



TÜRKİYE ODALAR VE BORSALAR BİRLİĞİ



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

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Sayı : E-34221550-720-8953

Tarih: 03.09.2024

Konu : Sri Lanka Devlet İlaç Kurumu Tarafından Yayınlanan İhale Duyuruları

TÜM ODA VE BORSALARA (Genel Sekreterlik)

İlgi : Sri Lanka Ankara Büyükelçiliği'nin 28.08.2024 tarihli e-postası

İlgide kayıtlı e-postada, Sri Lanka Devlet İlaç Kurumu tarafından yayınlanan ihale ilanı duyuruları iletilmekte ve söz konusu ihalenin kapanış tarihlerinin 4 Ekim 2024 olduğu bildirilmektedir. Bilgilerinizi ve söz konusu ihalelerin ilgili üyelerinize duyurulmasını rica ederim.

Saygılarımla,

e-imza

Ali Emre YURDAKUL
Genel Sekreter Yardımcısı

EK:

- 1- İhale Duyurusu - 1 (12 sayfa)
- 2- İhale Duyurusu - 2 (12 sayfa)
- 3- İhale Duyurusu - 3 (12 sayfa)
- 4- İhale Duyurusu - 4 (12 sayfa)
- 5- İhale Duyurusu - 5 (12 sayfa)
- 6- İhale Duyurusu - 6 (12 sayfa)
- 7- İhale Duyurusu - 7 (11 sayfa)
- 8- İhale Duyurusu - 8 (11 sayfa)
- 9- İhale Duyurusu - 9 (12 sayfa)
- 10- İhale Duyurusu - 10 (10 sayfa)
- 11- İhale Duyurusu - 11 (11 sayfa)
- 12- İhale Duyurusu - 12 (11 sayfa)
- 13- İhale Duyurusu - 13 (12 sayfa)
- 14- İhale Duyurusu - 14 (12 sayfa)
- 15- İhale Duyurusu - 15 (14 sayfa)

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

Evrakı Doğrulamak İçin : <https://belgedogrula.tobb.org.tr/belgedogrulama.aspx?eD=BSEK7S8E8E>

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ANNEX – 1

BID NO. : DHS/SA/WW/82/25
DATE OF ISSUE : 20.08.2024
CLOSING DATE & TIME : 04.10.2024 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 (m³)
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 29.03.2025**

CONDITIONS FOR SUPPLY OF SURGICAL 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 and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (Total charge = $[a]+[a]\times 0.25$) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 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 at the MSD stores) 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 1/6th (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. **Standards**; 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 charge 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 & 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.

- 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 quantity in the purchase order is less than 100,000 tablets/capsules, with deliveries in one/more lots or 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 nos. of surgical items,, 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 (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.

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 Bar coded (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 30⁰c +/- 2⁰c 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. $< 25^{\circ}\text{c}$, $2-25^{\circ}\text{c}$, $15-20^{\circ}\text{c}/30^{\circ}\text{c}$, $2-8^{\circ}\text{c}$ etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at $30^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $75\% \pm 5\%$ RH for **AC stored** items and at $25^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $60\% \pm 5\%$ 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 15th 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 www.msd.gov.lk)
If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 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: SOC's 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.

(i) -

(ii) -

(iii) -

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 should also be valid until at least six (06) months after the last consignment of the products to be procured are due to be received in Sri Lanka.**

b) For products which are manufactured in Sri Lanka the registration should be valid for at least six (06) months after the last consignment of the products to be procured are received by the Procurement Entity.

(XII) Local Agent shall attend to renew the product registration with NMRA six months prior to expiration of the existing product registration.

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

(XIV) 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.

Note : A certified copy of Business registration Certificate (by an Attorney at law) should be submitted with the offer

BID NO: DHS/SA/WW/82/25 CLOSING ON : 04.10.2024 at 9.00 a.m.

