/2025

#### CONDITIONS FOR SUPPLY FOR SPC ORDERS – APPLICABLE FOR SURGICAL & LAB ITEMS

#### (a) Part A-General Order Conditions (GOC) of Supply

- 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 & 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 surcharge (as clause No. 37).

6. The specifications of the product offered by the suppliers in the tender, 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. In respect of Non consumables; laboratory items and surgical items: Manufacturer or supplier or local agent shall provide a warranty for a period, not less than as specified in the specification of the item and /or it's sub components/articles supplied (eg: Special Instrument sets), unless otherwise agreed upon prior to awarding the tender.

The supplier's invoice shall indicate, the validity period of the warrantee from the date of receiving goods at MSD and a warrantee card with all details, including the local contact details of warrantee services provider, shall also be inserted in each individual pack.

Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repair and spares, when necessary (**This clause No. 07 is not applicable for all Pharmaceuticals and all Consumable Surgical & Laboratory items**)

- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in 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 of 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.

(b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37)

#### **Standards & Quality**

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals 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.

- **11.** 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative surcharge of the same.
- **12.** 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.24)

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.

**13.** 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 and 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 and testing charges, etc, will be recovered from the supplier.

14. 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.11).

# Pack size, Labeling & Packaging

- **15.** 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.
- **16.** In respect of bulk packs of all pharmaceuticals (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 purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots <u>or</u> when an exemption is notified in the special order conditions of the relevant MSD order list (**This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items**)

**17.** Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Product Reference/Catalogue No.s of Surgical items), Date of Manufacture, Date of Expiry (of consumables only) and "STATE LOGO" of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (not applicable for Surgical Nonconsumables) & date of Manufacture (in any form as "Year & Month" or "No Exp."), in the innermost pack and supplier's invoice.

**18.** 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.

- **19.** 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.
- 20. 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).
- **21.** 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**

- **22.** 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  $30^{\circ}$ c +/-  $2^{\circ}$ c temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. 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 coldchain 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.
- 24. 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.12)

# **Delivery Requirements**

**25.** 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. 27 on delayed deliveries, shall be applied.

26. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.

**27.** 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 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.

**28.** (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.

**29.** 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. 27 (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 other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** 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. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** 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. 27, 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**

- **32.** 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.
- **33.** 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 laboratory regular items except when specified in respective order lists).

The product artwork or dimensional detail diagrams, product Catalogues and Catalog No's, as necessary for the surgical items (**not relevant to pharmaceutical & Laboratory items**) shall be provided with the bid document, for reference in the; tender evaluation by SPC, ascertaining (before awarding) user acceptance of deviations from the spec by MSD and inspecting the consignments delivered to MSD.

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

- 34 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.
- 35. 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 <u>www.msd.gov.lk</u>)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 condition No. 27 will not be applicable.

#### **Common conditions**

- 36. 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.
- 37. 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. 08,05,10,13)
- **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. and SR No. s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

# Sufficient quantity of samples should be forwarded for evaluation.

#### Special Conditions

(I) Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments 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.

- (II) In the event of an award made to you on this tender, SPC reserve 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.
- (III) 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.
- (IV) Where a purchase for a particular item is being made for the first time from a supplier, or where there are previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.
- (V) 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.
- (VI) 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 submit 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.
- (VII) In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- (VIII) All Shipment 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 vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely 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.
- (IX) 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.
- (X) 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.
- (XI) a) For products which are imported to Sri Lanka, the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE).

b) For products which are manufactured in Sri Lanka, the registration shall be valid until the last delivery of the products to be procured is received by the PE.

# (XII) Supplier shall submit the signed contract within 14 days of receiving of the contract agreement from SPC.

- (XIII) The below mentioned documents (the original or copies certified by the attorney at law) should be submitted along with copy documents to SPC.
  - 1. A certified copy of the Certificate of Analysis/warranty
  - 2. A certified copy of the Customs declaration

- 4. Original of the Customs Assessment Notice
- 5. Certificate copy of NMRA or WOR.

<u>Note</u>: A certified copy of Business registration Certificate (by an Attorney at low) should be submitted with the offer

# BID NO: DHS/SA/WW/32/23 CLOSING ON : 12/11/2024 at 9.00 a.m.

#### ORDER LIST NUMBER: 2023/SPC/N/R/S/0003

-	A B	C	D	E	F
ITEM	SR NO	ITEM	QTY	DELIVERY	Bid Bond
NO			-		value (LKR)
1	22302006	Digital Humidity	1,500	750-Immediately	75,000.00
		Thermometers(Thermo -	nos	750-4 Months after 1 <sup>st</sup>	,
		hygrometer) to measure the		lot	
		temperature & relative humidity			
		of pharmaceutical			
		refrigerators/freezers.			
		Digital Humidity			
		e .			
		Thermometers(Thermo -hygrometer)			
		with holder and magnet for easy			
		installation on the outside of			
		refrigerators/freezers to measure			
		temperature & relative humidity of			
		pharmaceutical			
		refrigerators/freezers.			
		Temperature measurement range			
		10'C up to +50'C (+14'F up to + 122			
		'F)			
		Temperature resolution: $+/-$ 0.1			
		'C/0.2'F			
		Temperature measurement accuracy:			
		+ / - 1'C (1.8'F)			
		Humidity			
		measurement range: 10% to 99%			
		Humidity			
		measurement resolution: 1%			
		Humidity measurement accuracy: +/-			
		5 RH			
		5 KH Display: 4 Digit LCD display			
		User definable alarm function (LED			
		alarm indicator)of maximum and			
		minimum temperatures.			
		Power supply- 1.5V AAA Battery			
		Supply with 1- 1.5 m sensor probe			
		cable for outdoor minimum and			
		maximum temperature			
		measurement			
		Dimensions: Length: 65-125 mm			
		Width: 55-70 mm			
		Width: 55-70 mm			

	10		
War	ght: 20-30mm ranty period: Minimum 6		
mon	itiis		

All tenderers should furnish an unconditional Bid Bond for each SR No. encashable on demand to the value mentioned in the Column F.

10

Amount of Bid Bond should be 2% of the bid value of each item to be submitted along with the bid, when the tendered value of each item exceeds LKR 01 million. (when not indicated in the Column F).

#### Bid Bond should be submitted with valid up to 09/06/2025 together with the tender

**Bidding Document Fee- As per the guideline 6.1.1 (a) of the Government Procurement Guidelines 2006.** 

A non refundable fee of Rs. 3,000/=+ taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

#### NOTE

Amemndments to Global tender Book,

- (I) Clause No 27 (Page 18) To be deleted 27.4 & 27.5
- (II) Cluse No 19 [REGISTRATION Page 13] To be include to read as

(c) For products which are imported to Sri Lanka the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE).

(d) For products which are manufactured in Sri Lanka the registration shall be valid until the last delivery of the products to be procured is received by the Procuring Entity (PE).

(III) To replace the clause No 17.4 & 17.5 in contract documents on page No 44 as above (c) & (d).

# <u>ANNEX – 1</u>

# BID NO. : DHS/SA/WW/128/24 DATE OF ISSUE : 01/10/2024 CLOSING DATE & TIME : 12/11/2024 AT 09.00 HOURS SRI LANKA TIME

#### Special Conditions for tendering :

- 1. Offers should be accompanied with the original of valid registration certificate/any **Subsequent renewal** certificates where applicable or a copy certified by an Attorney at law, of aforesaid document issued by the National Medicine Regulatory Authority in Sri Lanka.
- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. **A break-up of** FOB and Freight charges should be quoted separately against each item in addition to quoted C&F price.
- 4. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>)
- 5. Foreign offers should be on C&F {CPT/CFR (into FOB and freight]} Colombo basis. Only 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 in LKR for the total delivery price to MSD stores.
- **6.** 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 Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere 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.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.

#### 10. The offer should be valid up to 11/05/2025

#### CONDITIONS FOR SUPPLY FOR SPC ORDERS – APPLICABLE FOR SURGICAL & LAB ITEMS

#### (a) Part A-General Order Conditions (GOC) of Supply

- 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 & 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 surcharge (as clause No. 37).