ORDER LIST NUMBER: 2025/SPC/N/R/S/00179

(A) ITEM NO	(B) SR NO	(C) ITEM	(D) QTY	(E) DELIVERY	(F) Bid Bond value (LKR)
1.	14000502	Hypodermic Syringe with luer slip, 20ml, without Needle, with 1ml graduations, with double seal piston (3 part) or medical grade plastic plunger (2 part), with centric or eccentric nozzle and luer conical fitting with 6% taper (luer slip type) ISO 594, non toxic and pyrogen free, sterile. Conforming to sterile single use plastic syringes BP1993 (complying with international standard ISO 7886 -1984(E) for hypodermic syringes for single use and British Standard BS 5081 : Part 1 and 2 1987 for sterile hypodermic syringes and needles).	1,400,000 Nos	700,000 – Jan/2025 700,000 – 4 months after 1 st lot	911,680.00

2.	14000503	Hypodermic Syringe luer lock, 20ml, without needle, with 1ml graduations, with double seal piston (3 part), non toxic and pyrogen free, sterile. Conforming to sterile single use plastic syringes BP1993 (complying with international standard ISO 7886 -1984(E) for hypodermic syringes for single use and British Standard BS 5081 : Part 1 and 2 1987 for sterile hypodermic syringes and needles).	900,000 Nos	500,000 – Jan/2025 400,000 – 4 months after 1 st lot	282,060.00
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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 28.04.2025 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. 20,000/ + taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

ANNEX – 1

BID NO. : DHS/SA/WW/81/25
DATE OF ISSUE : 20.08.2024
CLOSING DATE & TIME : 04.10.2024 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.
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4. The volume of the total quantity of each item should be given in cubic meters (m³)
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 29.03.2025**

CONDITIONS FOR SUPPLY OF SURGICAL 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 and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (Total charge = $[a]+[a]\times 0.25$) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 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 at the MSD stores) 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 1/6th (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. **Standards**; 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 charge 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 & 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.

- 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 quantity in the purchase order is less than 100,000 tablets/capsules, with deliveries in one/more lots or 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 nos. of surgical items,, 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 (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.

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 Bar coded (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 30⁰c +/- 2⁰c 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. $< 25^{\circ}\text{c}$, $2-25^{\circ}\text{c}$, $15-20^{\circ}\text{c}/30^{\circ}\text{c}$, $2-8^{\circ}\text{c}$ etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment. (report shall include studies; at $30^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $75\% \pm 5\%$ RH for **AC stored** items and at $25^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $60\% \pm 5\%$ 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 15th 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 www.msd.gov.lk)
If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 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: SOC's 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.

(i) -

(ii) -

(iii) -

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 should also be valid until at least six (06) months after the last consignment of the products to be procured are due to be received in Sri Lanka.**

b) For products which are manufactured in Sri Lanka the registration should be valid for at least six (06) months after the last consignment of the products to be procured are received by the Procurement Entity.

(XII) Local Agent shall attend to renew the product registration with NMRA six months prior to expiration of the existing product registration.

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

(XIV) 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.

Note : A certified copy of Business registration Certificate (by an Attorney at law) should be submitted with the offer

BID NO: DHS/SA/WW/81/25 CLOSING ON : 04.10.2024 at 9.00 a.m.

ORDER LIST NUMBER: 2025/SPC/N/R/S/00178

(A) ITEM NO	(B) SR NO	(C) ITEM	(D) QTY	(E) DELIVERY	(F) Bid Bond value (LKR)
1.	14000601	Hypodermic Syringe luer slip, 50ml, without Needle, with 01ml graduations, indicated with prominent line at 05ml intervals and indicated numerically at 10ml intervals, With double seal piston (3 part) or medical grade plastic plunger (2 part), with centric or eccentric nozzle and luer conical fitting with 6% taper (luer slip type) ISO 594, non toxic and pyrogen free, sterile. Conforming to sterile single use plastic syringes BP1993 (complying with international standard ISO 7886 -1984(E) for hypodermic syringes for single use and British Standard BS 5081 : Part 1 and 2 1987 for sterile hypodermic syringes and needles)	850,000 Nos	850,000 – May/2025	681,020.00
2.	14000602	Hypodermic Syringe luer lock, 50ml, without Needle, with 01ml graduations, indicated with prominent line at 05ml intervals and indicated numerically at 10ml intervals, With double seal piston (3 part) or medical grade plastic plunger (2 part), non toxic and pyrogen free, sterile. Conforming to sterile single use plastic syringes	700,000 Nos	400,000 – Jan/2025 300,000 – 4 months after 1 st lot	750,400.00

		BP1993 (complying with international standard ISO 7886 -1984(E) for hypodermic syringes for single use and British Standard BS 5081 : Part 1 and 2 1987 for sterile hypodermic syringes and needles)			
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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 28.04.2025 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. 20,000/ + taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

ANNEX – 1

BID NO. : DHS/SA/WW/80/25
DATE OF ISSUE : 20.08.2024
CLOSING DATE & TIME : 04.10.2024 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 (m³)
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 29.03.2025

CONDITIONS FOR SUPPLY OF SURGICAL 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 and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (Total charge = $[a]+[a]\times 0.25$) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 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 at the MSD stores) 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 1/6th (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. **Standards**; 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 charge 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 & 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.

- 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 quantity in the purchase order is less than 100,000 tablets/capsules, with deliveries in one/more lots or 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 nos. of surgical items,, 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 (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.

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 Bar coded (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 30⁰c +/- 2⁰c 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. $< 25^{\circ}\text{c}$, $2-25^{\circ}\text{c}$, $15-20^{\circ}\text{c}/30^{\circ}\text{c}$, $2-8^{\circ}\text{c}$ etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at $30^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $75\% \pm 5\%$ RH for **AC stored** items and at $25^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $60\% \pm 5\%$ 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 15th 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 www.msd.gov.lk)
If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 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: SOC's 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.

(i) -

(ii) -

(iii) -

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 should also be valid until at least six (06) months after the last consignment of the products to be procured are due to be received in Sri Lanka.**

b) For products which are manufactured in Sri Lanka the registration should be valid for at least six (06) months after the last consignment of the products to be procured are received by the Procurement Entity.

(XII) Local Agent shall attend to renew the product registration with NMRA six months prior to expiration of the existing product registration.

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

(XIV) 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.

Note : A certified copy of Business registration Certificate (by an Attorney at law) should be submitted with the offer

BID NO: DHS/SA/WW/80/25 CLOSING ON : 04.10.2024 at 9.00 a.m.

ORDER LIST NUMBER: 2025/SPC/N/R/S/00176

(A) ITEM NO	(B) SR NO	(C) ITEM	(D) QTY	(E) DELIVERY	(F) Bid Bond value (LKR)
1.	14000201	Hypodermic Syringe with luer slip, 2.5ml/3ml, with mounted 23G x 31 mm Needle, with 0.1ml graduations, with double seal piston (3 part) or medical grade plastic plunger (2 part), non toxic and pyrogen free, sterile. Conforming to sterile single use plastic syringes BP1993 (complying with international standard ISO 7886 -1984(E) for hypodermic syringes for single use and British Standard BS 5081 : Part 1 and 2 1987 for sterile hypodermic syringes and needles).	23,800,000 Nos	13,800,000 – Jan/2025 10,000,000 – 4 months after 1 st lot	2,275,280.00
2.	14000203	Hypodermic Syringe with luer lock, 2.5ml/3ml, without Needle, with 0.1ml graduations, with double seal piston (3 part) or medical grade plastic plunger (2 part), non toxic and pyrogen free, sterile. Conforming to sterile single use plastic syringes BP1993 (complying with international standard ISO 7886 -1984(E) for hypodermic syringes for single use and British Standard BS 5081 : Part 1 and 2 1987 for sterile hypodermic syringes and needles).	550,000 Nos	550,000 – Apr/2025	55,550.00

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 28.04.2025 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. 35,000/ + taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

ANNEX – 1

BID NO. : DHS/SA/WW/79/25
DATE OF ISSUE : 20.08.2024
CLOSING DATE & TIME : 04.10.2024 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 (m³)
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 01.04.2025

CONDITIONS FOR SUPPLY OF SURGICAL 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 and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (Total charge = $[a]+[a]\times 0.25$) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 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 at the MSD stores) 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 1/6th (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. **Standards**; 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 charge 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 & 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.