6. The specifications of the product offered by the suppliers in the tender, 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. In respect of Non consumables; laboratory items and surgical items: Manufacturer or supplier or local agent shall provide a warranty for a period, not less than as specified in the specification of the item and /or it's sub components/articles supplied (eg: Special Instrument sets), unless otherwise agreed upon prior to awarding the tender.

The supplier's invoice shall indicate, the validity period of the warrantee from the date of receiving goods at MSD and a warrantee card with all details, including the local contact details of warrantee services provider, shall also be inserted in each individual pack.

Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repair and spares, when necessary (**This clause No. 07 is not applicable for all Pharmaceuticals and all Consumable Surgical & Laboratory items**)

- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in 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 of 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.

(b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01)

#### **Standards & Quality**

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals 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.

- **11.** 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative surcharge of the same.
- **12.** 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.24)

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.

**13.** 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 and 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 and testing charges, etc, will be recovered from the supplier.

14. 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.11).

# Pack size, Labeling & Packaging

- **15.** 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.
- **16.** In respect of bulk packs of all pharmaceuticals (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 purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots <u>or</u> when an exemption is notified in the special order conditions of the relevant MSD order list (**This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items**)

**17.** Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Product Reference/Catalogue No.s of Surgical items), Date of Manufacture, Date of Expiry (of consumables only) and "STATE LOGO" of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (not applicable for Surgical Nonconsumables) & date of Manufacture (in any form as "Year & Month" or "No Exp."), in the innermost pack and supplier's invoice.

**18.** 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.

- **19.** 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.
- 20. 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).
- **21.** 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**

- **22.** 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  $30^{\circ}$ c +/-  $2^{\circ}$ c temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. 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 coldchain 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.
- 24. 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.12)

# **Delivery Requirements**

**25.** 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. 27 on delayed deliveries, shall be applied.

26. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.

**27.** 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 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.

**28.** (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.

**29.** 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. 27 (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 other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** 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. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** 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. 27, 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**

- **32.** 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.
- **33.** 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 laboratory regular items except when specified in respective order lists).

The product artwork or dimensional detail diagrams, product Catalogues and Catalog No's, as necessary for the surgical items (**not relevant to pharmaceutical & Laboratory items**) shall be provided with the bid document, for reference in the; tender evaluation by SPC, ascertaining (before awarding) user acceptance of deviations from the spec by MSD and inspecting the consignments delivered to MSD.

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

- 34 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 <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. 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 <u>www.msd.gov.lk</u>)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 condition No. 27 will not be applicable.

#### **Common conditions**

- 36. 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.
- 37. 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. 08,05,10,13)
- **Abbreviations :***NMRA ; National Medicines Regulatory Authority/Sri Lanka,* SPC ; State *Pharmaceuticals Corporation, MSD; Medical Supplies Division,*

#### (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. and SR No. s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### Sufficient quantity of samples should be forwarded for evaluation.

#### Special Conditions

(I) Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments 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.

- (II) In the event of an award made to you on this tender, SPC reserve 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.
- (III) 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.
- (IV) Where a purchase for a particular item is being made for the first time from a supplier, or where there are previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.
- (V) 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.
- (VI) 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 submit 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.
- (VII) In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- (VIII) All Shipment 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 vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely 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.
- (IX) 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.
- (X) 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.
- a)For products which are imported to Sri Lanka, the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE).
   b)For products which are manufactured in Sri Lanka, the registration shall be valid until the last delivery of the products to be procured is received by the PE.

# (XII) Supplier shall submit the signed contract within 14 days of receiving of the contract agreement from SPC.

- (XIII) The below mentioned documents (the original or copies certified by the attorney at law) should be submitted along with copy documents to SPC.
  - 1. A certified copy of the Certificate of Analysis/warranty
  - 2. A certified copy of the Customs declaration

- 3. Original of the Import License
- 4. Original of the Customs Assessment Notice
- 5. Certificate copy of NMRA or WOR.

<u>Note</u>: A certified copy of Business registration Certificate (by an Attorney at low) should be submitted with the offer

# BID NO: DHS/SA/WW/128/24 CLOSING ON : 12/11/2024 at 9.00 a.m.

#### ORDER LIST NUMBER: 2024/SPC/N/R/S/00010

_ <u>_</u> A	А В	C	D	E	F
ITEM NO	SR NO	ITEM	QTY	DELIVERY	Bid Bond value (LKR)
1	12500301	Toomey tip 60 ml graduated syringe with plunger for bladder wash, disposable,sterile.	3,300 nos	100% Immediately	35,110.00
2	12504302	Bladder Evaquator plastic,Ellick type or similar,complete with connector.	20 nos	100% Immediately	

All tenderers should furnish an unconditional Bid Bond for each SR No. encashable on demand to the value mentioned in the Column F.

Amount of Bid Bond should be 2% of the bid value of each item to be submitted along with the bid, when the tendered value of each item exceeds LKR 01 million. (when not indicated in the Column F).

#### Bid Bond should be submitted with valid up to 10/06/2025 together with the tender

**Bidding Document Fee- As per the guideline 6.1.1 (a) of the Government Procurement Guidelines 2006.** 

# A non refundable fee of Rs. 3,000/=+ taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

#### NOTE

Amemndments to Global tender Book,

(I) Clause No 27 (Page 18) To be deleted 27.4 & 27.5

#### (II) Cluse No 19 [REGISTRATION - Page 13] To be include to read as

(c) For products which are imported to Sri Lanka the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE).

(d) For products which are manufactured in Sri Lanka the registration shall be valid until the last delivery of the products to be procured is received by the Procuring Entity (PE).

#### (III) To replace the clause No 17.4 & 17.5 in contract documents on page No 44 as above (c) & (d).

# <u>ANNEX – 1</u>

# BID NO. : DHS/SA/WW/33/23 DATE OF ISSUE : 01/10/2024 CLOSING DATE & TIME : 12/11/2024 AT 09.00 HOURS SRI LANKA TIME

#### **Special Conditions for tendering :**

- 1. Offers should be accompanied with the original of valid registration certificate/any **Subsequent renewal** certificates where applicable or a copy certified by an Attorney at law, of aforesaid document issued by the National Medicine Regulatory Authority in Sri Lanka.
- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. **A break-up of** FOB and Freight charges should be quoted separately against each item in addition to quoted C&F price.
- 4. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>)
- 5. Foreign offers should be on C&F {CPT/CFR (into FOB and freight]} Colombo basis. Only 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 in LKR for the total delivery price to MSD stores.
- **6.** 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 Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere 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.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.

#### 10. The offer should be valid up to 11/05/2025

#### CONDITIONS FOR SUPPLY FOR SPC ORDERS – APPLICABLE FOR SURGICAL & LAB ITEMS

#### (a) Part A-General Order Conditions (GOC) of Supply

- 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 & 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 surcharge (as clause No. 37).

6. The specifications of the product offered by the suppliers in the tender, 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. In respect of Non consumables; laboratory items and surgical items: Manufacturer or supplier or local agent shall provide a warranty for a period, not less than as specified in the specification of the item and /or it's sub components/articles supplied (eg: Special Instrument sets), unless otherwise agreed upon prior to awarding the tender.

The supplier's invoice shall indicate, the validity period of the warrantee from the date of receiving goods at MSD and a warrantee card with all details, including the local contact details of warrantee services provider, shall also be inserted in each individual pack.

Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repair and spares, when necessary (**This clause No. 07 is not applicable for all Pharmaceuticals and all Consumable Surgical & Laboratory items**)

- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in 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 of 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.

(b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37)

#### **Standards & Quality**

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals 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.

- **11.** 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative surcharge of the same.
- **12.** 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.24)

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.

**13.** 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 and 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 and testing charges, etc, will be recovered from the supplier.

14. 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.11).

# Pack size, Labeling & Packaging

- **15.** 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.
- **16.** In respect of bulk packs of all pharmaceuticals (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 purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots <u>or</u> when an exemption is notified in the special order conditions of the relevant MSD order list (**This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items**)

**17.** Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Product Reference/Catalogue No.s of Surgical items), Date of Manufacture, Date of Expiry (of consumables only) and "STATE LOGO" of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (not applicable for Surgical Nonconsumables) & date of Manufacture (in any form as "Year & Month" or "No Exp."), in the innermost pack and supplier's invoice.

**18.** 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.

- **19.** 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.
- 20. 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).