- 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 quantity in the purchase order is less than 100,000 tablets/capsules, with deliveries in one/more lots or 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 nos. of surgical items,, 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 (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.

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 Bar coded (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 30⁰c +/- 2⁰c 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. $< 25^{\circ}\text{c}$, $2-25^{\circ}\text{c}$, $15-20^{\circ}\text{c}/30^{\circ}\text{c}$, $2-8^{\circ}\text{c}$ etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at $30^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $75\% \pm 5\%$ RH for **AC stored** items and at $25^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $60\% \pm 5\%$ 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 15th 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 www.msd.gov.lk)
If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 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: SOC's 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.

(i) -

(ii) -

(iii) -

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 should also be valid until at least six (06) months after the last consignment of the products to be procured are due to be received in Sri Lanka.**

b) For products which are manufactured in Sri Lanka the registration should be valid for at least six (06) months after the last consignment of the products to be procured are received by the Procurement Entity.

(XII) Local Agent shall attend to renew the product registration with NMRA six months prior to expiration of the existing product registration.

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

(XIV) 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.

Note : A certified copy of Business registration Certificate (by an Attorney at law) should be submitted with the offer

BID NO: DHS/SA/WW/79/25 CLOSING ON : 04.10.2024 at 9.00 a.m.

ORDER LIST NUMBER: 2025/SPC/N/R/S/00175

(A) ITEM NO	(B) SR NO	(C) ITEM	(D) QTY	(E) DELIVERY	(F) Bid Bond value (LKR)
1.	14000301	Hypodermic Syringe with luer slip, 5ml, with mounted 22G x 31 mm Needle, with 0.2ml graduations, with double seal piston (3 part) or medical grade plastic plunger (2 part), non toxic and pyrogen free, sterile. Conforming to sterile single use plastic syringes BP1993 (complying with international standard ISO 7886 -1984(E) for hypodermic syringes for single use and British Standard BS 5081 : Part 1 and 2 1987 for sterile hypodermic syringes and needles).	24,900,000 Nos	14,900,000 – Jan/2025 10,000,000 – 4 months after 1 st lot	3,017,880.00

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 30.04.2025 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. 35,000/ + taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

ANNEX – 1

BID NO. : DHS/SA/WW/78/25
DATE OF ISSUE : 20.08.2024
CLOSING DATE & TIME : 04.10.2024 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 (m³)
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 01.04.2025

CONDITIONS FOR SUPPLY OF SURGICAL 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 and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (Total charge = $[a]+[a]\times 0.25$) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 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 at the MSD stores) 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 1/6th (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. **Standards**; 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 charge 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 & 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.

- 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 quantity in the purchase order is less than 100,000 tablets/capsules, with deliveries in one/more lots or 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 nos. of surgical items,, 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 (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.

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 Bar coded (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 30⁰c +/- 2⁰c 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. $< 25^{\circ}\text{c}$, $2-25^{\circ}\text{c}$, $15-20^{\circ}\text{c}/30^{\circ}\text{c}$, $2-8^{\circ}\text{c}$ etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at $30^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $75\% \pm 5\%$ RH for **AC stored** items and at $25^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $60\% \pm 5\%$ 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 15th 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 www.msd.gov.lk)
If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 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: SOC's 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.

(i) -

(ii) -

(iii) -

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 should also be valid until at least six (06) months after the last consignment of the products to be procured are due to be received in Sri Lanka.**

b) For products which are manufactured in Sri Lanka the registration should be valid for at least six (06) months after the last consignment of the products to be procured are received by the Procurement Entity.