**21.** 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**

- 22. 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  $30^{\circ}c$  +/-  $2^{\circ}c$  temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. 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 coldchain 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.
- 24. 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.12)

#### **Delivery Requirements**

**25.** 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. 27 on delayed deliveries, shall be applied.

- 26. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- **27.** 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 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.

**28.** (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.

**29.** 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. 27 (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 other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** 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. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** 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. 27, 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**

**32.** 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.

**33.** 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 laboratory regular items except when specified in respective order lists).

The product artwork or dimensional detail diagrams, product Catalogues and Catalog No's, as necessary for the surgical items (**not relevant to pharmaceutical & Laboratory items**) shall be provided with the bid document, for reference in the; tender evaluation by SPC, ascertaining (before awarding) user acceptance of deviations from the spec by MSD and inspecting the consignments delivered to MSD.

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

- 34 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 <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. 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 <u>www.msd.gov.lk</u>)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 condition No. 27 will not be applicable.

### **Common conditions**

- 36. 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.
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- **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. and SR No. s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### Sufficient quantity of samples should be forwarded for evaluation.

#### **Special Conditions**

(I) Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.

Demurrage / additional charges if any which

requirement will be claimed from the supplier.

this

- (II) In the event of an award made to you on this tender, SPC reserve 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.
- (III) 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.
- (IV) Where a purchase for a particular item is being made for the first time from a supplier, or where there are previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.
- (V) 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.
- (VI) 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 submit 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.
- (VII) In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- (VIII) All Shipment 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 vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely 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.
- (IX) 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.
- (X) 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.
- (XI) a) For products which are imported to Sri Lanka, the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE).

b) For products which are manufactured in Sri Lanka, the registration shall be valid until the last delivery of the products to be procured is received by the PE.

# (XII) Supplier shall submit the signed contract within 14 days of receiving of the contract agreement from SPC.

(XIII) The below mentioned documents (the original or copies certified by the attorney at law) should be submitted along with copy documents to SPC.

- 1. A certified copy of the Certificate of Analysis/warranty
- 2. A certified copy of the Customs declaration
- 3. Original of the Import License
- 4. Original of the Customs Assessment Notice
- 5. Certificate copy of NMRA or WOR.

<u>Note</u>: A certified copy of Business registration Certificate (by an Attorney at low) should be submitted with the offer

# BID NO: DHS/SA/WW/33/23 CLOSING ON : 12/11/2024 at 9.00 a.m.

### ORDER LIST NUMBER: 2023/SPC/N/R/S/00404

	A B	С		D E	F
ITEM NO	SR NO	ITEM	QTY	DELIVERY	Bid Bond value (LKR)
1	12001500	Transjugular Liver Biopsy Set, with 16G x 55cm length needle, 9Fr x 45cm length catheter with angled tip, compatible guidewire, introducer sheath and introducer needle, sterile.	25 nos	100% Immediately	34,860.00

All tenderers should furnish an unconditional Bid Bond for each SR No. encashable on demand to the value mentioned in the Column F.

Amount of Bid Bond should be 2% of the bid value of each item to be submitted along with the bid, when the tendered value of each item exceeds LKR 01 million. (when not indicated in the Column F).

Bid Bond should be submitted with valid up to 10/06/2025 together with the tender

Bidding Document Fee- As per the guideline 6.1.1 (a) of the Government Procurement Guidelines 2006.

A non refundable fee of Rs.3,000/=+ taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the  $Bid_{.}$ 

#### NOTE

Amemndments to Global tender Book,

- (I) Clause No 27 (Page 18) To be deleted 27.4 & 27.5
- (II) Clause No 19 [REGISTRATION Page 13] To be include to read as

(c) For products which are imported to Sri Lanka the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE).

(d) For products which are manufactured in Sri Lanka the registration shall be valid until the last delivery of the products to be procured is received by the Procuring Entity (PE).

(III) To replace the clause No 17.4 & 17.5 in contract document on page No 44 to read as above (c) & (d).

# <u>ANNEX – 1</u>

# BID NO. : DHS/SA/WW/129/24 DATE OF ISSUE : 01/10/2024 CLOSING DATE & TIME : 12/11/2024 AT 09.00 HOURS SRI LANKA TIME

#### **Special Conditions for tendering :**

- 1. Offers should be accompanied with the original of valid registration certificate/any **Subsequent renewal** certificates where applicable or a copy certified by an Attorney at law, of aforesaid document issued by the National Medicine Regulatory Authority in Sri Lanka.
- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. **A break-up of** FOB and Freight charges should be quoted separately against each item in addition to quoted C&F price.
- 4. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>)
- Foreign offers should be on C&F {CPT/CFR (into FOB and freight]} Colombo basis. Only 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 in LKR for the total delivery price to MSD stores.
- **6.** 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 Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere 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.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.

#### 10. The offer should be valid up to 11/05/2025

#### CONDITIONS FOR SUPPLY FOR SPC ORDERS – APPLICABLE FOR SURGICAL & LAB ITEMS

#### (a) Part A-General Order Conditions (GOC) of Supply

- 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 & 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 surcharge (as clause No. 37).

6. The specifications of the product offered by the suppliers in the tender, 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. In respect of Non consumables; laboratory items and surgical items: Manufacturer or supplier or local agent shall provide a warranty for a period, not less than as specified in the specification of the item and /or it's sub components/articles supplied (eg: Special Instrument sets), unless otherwise agreed upon prior to awarding the tender.

The supplier's invoice shall indicate, the validity period of the warrantee from the date of receiving goods at MSD and a warrantee card with all details, including the local contact details of warrantee services provider, shall also be inserted in each individual pack.

Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repair and spares, when necessary (**This clause No. 07 is not applicable for all Pharmaceuticals and all Consumable Surgical & Laboratory items**)

- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in 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 of 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.

(b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37)

#### **Standards & Quality**

- **9.** <u>Standards</u>: In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals 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.

- 11. 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative surcharge of the same.
- **12.** 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.24)

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.

**13.** 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 and 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 and testing charges, etc, will be recovered from the supplier.

14. 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.11).

### Pack size, Labeling & Packaging

- **15.** 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.
- **16.** In respect of bulk packs of all pharmaceuticals (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 purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots <u>or</u> when an exemption is notified in the special order conditions of the relevant MSD order list (**This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items**)

**17.** Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Product Reference/Catalogue No.s of Surgical items), Date of Manufacture, Date of Expiry (of consumables only) and "STATE LOGO" of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (not applicable for Surgical Nonconsumables) & date of Manufacture (in any form as "Year & Month" or "No Exp."), in the innermost pack and supplier's invoice.

- 18. 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.
- **19.** 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.
- 20. 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).
- **21.** 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**

- 22. 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  $30^{\circ}c$  +/-  $2^{\circ}c$  temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. 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 coldchain 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.
- 24. 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.12)

#### **Delivery Requirements**

**25.** 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. 27 on delayed deliveries, shall be applied.

- 26. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- **27.** 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 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.

**28.** (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.

**29.** 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. 27 (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 other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** 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. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** 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. 27, 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**

**32.** 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.

**33.** 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 laboratory regular items except when specified in respective order lists).

The product artwork or dimensional detail diagrams, product Catalogues and Catalog No's, as necessary for the surgical items (**not relevant to pharmaceutical & Laboratory items**) shall be provided with the bid document, for reference in the; tender evaluation by SPC, ascertaining (before awarding) user acceptance of deviations from the spec by MSD and inspecting the consignments delivered to MSD.

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

- 34 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 <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. 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 <u>www.msd.gov.lk</u>)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 condition No. 27 will not be applicable.

#### **Common conditions**

- 36. 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.
- 37. 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. 08,05,10,13)
- **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. and SR No. s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### Sufficient quantity of samples should be forwarded for evaluation.

#### **Special Conditions**

(I) Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.

Demurrage / additional charges if any which

requirement will be claimed from the supplier.

this

- (II) In the event of an award made to you on this tender, SPC reserve 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.
- (III) 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.
- (IV) Where a purchase for a particular item is being made for the first time from a supplier, or where there are previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.
- (V) 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.
- (VI) 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 submit 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.
- (VII) In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- (VIII) All Shipment 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 vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely 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.
- (IX) 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.
- (X) 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.
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b) For products which are manufactured in Sri Lanka, the registration shall be valid until the last delivery of the products to be procured is received by the PE.

# (XII) Supplier shall submit the signed contract within 14 days of receiving of the contract agreement from SPC.

(XIII) The below mentioned documents (the original or copies certified by the attorney at law) should be submitted along with copy documents to SPC.

- 1. A certified copy of the Certificate of Analysis/warranty
- 2. A certified copy of the Customs declaration
- 3. Original of the Import License
- 4. Original of the Customs Assessment Notice
- 5. Certificate copy of NMRA or WOR.

<u>Note</u>: A certified copy of Business registration Certificate (by an Attorney at low) should be submitted with the offer

# BID NO: DHS/SA/WW/129/24 CLOSING ON : 12/11/2024 at 9.00 a.m.

#### ORDER LIST NUMBER: 2024/SPC/N/R/S/00142

_	A B	С		D E	F
ITEM NO	SR NO	ITEM	QTY	DELIVERY	Bid Bond value (LKR)
1	14001702	Hypodermic Needle, size 26G x 50mm(+/- 2mm) length, Single Use with plastic hub and steel needle, Conforming to ISO Standards and British Standard BS 5081 : Part 1 and 2 : 1987 for sterile hypodermic syringes and needles, Plastic hub of luer slip fitting, compatible with syringes with 6% taper ISO 594 and stainless steel needle. non toxic and pyrogen free, sterile.	50,000 Ndl	100% Immediatly	

All tenderers should furnish an unconditional Bid Bond for each SR No. encashable on demand to the value mentioned in the Column F.

Amount of Bid Bond should be 2% of the bid value of each item to be submitted along with the bid, when the tendered value of each item exceeds LKR 01 million. (when not indicated in the Column F).

#### Bid Bond should be submitted with valid up to 10/06/2025 together with the tender

Bidding Document Fee- As per the guideline 6.1.1 (a) of the Government Procurement Guidelines 2006.

# A non refundable fee of Rs. 3,000/=+ taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

#### NOTE

Amemndments to Global tender Book,

- (I) Clause No 27 (Page 18) To be deleted 27.4 & 27.5
- (II) Cluse No 19 [REGISTRATION Page 13] To be include to read as

(c) For products which are imported to Sri Lanka the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE).

(d) For products which are manufactured in Sri Lanka the registration shall be valid until the last delivery of the products to be procured is received by the Procuring Entity (PE).

(III) To replace the clause No 17.4 & 17.5 in contract documents on page No 44 as above (c) & (d).

# <u>ANNEX – 1</u>

# BID NO.: DHS/SA/WW/130/24DATE OF ISSUE: 01/10/2024CLOSING DATE & TIME: 12/11/2024 AT 09.00 HOURS SRI LANKA TIME

#### Special Conditions for tendering :

- 1. Offers should be accompanied with the original of valid registration certificate/any **Subsequent renewal** certificates where applicable or a copy certified by an Attorney at law, of aforesaid document issued by the National Medicine Regulatory Authority in Sri Lanka.
- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. **A break-up of** FOB and Freight charges should be quoted separately against each item in addition to quoted C&F price.
- 4. The volume of the total quantity of each item should be given in cubic meters  $(m^3)$
- 5. Foreign offers should be on C&F {CPT/CFR (into FOB and freight]} Colombo basis. Only 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 in LKR for the total delivery price to MSD stores.
- **6.** 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 Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere 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.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.

#### 10. The offer should be valid up to 10/05/2025

#### CONDITIONS FOR SUPPLY FOR SPC ORDERS – APPLICABLE FOR SURGICAL & LAB ITEMS

#### (a) Part A-General Order Conditions (GOC) of Supply

- 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 & 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. 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.
- 5. The specifications of the product offered by the suppliers in the tender, shall match with the tender specifications for the item and any form of alternate offers will not be entertained.

# Shelf life & Warrantees

6. In the supply of all Non consumables; Manufacturer or supplier or local agent shall provide a minimum of 02 year warranty period or as specified in the specification, for each such item or it's sub components supplied (through the local agent), unless otherwise agreed upon with MSD, prior to awarding the tender. Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repairs & spares, when necessary.

(This condition is not applicable for Pharmaceuticals)

8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores in case of local supplies) of the product, shall be 85% of the shelf life requested (specified in order/Indent/PO).

In respect of the items with requested shelf life equal orn more than 24 months, any deficit between the residual shelf life and requested shelf, shall not be more than 04 months.

In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37)

When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for surgical items and 24 months for Pharma/Laboratory items.

# **Standards & Quality**

9. <u>Standards</u>; In addition to Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards that are registered at National Medicines Regulatory Authority in Sri Lanka are also acceptable when no bidders have quoted for the standard specified in the specification.

10. 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.

11.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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative surcharge of the same.

12. 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.24)

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.

13. 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/semigovernment/accredited laboratory (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology and 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 and testing charges, etc, will be recovered from the supplier.

14. 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.11).

#### Pack size, Labeling & Packaging

15.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.

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Product Reference/Catalogue No.s of Surgical items), Date of Manufacture, Date of Expiry (of consumables only) and "STATE LOGO" of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (not applicable for Surgical Non-consumables) & 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. 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**

20. 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  $30^{\circ}c$  +/- $2^{\circ}c$  temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

- 21. 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 coldchain 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.

22. 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.12)

#### **Delivery Requirements**

25. 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. 27 on delayed deliveries, shall be applied.

26. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.

27. 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 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.

28. 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. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

29. 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. 27, 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**

30. 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.

31. 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.

32. 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 condition No. 27 will not be applicable.

#### **Common conditions**

- 36. 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 records.
- 37. 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. 08,05,10,13)
- **Abbreviations :***NMRA ; National Medicines Regulatory Authority/Sri Lanka, SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division,/Ministry of Health-Sri Lanka.*

#### **Special Conditions**

(I) Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments 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.

- (II) In the event of an award made to you on this tender, SPC reserve 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.
- (III) 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.
- (IV) Where a purchase for a particular item is being made for the first time from a supplier, or where there are previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.
- (V) 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.
- (VI) 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 submit 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.
- (VII) In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of

supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.

- (VIII) All Shipment 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 vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely 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.
- (IX) 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.
- (X) 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.
- (XI) a) For products which are imported to Sri Lanka, the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE).

b) For products which are manufactured in Sri Lanka, the registration shall be valid until the last delivery of the products to be procured is received by the PE.

# (XII) Supplier shall submit the signed contract within 14 days of receiving of the contract agreement from SPC.

- (XIII) The below mentioned documents (the original or copies certified by the attorney at law) should be submitted along with copy documents to SPC.
  - 1. A certified copy of the Certificate of Analysis/warranty
  - 2. A certified copy of the Customs declaration
  - 3. Original of the Import License
  - 4. Original of the Customs Assessment Notice
  - 5. Certificate copy of NMRA or WOR.

<u>Note</u>: A certified copy of Business registration Certificate (by an Attorney at low) should be submitted with the offer

# BID NO: DHS/SA/WW/130/24 CLOSING ON : 12/11/2024 at 9.00 a.m.

#### ORDER LIST NUMBER: 2024/SPC/N/R/S/00316

_	A B	С	D	E	F
ITEM NO	SR NO	ITEM	QTY	DELIVERY	Bid Bond value (LKR)
1	13002002	Implant Valve for glucoma, Ahamad type, with flexible plate, for paediatrics, sterile.	20 nos	100% Immediately	28,380.00

All tenderers should furnish an unconditional Bid Bond for each SR No. encashable on demand to the value mentioned in the Column F.

Amount of Bid Bond should be 2% of the bid value of each item to be submitted along with the bid, when the tendered value of each item exceeds LKR 01 million. (when not indicated in the Column F).

#### Bid Bond should be submitted with valid up to 09/06/2025 together with the tender

**Bidding Document Fee- As per the guideline 6.1.1 (a) of the Government Procurement Guidelines 2006.** 

A non refundable fee of Rs. 3,000/=+ taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

#### NOTE

Amendments to Global tender Book,

- (I) Clause No 27 (Page 18) To be deleted 27.4 & 27.5
- (II) Clause No 19 [REGISTRATION Page 13] To be include to read as

(c) For products which are imported to Sri Lanka the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE).