(XII) Local Agent shall attend to renew the product registration with NMRA six months prior to expiration of the existing product registration.

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

(XIV) 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.

Note : A certified copy of Business registration Certificate (by an Attorney at law) should be submitted with the offer

BID NO: DHS/SA/WW/78/25 CLOSING ON : 04.10.2024 at 9.00 a.m.

ORDER LIST NUMBER: 2025/SPC/N/R/S/00173

(A) ITEM NO	(B) SR NO	(C) ITEM	(D) QTY	(E) DELIVERY	(F) Bid Bond value (LKR)
1.	14000501	Hypodermic Syringe with luer slip, 20ml, with mounted 18G x 25mm Needle, with 1ml graduations, with double seal piston (3 part) or medical grade plastic plunger (2 part), non toxic and pyrogen free, sterile. Conforming to sterile single use plastic syringes BP1993 (complying with international standard ISO 7886 -1984(E) for hypodermic syringes for single use and British Standard BS 5081 : Part 1 and 2 1987 for sterile hypodermic syringes and needles).	7,500,000 Nos	4,500,000 Jan/2025 3,000,000 – 4 months after 1 st lot	2,550,000.00

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 30.04.2025 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. 35,000/ + taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

ANNEX – 1

BID NO. : DHS/SA/WW/77/25
DATE OF ISSUE : 20.08.2024
CLOSING DATE & TIME : 01.10.2024 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 (m³)
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 29.03.2025**

CONDITIONS FOR SUPPLY OF SURGICAL 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 and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (Total charge = $[a]+[a]\times 0.25$) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 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 at the MSD stores) 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 1/6th (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. **Standards**; 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 charge 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 & 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.

- 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 quantity in the purchase order is less than 100,000 tablets/capsules, with deliveries in one/more lots or 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 nos. of surgical items,, 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 (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.

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 Bar coded (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 30⁰c +/- 2⁰c 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. $< 25^{\circ}\text{c}$, $2-25^{\circ}\text{c}$, $15-20^{\circ}\text{c}/30^{\circ}\text{c}$, $2-8^{\circ}\text{c}$ etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at $30^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $75\% \pm 5\%$ RH for **AC stored** items and at $25^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $60\% \pm 5\%$ 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 15th 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 www.msd.gov.lk)
If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 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: SOC's 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.

(i) -

(ii) -

(iii) -

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 should also be valid until at least six (06) months after the last consignment of the products to be procured are due to be received in Sri Lanka.**

b) For products which are manufactured in Sri Lanka the registration should be valid for at least six (06) months after the last consignment of the products to be procured are received by the Procurement Entity.

(XII) Local Agent shall attend to renew the product registration with NMRA six months prior to expiration of the existing product registration.

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

(XIV) 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.

Note : A certified copy of Business registration Certificate (by an Attorney at law) should be submitted with the offer

BID NO: DHS/SA/WW/77/25 CLOSING ON : 01.10.2024 at 9.00 a.m.

ORDER LIST NUMBER: 2025/SPC/N/R/S/00182

(A) ITEM NO	(B) SR NO	(C) ITEM	(D) QTY	(E) DELIVERY	(F) Bid Bond value (LKR)
1.	14000101	Hypodermic Syringe with luer slip, 1ml, with mounted 26G x 15 mm Needle, with 0.01ml graduations, with double seal piston (3 part) or medical grade plastic plunger (2 part), non toxic and pyrogen free, sterile. Conforming to sterile single use plastic syringes BP1993 (complying with international standard ISO 7886 -1984(E) for hypodermic syringes for single use and British Standard BS 5081 : Part 1 and 2 1987 for sterile hypodermic syringes and needles).	10,000,000 Nos	5,000,000 – Jan/2025 500,000 – 4 months after 1 st lot	2,132,000.00
2.	14000102	Hypodermic Syringe with luer slip, for Tuberculin, 1ml, with mounted 25G x 15mm long Needle, with 0.01ml graduations, with double seal piston (3 part) or medical grade plastic plunger (2 part), non toxic and pyrogen free, sterile. Conforming to sterile single use plastic syringes BP1993 (complying with international standard ISO 7886 -1984(E) for hypodermic syringes for single use and British Standard BS 5081 : Part 1 and 2 1987 for sterile hypodermic syringes and needles).	730,000 Nos	730,000 – Mar/2025	171,110.00