(d) For products which are manufactured in Sri Lanka the registration shall be valid until the last delivery of the products to be procured is received by the Procuring Entity (PE).

(III) To replace the clause No 17.4 & 17.5 in contract document on page No 44 as above (c) & (d).

# <u>ANNEX – 1</u>

# BID NO. : DHS/SA/WW/142/25 DATE OF ISSUE : 01/10/2024 CLOSING DATE & TIME : 12/11/2024 AT 09.00 HOURS SRI LANKA TIME

#### Special Conditions for tendering :

- 1. Offers should be accompanied with the original of valid registration certificate/any **Subsequent renewal** certificates where applicable or a copy certified by an Attorney at law, of aforesaid document issued by the National Medicine Regulatory Authority in Sri Lanka.
- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. **A break-up of** FOB and Freight charges should be quoted separately against each item in addition to quoted C&F price.
- 4. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>)
- 5. Foreign offers should be on C&F {CPT/CFR (into FOB and freight]} Colombo basis. Only 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 in LKR for the total delivery price to MSD stores.
- **6.** 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 Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere 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.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.

#### 10. The offer should be valid up to 11/05/2025

#### CONDITIONS FOR SUPPLY FOR SPC ORDERS – APPLICABLE FOR SURGICAL & LAB ITEMS

#### (a) Part A-General Order Conditions (GOC) of Supply

- 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 & 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 surcharge (as clause No. 37).

6. The specifications of the product offered by the suppliers in the tender, 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. In respect of Non consumables; laboratory items and surgical items: Manufacturer or supplier or local agent shall provide a warranty for a period, not less than as specified in the specification of the item and /or it's sub components/articles supplied (eg: Special Instrument sets), unless otherwise agreed upon prior to awarding the tender.

The supplier's invoice shall indicate, the validity period of the warrantee from the date of receiving goods at MSD and a warrantee card with all details, including the local contact details of warrantee services provider, shall also be inserted in each individual pack.

Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repair and spares, when necessary (**This clause No. 07 is not applicable for all Pharmaceuticals and all Consumable Surgical & Laboratory items**)

- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in 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 of 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.

(b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37)

#### **Standards & Quality**

- **9.** <u>Standards</u>: In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals 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.

- 11. 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative surcharge of the same.
- **12.** 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.24)

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.

**13.** 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 and 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 and testing charges, etc, will be recovered from the supplier.

14. 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.11).

### Pack size, Labeling & Packaging

- **15.** 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.
- **16.** In respect of bulk packs of all pharmaceuticals (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 purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots <u>or</u> when an exemption is notified in the special order conditions of the relevant MSD order list (**This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items**)

**17.** Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Product Reference/Catalogue No.s of Surgical items), Date of Manufacture, Date of Expiry (of consumables only) and "STATE LOGO" of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (not applicable for Surgical Nonconsumables) & date of Manufacture (in any form as "Year & Month" or "No Exp."), in the innermost pack and supplier's invoice.

- 18. 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.
- **19.** 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.
- 20. 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).
- **21.** 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**

- 22. 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  $30^{\circ}c$  +/-  $2^{\circ}c$  temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. 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.
- 24. 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.12)

#### **Delivery Requirements**

**25.** 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. 27 on delayed deliveries, shall be applied.

- 26. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- **27.** 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 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.

**28.** (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.

**29.** 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. 27 (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 other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** 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. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** 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. 27, 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**

**32.** 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.

**33.** 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 laboratory regular items except when specified in respective order lists).

The product artwork or dimensional detail diagrams, product Catalogues and Catalog No's, as necessary for the surgical items (**not relevant to pharmaceutical & Laboratory items**) shall be provided with the bid document, for reference in the; tender evaluation by SPC, ascertaining (before awarding) user acceptance of deviations from the spec by MSD and inspecting the consignments delivered to MSD.

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

- 34 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 <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. 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 <u>www.msd.gov.lk</u>)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 condition No. 27 will not be applicable.

#### **Common conditions**

- 36. 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.
- 37. 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. 08,05,10,13)
- **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. and SR No. s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### Sufficient quantity of samples should be forwarded for evaluation.

#### **Special Conditions**

(I) Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.

Demurrage / additional charges if any which

requirement will be claimed from the supplier.

- (II) In the event of an award made to you on this tender, SPC reserve 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.
- (III) 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.

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- (IV) Where a purchase for a particular item is being made for the first time from a supplier, or where there are previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.
- (V) 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.
- (VI) 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 submit 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.
- (VII) In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- (VIII) All Shipment 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 vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely 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.
- (IX) 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.
- (X) 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.
- (XI) a) For products which are imported to Sri Lanka, the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE).

b) For products which are manufactured in Sri Lanka, the registration shall be valid until the last delivery of the products to be procured is received by the PE.

# (XII) Supplier shall submit the signed contract within 14 days of receiving of the contract agreement from SPC.

(XIII) The below mentioned documents (the original or copies certified by the attorney at law) should be submitted along with copy documents to SPC.

this

- 1. A certified copy of the Certificate of Analysis/warranty
- 2. A certified copy of the Customs declaration
- 3. Original of the Import License
- 4. Original of the Customs Assessment Notice
- 5. Certificate copy of NMRA or WOR.

<u>Note</u>: A certified copy of Business registration Certificate (by an Attorney at low) should be submitted with the offer

# BID NO: DHS/SA/WW/142/25 CLOSING ON : 12/11/2024 at 9.00 a.m.

### ORDER LIST NUMBER: 2025/SPC/N/R/S/00300

_ <u>A</u>	В	С	D	E	F
ITEM NO	SR NO	ITEM	QTY	DELIVERY	Bid Bond value (LKR)
1	21505303	Phaco Chopper, 1.7mm long chopping edge, sharp tip, 12.5cm (approx.) overall length, stainless steel.	75 Nos	40-Jan/2025 35-May/2025	

All tenderers should furnish an unconditional Bid Bond for each SR No. encashable on demand to the value mentioned in the Column F.

Amount of Bid Bond should be 2% of the bid value of each item to be submitted along with the bid, when the tendered value of each item exceeds LKR 01 million. (when not indicated in the Column F).

### Bid Bond should be submitted with valid up to 10/06/2025 together with the tender

Bidding Document Fee- As per the guideline 6.1.1 (a) of the Government Procurement Guidelines 2006.

A non refundable fee of Rs. 3,000/=+ taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

#### NOTE

Amendments to Global tender Book,

- (I) Clause No 27 (Page 18) To be deleted 27.4 & 27.5
- (II) Clause No 19 [REGISTRATION Page 13] To be include to read as

(c) For products which are imported to Sri Lanka the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE).

(d) For products which are manufactured in Sri Lanka the registration shall be valid until the last delivery of the products to be procured is received by the Procuring Entity (PE).

(III) To replace the clause No 17.4 & 17.5 in contract document on page No 44 as above (c) & (d).

### <u>ANNEX – 1</u>

# BID NO. : DHS/SA/WW/143/25 DATE OF ISSUE : 01/10/2024 CLOSING DATE & TIME : 12/11/2024 AT 09.00 HOURS SRI LANKA TIME

### Special Conditions for tendering :

- 1. Offers should be accompanied with the original of valid registration certificate/any **Subsequent renewal** certificates where applicable or a copy certified by an Attorney at law, of aforesaid document issued by the National Medicine Regulatory Authority in Sri Lanka.
- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. **A break-up of** FOB and Freight charges should be quoted separately against each item in addition to quoted C&F price.
- 4. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>)
- 5. Foreign offers should be on C&F {CPT/CFR (into FOB and freight]} Colombo basis. Only 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 in LKR for the total delivery price to MSD stores.
- **6.** 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 Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere 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.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.

### 10. The offer should be valid up to 10/05/2025

### CONDITIONS FOR SUPPLY FOR SPC ORDERS – APPLICABLE FOR SURGICAL & LAB ITEMS

### (a) Part A-General Order Conditions (GOC) of Supply

- 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 & 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 surcharge (as clause No. 37).

6. The specifications of the product offered by the suppliers in the tender, 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. In respect of Non consumables; laboratory items and surgical items: Manufacturer or supplier or local agent shall provide a warranty for a period, not less than as specified in the specification of the item and /or it's sub components/articles supplied (eg: Special Instrument sets), unless otherwise agreed upon prior to awarding the tender.

The supplier's invoice shall indicate, the validity period of the warrantee from the date of receiving goods at MSD and a warrantee card with all details, including the local contact details of warrantee services provider, shall also be inserted in each individual pack.

Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repair and spares, when necessary (**This clause No. 07 is not applicable for all Pharmaceuticals and all Consumable Surgical & Laboratory items**)

- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in 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 of 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.

(b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37)

### **Standards & Quality**

- **9.** <u>Standards</u>: In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals 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.

- **11.** 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative surcharge of the same.
- **12.** 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.24)

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.

**13.** 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 and 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 and testing charges, etc, will be recovered from the supplier.

14. 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.11).

### Pack size, Labeling & Packaging

- **15.** 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.
- **16.** In respect of bulk packs of all pharmaceuticals (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 purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots <u>or</u> when an exemption is notified in the special order conditions of the relevant MSD order list (**This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items**)

**17.** Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Product Reference/Catalogue No.s of Surgical items), Date of Manufacture, Date of Expiry (of consumables only) and "STATE LOGO" of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (not applicable for Surgical Nonconsumables) & date of Manufacture (in any form as "Year & Month" or "No Exp."), in the innermost pack and supplier's invoice.

- 18. 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.
- **19.** 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.
- 20. 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).
- **21.** 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**

- 22. 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  $30^{\circ}c$  +/-  $2^{\circ}c$  temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. 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.
- 24. 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.12)

### **Delivery Requirements**

**25.** 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. 27 on delayed deliveries, shall be applied.

- 26. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- **27.** 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 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.

**28.** (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.

**29.** 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. 27 (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 other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** 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. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** 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. 27, 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**

**32.** 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.

**33.** 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 laboratory regular items except when specified in respective order lists).

The product artwork or dimensional detail diagrams, product Catalogues and Catalog No's, as necessary for the surgical items (**not relevant to pharmaceutical & Laboratory items**) shall be provided with the bid document, for reference in the; tender evaluation by SPC, ascertaining (before awarding) user acceptance of deviations from the spec by MSD and inspecting the consignments delivered to MSD.

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

- 34 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 <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. 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 <u>www.msd.gov.lk</u>)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 condition No. 27 will not be applicable.

### **Common conditions**

- 36. 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.
- 37. 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. 08,05,10,13)
- **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. and SR No. s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

### Sufficient quantity of samples should be forwarded for evaluation.

### **Special Conditions**

(I) Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.

Demurrage / additional charges if any which

requirement will be claimed from the supplier.

this

- (II) In the event of an award made to you on this tender, SPC reserve 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.
- (III) 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.
- (IV) Where a purchase for a particular item is being made for the first time from a supplier, or where there are previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.
- (V) 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.
- (VI) 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 submit 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.
- (VII) In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- (VIII) All Shipment 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 vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely 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.
- (IX) 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.
- (X) 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.
- (XI) a) For products which are imported to Sri Lanka, the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE).

b) For products which are manufactured in Sri Lanka, the registration shall be valid until the last delivery of the products to be procured is received by the PE.

# (XII) Supplier shall submit the signed contract within 14 days of receiving of the contract agreement from SPC.

(XIII) The below mentioned documents (the original or copies certified by the attorney at law) should be submitted along with copy documents to SPC.

- 1. A certified copy of the Certificate of Analysis/warranty
- 2. A certified copy of the Customs declaration
- 3. Original of the Import License
- 4. Original of the Customs Assessment Notice
- 5. Certificate copy of NMRA or WOR.

<u>Note</u>: A certified copy of Business registration Certificate (by an Attorney at low) should be submitted with the offer

# BID NO: DHS/SA/WW/143/25 CLOSING ON : 12/11/2024 at 9.00 a.m.

### ORDER LIST NUMBER: 2025/SPC/N/R/S/00302

<u>_</u> A	В	С	D	E	F
ITEM NO	SR NO	ITEM	QTY	DELIVERY	Bid Bond value (LKR)
1	21301700	Tray for Yasargil type or similar titanium cerebrovascular clips applying forceps, stainless steel.	4 Nos	4-Mar/2025	
2	21301702	Utility Tray, half size for storage and sterilizaion of Yasargil type or similar titanium cerebrovascular clips,stainless steel.	1 Nos	1-Jun/2025	
3	21303402	Forceps Micro, curved, bayonet shaped, 0.5mm tip, 150mm (approx.) length, stainless steel.	1 Nos	1-May/2025	
4	21303405	Forceps Micro, straight, bayonet shaped, 0.5mm tip, 150mm (approx.) length, stainless steel.	10 Nos	5-Jan/2025 5-Jul/2025	

All tenderers should furnish an unconditional Bid Bond for each SR No. encashable on demand to the value mentioned in the Column F.

Amount of Bid Bond should be 2% of the bid value of each item to be submitted along with the bid, when the tendered value of each item exceeds LKR 01 million. (when not indicated in the Column F).

### Bid Bond should be submitted with valid up to 09/06/2025 together with the tender

**Bidding Document Fee- As per the guideline 6.1.1 (a) of the Government Procurement Guidelines 2006.** 

A non refundable fee of Rs. 3,000/=+ taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

### NOTE

Amemndments to Global tender Book,

- (I) Clause No 27 (Page 18) To be deleted 27.4 & 27.5
- (II) Clause No 19 [REGISTRATION Page 13]

#### To be include to read as

(c) For products which are imported to Sri Lanka the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE).

(d) For products which are manufactured in Sri Lanka the registration shall be valid until the last delivery of the products to be procured is received by the Procuring Entity (PE).

(III) To replace the clause No 17.4 & 17.5 in contract document on page No 44 as above (c) & (d).

### MEMORANDUM

TO : MANAGER ADMINISTRATION

FROM : PROCUREMENT OFFICER –SURGICAL SPECIAL

DATE : 01.10.2024

#### WORLD WIDE TENDER NOS.;

#### DHS/SA/WW/141/25,DHS/SA/WW/142/25,DHS/SA/WW/143/25,DHS/SA/WW/128/24 DHS/SA/WW/129/24,DHS/SA/WW/130/24,DHS/SA/WW/31/23,DHS/SA/WW/32/23 DHS/SA/WW/33/23, CLOSING ON 12.11.2024 AT 0900 HOURS

4.

The above Tender was published in the "Sunday Observer" of 29<sup>th</sup> September 2024.

The tender forms to be available at the counter for sale on working days from 01.10.2024

The closing date of this tender is 12<sup>th</sup> November 2024.

Please make necessary arrangements with Internal Audit Dept. to provide a sealed tender box with markings DHS/SA/WW/141/25,DHS/SA/WW/142/25,DHS/SA/WW/143/25,DHS/SA/WW/128/24 DHS/SA/WW/129/24,DHS/SA/WW/130/24,DHS/SA/WW/31/23,DHS/SA/WW/32/23 DHS/SA/WW/33/23, CLOSING ON 12.11.2024 AT 0900 HOURS

Seating accommodation for approximately 25 representatives and a public address system for the reading of the prices will also be necessary please.

10 2h

### PROCUREMENT OFFICER SURGICAL ANNUAL

CC: DGM (Technical & Laboratory) DGM (Finance) Asst. Manager Procuring Unit Internal Auditor Receptionist - **Non-refundable Bid document fee as per Annex-I** File

-/CS

TO: THE RECEPTIONISTFROM: PROCUREMENT OFFICER

DATE : 01.10.2024

# WORLD WIDE TENDER NO.:

Unit	Bid Number
Surgical Annual	DHS/SA/WW/141/25,DHS/SA/WW/142/25,DHS/SA/WW/143/25,DHS/SA/WW/128/24 DHS/SA/WW/129/24,DHS/SA/WW/130/24,DHS/SA/WW/31/23,DHS/SA/WW/32/23 DHS/SA/WW/33/23,DHS/SA/WW/102/24

Reference above, the tenders to be issued from 01.10.2024.

Any person who acts as an agent or sub agent, representative or nominee for and on behalf of any tenderer to register in the Registrar of companies.

Therefore not to issue document without a copy of registration with the Dept. of Registrar of companies.

# Non-refundable Bidding Document Fee as per Annex-1

111.124 MENT OFFICER PROCI

CC : DGM (Finance)



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Departmental Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Ministry of Health.