3.	14000104	Hypodermic Syringe,1ml, with fixed 31G needle,6mm in length, with 0.01ml graduations,double seal piston (3 part) without any dead space between the syringe and the needle "O" mark, non toxic and pyrogen free, sterile,for administration of insulin.Conforming to sterile single use plastic syringes BP1993 (complying with international standard ISO 7886 -1984(E) for hypodermic syringes for single use and British Standard BS 5081 : Part 1 and 2 1987 for sterile hypodermic syringes and needles).	2,500,000 Nos	1,500,000 – Jan/2025 1,000,000 – 4 months after 1 st lot	682,000.00
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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 28.04.2025 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. 35,000/ + taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

ANNEX – 1

BID NO. : DHS/SA/WW/76/25
DATE OF ISSUE : 20.08.2024
CLOSING DATE & TIME : 01.10.2024 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 (m³)
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 29.03.2025

CONDITIONS FOR SUPPLY OF SURGICAL 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 and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (Total charge = $[a]+[a]\times 0.25$) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 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 at the MSD stores) 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 1/6th (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. Standards; 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 charge 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 & 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.

- 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 quantity in the purchase order is less than 100,000 tablets/capsules, with deliveries in one/more lots or 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 nos. of surgical items,, 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 (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.

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 Bar coded (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 30⁰c +/- 2⁰c 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. $< 25^{\circ}\text{c}$, $2-25^{\circ}\text{c}$, $15-20^{\circ}\text{c}/30^{\circ}\text{c}$, $2-8^{\circ}\text{c}$ etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at $30^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $75\% \pm 5\%$ RH for **AC stored** items and at $25^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $60\% \pm 5\%$ 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 15th 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 www.msd.gov.lk)
If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 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

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Demurrage / additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.

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

Note : A certified copy of Business registration Certificate (by an Attorney at law) should be submitted with the offer

BID NO: DHS/SA/WW/76/25 CLOSING ON : 01.10.2024 at 9.00 a.m.

ORDER LIST NUMBER: 2025/SPC/N/R/S/00169

(A) ITEM NO	(B) SR NO	(C) ITEM	(D) QTY	(E) DELIVERY	(F) Bid Bond value (LKR)
1.	14300503	Hollow Fibre Dialyzer, Polysulphone/ polyethersulphone/ polyneprhone, low flux to medium flux, DEHP and BPA free, surface area 1.6 m ² - 1.8 m ² , sterilized by ETO free gamma radiation.	94,000 Nos	94,000 – May/2025	2,450,220.00

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 28.04.2025 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. 35,000/ + taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

ANNEX – 1

BID NO. : DHS/SA/WW/75/25
DATE OF ISSUE : 20.08.2024
CLOSING DATE & TIME : 01.10.2024 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 (m³)
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 29.03.2025**

CONDITIONS FOR SUPPLY OF SURGICAL 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 and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (Total charge = $[a]+[a]\times 0.25$) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 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 at the MSD stores) 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 1/6th (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. **Standards**; 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 charge 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 & 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.

- 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 quantity in the purchase order is less than 100,000 tablets/capsules, with deliveries in one/more lots or 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 nos. of surgical items,, 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 (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.