Bid Number	Closing Date & Time	Item Description	Date of issuing of Bid Documents	Non- refundable Bid Fee (LKR)
DHS/SS/WW/138/22	20.11.2024 @ 09.00 a.m.	Scalpel handle, Micro vascular vessel dialator	06.10.2024	3,000/- + Tax
DHS/SS/WW/22/23	11.11.2024 @ 09.00 a.m.	Umbilical catheter, Cervical wooden spatula	01.10.2024	3,000/- + Tax
DHS/SS/WW/23/23	11.11.2024 @ 09.00 a.m.	Linear stapler device, linear stapler cartridges	01.10.2024	12,500/- + Tax
DHS/SS/WW/152/24	11.11.2024 @ 09.00 a.m.	Cardiothoracic Consumables	01.10.2024	3,000/- + Tax
DHS/SS/WW/153/24	11.11.2024 @ 09.00 a.m.	Cervical wooden spatula	01.10.2024	3,000/- + Tax
DHS/SS/WW/154/24	20.11.2024 @ 09.00 a.m.	Cerclage wire soft tissue	06.10.2024	3,000/- + Tax
DHS/SS/WW/112/25	11.11.2024 @ 09.00 a.m.	Drug Eluting coronary stents	01.10.2024	35,000/- + Tax
DHS/SS/WW/113/25	11.11.2024 @ 09.00 a.m.	Balloon dilatation catheters	01.10.2024	35,000/- + Tax
DHS/SS/WW/114/25	11.11.2024 @ 09.00 a.m.	Permanent pacemaker single chamber	01.10.2024	60,000/- + Tax
DHS/SS/WW/115/25	11.11.2024 @ 09.00 a.m.	Permanent pacemaker dual chamber	01.10.2024	60,000/- + Tax
DHS/SS/WW/116/25	11.11.2024 @ 09.00 a.m.	Implantable cardiovertor defibrillator (ICD) single chamber	01.10.2024	60,000/- + Tax
DHS/SS/WW/117/25	11.11.2024 @ 09.00 a.m.	Drug Eluting coronary stents	01.10.2024	20,000/- + Tax
DHS/SS/WW/118/25	20.11.2024 @ 09.00 a.m.	Cardiology Consumables	06.10.2024	12,500/- + Tax
DHS/SS/WW/119/25	20.11.2024 @ 09.00 a.m.	Coronary guiding catheter	06.10.2024	12,500/- + Tax
DHS/SS/WW/120/25	20.11.2024 @ 09.00 a.m.	Guidewires	06.10.2024	12,500/- + Tax
DHS/SS/WW/121/25	20.11.2024 @ 09.00 a.m.	Cardiology Consumables	06.10.2024	3,000/- + Tax
DHS/SS/WW/122/25	20.11.2024 @ 09.00 a.m.	Ablation catheters	06.10.2024	3,000/- + Tax
DHS/SS/WW/123/25	20.11.2024 @ 09.00 a.m.	Compatible connecting cable for ablation catheters	06.10.2024	3,000/- + Tax
DHS/SS/WW/124/25	20.11.2024 @ 09.00 a.m.	Irrlgation pump, vascular sheath, diagnostic catheters	06.10.2024	12,500/- + Tax
DHS/SS/WW/125/25	20.11.2024 @ 09.00 a.m.	ASD Occlusion Devices	06.10.2024	12,500/- + Tax
DHS/SS/WW/126/25	20.11.2024 @ 09.00 a.m.	Surgical Gonio Knife, Cannulated Extrusion Needle	06.10.2024	3,000/- + Tax
DHS/L/WW/103/24	11.11.2024 @ 09.00 a.m.	Quality Control Reagents	01.10.2024	3,000/- + Tax
DHS/L/WW/98/25	11.11.2024 @ 09.00 a.m.	Blood Bank serological and STD items	01.10.2024	20,000/- + Tax

DHS/SA/WW/141/25	12.11.2024 @ 09.00 a.m	Ophthalmic Surgery Instruments	01.10.2024	3,000/- + Tax
DHS/SA/WW/142/25	12.11.2024 @ 09.00 a.m	Phaco Chopper, 1.7mm longchopping edge sharp tip	01.10.2024	3,000/- + Tax
DHS/SA/WW/143/25	12.11.2024 @ 09.00 a.m	Neurosurgical Instruments	01.10.2024	3,000/- + Tax
DHS/SA/WW/128/24	12.11.2024 @ 09.00 a.m	Urological consumables	01.10.2024	3,000/- + Tax
DHS/SA/WW/129/24	12.11.2024 @ 09.00 a.m	Hypodermic Needle,26G X 50mm.	01.10.2024	3,000/- + Tax
DHS/SA/WW/130/24	12.11.2024 @ 09.00 a.m	Implant Valve for glucoma, Ahamad type, for paediatrics	01.10.2024	3,000/- + Tax
DHS/SA/WW/31/23	12.11.2024 @ 09.00 a.m	Threaded Guide pin 2.0mm for6.5/7.0 mm	01.10.2024	3,000/- + Tax
DHS/SA/WW/32/23	12.11.2024 @ 09.00 a.m	Disitas Humidity Thermometer	01.10.2024	3,000/- + Tax
DHS/SA/WW/33/23	12.11.2024 @ 09.00 a.m	Transjugular liver biopsy set	01.10.2024	3,000/- + Tax
DHS/SA/WW/102/24	08.10.2024 @ 09.00 a.m (New closing date)	Stainless Steel Sutures & Suture wires and Stapling Items. (Postpone Tender)	13.08.2024	3,000/- + Tax

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

Wherever necessary 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" 16<sup>th</sup> 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 authorized 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 -PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 16<sup>TH</sup> FLOOR, NO. 41, KIRULA ROAD, COLOMBO 5. SRI LANKA.

FAX	: 00 94-11- 2582495		
E-MAIL	: mgrsurgical@spc.lk		
E-MAIL	: mgrsurgical@spc.lk		

GENERAL MANAGER- STATE PHARMACEUTICALS CORPORATION On behalf of CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA "MEHEWARA PIYASA", 16<sup>TH</sup> FLOOR, NO. 41, KIRULA ROAD, COLOMBO 5. SRI LANKA

# <u>ANNEX – 1</u>

# BID NO. : DHS/SA/WW/141/25 DATE OF ISSUE : 01/10/2024 CLOSING DATE & TIME : 12/11/2024 AT 09.00 HOURS SRI LANKA TIME

### **Special Conditions for tendering :**

- 1. Offers should be accompanied with the original of valid registration certificate/any **Subsequent renewal** certificates where applicable or a copy certified by an Attorney at law, of aforesaid document issued by the National Medicine Regulatory Authority in Sri Lanka.
- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. **A break-up of** FOB and Freight charges should be quoted separately against each item in addition to quoted C&F price.
- 4. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>)
- 5. Foreign offers should be on C&F {CPT/CFR (into FOB and freight]} Colombo basis. Only 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 in LKR for the total delivery price to MSD stores.
- **6.** 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 Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere 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.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.

### 10. The offer should be valid up to 10/05/2025

### CONDITIONS FOR SUPPLY FOR SPC ORDERS – APPLICABLE FOR SURGICAL & LAB ITEMS

### (a) Part A-General Order Conditions (GOC) of Supply

- 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 & 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 surcharge (as clause No. 37).

6. The specifications of the product offered by the suppliers in the tender, 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. In respect of Non consumables; laboratory items and surgical items: Manufacturer or supplier or local agent shall provide a warranty for a period, not less than as specified in the specification of the item and /or it's sub components/articles supplied (eg: Special Instrument sets), unless otherwise agreed upon prior to awarding the tender.

The supplier's invoice shall indicate, the validity period of the warrantee from the date of receiving goods at MSD and a warrantee card with all details, including the local contact details of warrantee services provider, shall also be inserted in each individual pack.

Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repair and spares, when necessary (**This clause No. 07 is not applicable for all Pharmaceuticals and all Consumable Surgical & Laboratory items**)

- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in 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 of 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.

(b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37)

### **Standards & Quality**

- **9.** <u>Standards</u>: In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals 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.

- 11. 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative surcharge of the same.
- **12.** 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.24)

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.