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 Bar coded (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 30⁰c +/- 2⁰c 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. $< 25^{\circ}\text{c}$, $2-25^{\circ}\text{c}$, $15-20^{\circ}\text{c}/30^{\circ}\text{c}$, $2-8^{\circ}\text{c}$ etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at $30^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $75\% \pm 5\%$ RH for **AC stored** items and at $25^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $60\% \pm 5\%$ 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 15th 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 www.msd.gov.lk)
If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 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: SOC's 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.

(i) -

(ii) -

(iii) -

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 should also be valid until at least six (06) months after the last consignment of the products to be procured are due to be received in Sri Lanka.**

b) For products which are manufactured in Sri Lanka the registration should be valid for at least six (06) months after the last consignment of the products to be procured are received by the Procurement Entity.

(XII) Local Agent shall attend to renew the product registration with NMRA six months prior to expiration of the existing product registration.

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

(XIV) 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.

Note : A certified copy of Business registration Certificate (by an Attorney at law) should be submitted with the offer

BID NO: DHS/SA/WW/75/25 CLOSING ON : 01.10.2024 at 9.00 a.m.

ORDER LIST NUMBER: 2025/SPC/N/R/S/00163

(A) ITEM NO	(B) SR NO	(C) ITEM	(D) QTY	(E) DELIVERY	(F) Bid Bond value (LKR)
1.	14300103	Blood Lines Set Universal for Haemodialysis, comprising Arterial and Venous blood lines with filter, connector and transducer protector sterilized by gamma filtration. Should be DEHP free and compatible with any make of Haemodialysis machine.	320,000 Nos	160,000 – Jan/2025 160,000 – 4 months after 1 st lot	4,066,050.00

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 28.04.2025 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. 60,000/ + taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

ANNEX – 1

BID NO. : DHS/SA/WW/74/25
DATE OF ISSUE : 20.08.2024
CLOSING DATE & TIME : 01.10.2024 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 (m³)
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 29.03.2025**

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

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

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2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.

3. Maintaining the validity of the product registration during the period of supply (delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (Total charge = $[a]+[a]\times 0.25$) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 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 at the MSD stores) 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 1/6th (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. **Standards**; 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 charge 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 & 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.

- 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 quantity in the purchase order is less than 100,000 tablets/capsules, with deliveries in one/more lots or 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 nos. of surgical items,, 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 (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.

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 Bar coded (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 30⁰c +/- 2⁰c 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. $< 25^{\circ}\text{c}$, $2-25^{\circ}\text{c}$, $15-20^{\circ}\text{c}/30^{\circ}\text{c}$, $2-8^{\circ}\text{c}$ etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at $30^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $75\% \pm 5\%$ RH for **AC stored** items and at $25^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $60\% \pm 5\%$ 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 15th 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 www.msd.gov.lk)
If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 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: SOC's 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.

(i) -

(ii) -

(iii) -

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 should also be valid until at least six (06) months after the last consignment of the products to be procured are due to be received in Sri Lanka.**

b) For products which are manufactured in Sri Lanka the registration should be valid for at least six (06) months after the last consignment of the products to be procured are received by the Procurement Entity.

(XII) Local Agent shall attend to renew the product registration with NMRA six months prior to expiration of the existing product registration.

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

(XIV) 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.

Note : A certified copy of Business registration Certificate (by an Attorney at law) should be submitted with the offer

BID NO: DHS/SA/WW/74/25 CLOSING ON : 01.10.2024 at 9.00 a.m.

ORDER LIST NUMBER: 2025/SPC/N/R/S/00162

(A) ITEM NO	(B) SR NO	(C) ITEM	(D) QTY	(E) DELIVERY	(F) Bid Bond value (LKR)
1.	14300802	Double Lumen Catheter Sets for Haemodialysis, size 11FG - 12FG, 160mm length, curved extension. Complete set including guide wire, introducer needle, cannula dispenser, dilator and 2 injection caps, sterile.	4,500 Nos	4,500 – Mar/2025	733,720.00
2.	14300811	Double Lumen Catheter Sets for Haemodialysis, with straight extension, size 7FG, 125mm length. Complete set including guide wire, introducer needle, cannula dispenser, dilator and 2 injection caps, sterile. (Paediatric Item)	300 Nos	150 – Jan/2025 150 – 5 months after 1 st lot	56,220.00