**13.** 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 and 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 and testing charges, etc, will be recovered from the supplier.

14. 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.11).

### Pack size, Labeling & Packaging

- **15.** 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.
- **16.** In respect of bulk packs of all pharmaceuticals (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 purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots <u>or</u> when an exemption is notified in the special order conditions of the relevant MSD order list (**This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items**)

**17.** Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Product Reference/Catalogue No.s of Surgical items), Date of Manufacture, Date of Expiry (of consumables only) and "STATE LOGO" of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (not applicable for Surgical Nonconsumables) & date of Manufacture (in any form as "Year & Month" or "No Exp."), in the innermost pack and supplier's invoice.

- 18. 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.
- **19.** 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.
- 20. 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).
- **21.** 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**

- 22. 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  $30^{\circ}c$  +/-  $2^{\circ}c$  temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. 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.
- 24. 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.12)

### **Delivery Requirements**

**25.** 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. 27 on delayed deliveries, shall be applied.

- 26. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- **27.** 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 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.

**28.** (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.

**29.** 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. 27 (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 other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** 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. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** 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. 27, 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**

**32.** 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.

**33.** 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 laboratory regular items except when specified in respective order lists).

The product artwork or dimensional detail diagrams, product Catalogues and Catalog No's, as necessary for the surgical items (**not relevant to pharmaceutical & Laboratory items**) shall be provided with the bid document, for reference in the; tender evaluation by SPC, ascertaining (before awarding) user acceptance of deviations from the spec by MSD and inspecting the consignments delivered to MSD.

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

- 34 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 <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. 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 <u>www.msd.gov.lk</u>)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 condition No. 27 will not be applicable.

### **Common conditions**

- 36. 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.
- 37. 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. 08,05,10,13)
- **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. and SR No. s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

### Sufficient quantity of samples should be forwarded for evaluation.

### **Special Conditions**

(I) Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.

Demurrage / additional charges if any which

requirement will be claimed from the supplier.

- (II) In the event of an award made to you on this tender, SPC reserve 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.
- (III) 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.

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- (IV) Where a purchase for a particular item is being made for the first time from a supplier, or where there are previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.
- (V) 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.
- (VI) 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 submit 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.
- (VII) In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- (VIII) All Shipment 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 vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely 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.
- (IX) 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.
- (X) 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.
- (XI) a) For products which are imported to Sri Lanka, the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE).

b) For products which are manufactured in Sri Lanka, the registration shall be valid until the last delivery of the products to be procured is received by the PE.

# (XII) Supplier shall submit the signed contract within 14 days of receiving of the contract agreement from SPC.

(XIII) The below mentioned documents (the original or copies certified by the attorney at law) should be submitted along with copy documents to SPC.

this

- 1. A certified copy of the Certificate of Analysis/warranty
- 2. A certified copy of the Customs declaration
- 3. Original of the Import License
- 4. Original of the Customs Assessment Notice
- 5. Certificate copy of NMRA or WOR.

<u>Note</u>: A certified copy of Business registration Certificate (by an Attorney at low) should be submitted with the offer

# BID NO: DHS/SA/WW/141/25 CLOSING ON : 12/11/2024 at 9.00 a.m.

### ORDER LIST NUMBER: 2025/SPC/N/R/S/00298

A	В	С	D	E	F
ITEM	SR NO	ITEM	QTY	DELIVERY	Bid Bond value
NO					(LKR)
1	21505300	Phaco Chopper, 1mm long chopping edge,	120	60-Jan/2025	
		sharp tip, 12.5cm (approx.) overall length,	Nos	60-May/2025	
		stainless steel		-	
2	21505301	Phaco Chopper, 1mm long chopping edge,	80	40-Jan/2025	
		blunt tip, 12.5cm (approx.) overall length, stainless steel.	Nos	40-May/2025	
3	21505302	Phaco Chopper, 1.2mm long chopping	60	40-Jan/2025	
		edge, sharp tip, 12.5cm (approx.) overall length, stainless steel.	Nos	20-May/2025	
4	21505602	Lachrymal Probe, double ended, Bowman	32	16-Jan/2025	
		type or similar, set of 6 sizes, stainless steel.	Nos	16-May/2025	
5	21506000	Ophthalmic Caliper, 20mm, straight,	30	15-Jan/2025	
		stainless steel.	Nos	15-Jun/2025	
6	21506100	Ophthalmic Caliper, Castroviejo type or	65	35-Jan/2025	
		similar, 17mm, measuring range 40mm, stainless steel	Nos	30-May/2025	
7	21506200	Wire Speculum, Child size, Barraquer type	45	25-Jan/2025	
		or similar, 11 mm blades, 19mm spread, open blades, stainless steel.	Nos	20-May/2025	
8	21506203	Wire Speculum, Paediatric size, Barraquer	70	40-Jan/2025	
		type or similar, stainless steel.	Nos	30-May/2025	
9	21506300	Eye Speculum, Clark type or similar, open	30	20-Jan/2025	
		blades, stainless steel.	Nos	10-Jun/2025	
10	21506401	Wire Speculum, Kratz Barraquer type or	100	50-Jan/2025	
		similar, 14 mm blades, 18mm spread, solid blade, stainless steel.	Nos	50-Jun/2025	
11	21506601	Iris Spatula, Barraquer type or similar,	20	10-Jan/2025	
		angled tip, gently curved, 11mm shaft,	Nos	10-May/2025	
12	21507000	titanium. Cystotome & Curette, Moorefield type or	42	20 Jan/2025	
12	2120/000	similar, stainless steel.		20-Jan/2025	
12	21507400	Lens Expressor Loop, 13.5cm (approx.)	Nos	22-May/2025	
13	21507400	length, stainless steel.	10 Nos	10-Jan/2025	
14	21507500	Lens Expressor Hook, Arruga type or	30	30-Jan/2025	
		similar, stainless steel.	Nos		
15	21507600	Irrigating Vectus, size 27G, stainless steel.	50	50-Jan/2025	
			Nos		

		10			
16	21508501	Schocket double ended sclera depressor, rounded end with curved marking end. 6mm wide bar and 25mm teardrop shape tips, overall length 134mm.	15 Nos	8-Jan/2025 7-May/2025	
17	21508502	Spaide paediatric sclera depressor, curved tip, serrated surface, overall length 125mm.	5 Nos	5-Jan/2025	
18	21508601	Meyer-Schwickerath localizer (overall length 123mm)	1 Nos	1-Jan/2025	
19	21508701	Arruga Capsule Forceps, curved, flat handle, cup jaw, 111mm length, shaft pattern- valuated, 2.0mm tip, stainless steel	5 Nos	5-Jan/2025	
20	21508901	Forceps for scleral plugs width of tip 0.85mm, 100mm length.	12 Nos	6-Jan/2025 6-May/2025	
21	21509001	Watzke sleeve spreading forceps serrated 10mm tip, 30 degree angled , with cross action handle, overall length 114mm.	12 Nos	6-Jan/2025 6-May/2025	
22	21509101	23G Passive aspiration/extrusion hand piece (Air-Fluid needle handle)	12 Nos	6-Jan/2025 6-May/2025	
23	21509201	Blackflush hand piece (side port) with luer connecter, length 110mm.	15 Nos	8-Jan/2025 7-Jun/2025	

All tenderers should furnish an unconditional Bid Bond for each SR No. encashable on demand to the value mentioned in the Column F.

Amount of Bid Bond should be 2% of the bid value of each item to be submitted along with the bid, when the tendered value of each item exceeds LKR 01 million. (when not indicated in the Column F).

### Bid Bond should be submitted with valid up to 09/06/2025 together with the tender

**Bidding Document Fee- As per the guideline 6.1.1 (a) of the Government Procurement Guidelines 2006.** 

A non refundable fee of Rs. 3,000/=+ taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

### NOTE

Amendments to Global tender Book,

- (I) Clause No 27 (Page 18) To be deleted 27.4 & 27.5
- (II) Clause No 19 [REGISTRATION Page 13] To be include to read as

(c) For products which are imported to Sri Lanka the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE).

(d) For products which are manufactured in Sri Lanka the registration shall be valid until the last delivery of the products to be procured is received by the Procuring Entity (PE).

### (III) To replace the clause No 17.4 & 17.5 in contract document on page No 44 as above (c) & (d).

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