3.	14300814	Double Lumen Catheter Sets for Haemodialysis, with straight extension, size 8-9FG, 125-150mm length. Complete set including guide wire, introducer needle, cannula dispenser, dilator and 2 injection caps, sterile.(Paediatric Item)	250 Sets	250 – Jan/2025	
4.	14301104	Fully automated disposable Biopsy Gun with needle size 16G and 150mm - 210mm length,sterile.Out of total quantity 60% should be supplied from 150mm and 40% from 210mm.	325 Nos	325 – Jun/2025	24,010.00
5.	14301701	Arterial and Venous Fistula Needles rotatable with clamp and back eye, size 15G,sterile.	37,000 Nos	37,000 – Jun/2025	40,600.00
6.	14301703	Arteral and Venous Fistula Needles rotatable with clamp and back eye, size 17G,sterile.	100,000 Nos	100,000 – Jun/2025	109,780.00
7.	14302201	Citric Acid Solution 50% for Haemodialysis machine.	8,500 Nos	8,500 – Jun/2025	663,100.00

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 28.04.2025 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. 20,000/ + taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

ANNEX – 1

BID NO. : DHS/SA/WW/73/25
DATE OF ISSUE : 20.08.2024
CLOSING DATE & TIME : 01.10.2024 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 (m³)
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 29.03.2025

CONDITIONS FOR SUPPLY OF SURGICAL 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 and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

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

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty
(as clause No. 37).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers will not be entertained.

Shelf life & Warrantees

7. 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. (Only applicable for non-consumable 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 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 or 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 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, 24 months.

Standards & Quality

9. Standards; 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 item specification.
10. Any product deficient of 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 surcharged 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 MRI, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities) If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
14. Consignments supplied to MRI 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 (not applicable for blister/strip packs), “DHS” mark shall be ;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsulesAbove condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
(Only applicable for pharmaceutical product)
- 17.** 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.
- 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 30⁰c +/- 2⁰c 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;
- 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.
 - 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.
 - 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 **WDNor 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.
 - 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.
 - 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. < 25⁰c, 2-25⁰c, 15-20⁰c/30⁰c, 2-8⁰c etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30⁰c +/- 2⁰c & 75% +/- 5% RH for **AC stored** items and at 25⁰c +/- 2⁰c & 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 15th 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 adl. 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 regular category of laboratory items, when specified in respective order lists).
The images of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided within 14 days of releasing the indent by SPC.
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 MSD⁶ by the supplier.(follow instructions in the website www.msd.gov.lk)
If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 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.*

Special Conditions for Surgical Consumables item

- a. The product should have minimum of 36 months shelf life at the time of delivery to Medical Supplies Division. Requested shelf life for Surgical Consumable is 36 months unless specified in the special order conditions/specifications/order list remarks.**
- b. General condition 7 & 16 are not applicable for Surgical Consumable items.**
- c. Art works and diagrams with dimensions for relevant products with catalog numbers should be provided.**
- d. Usage instruction pamphlet/user manuals in print/pdf/video format should be provided. (Such instructions should carry details on maintenance, compatibility and storage)**
- e. Further to the condition 33, Tender Sample of the selected bid shall be forwarded to MSD to use as reference sample to check the consignment supplied on the indent/PO.**

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 contract 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 should also be valid until at least six (06) months after the last consignment of the products to be procured are due to be received in Sri Lanka.**
- b) For products which are manufactured in Sri Lanka the registration should be valid for at least six (06) months after the last consignment of the products to be procured are received by the Procurement Entity.**
- (XII) Local Agent shall attend to renew the product registration with NMRA six months prior to expiration of the existing product registration.**
- (XIII) Supplier shall submit the signed contract within 14 days of receiving of the contract agreement from SPC.**
- (XIV) 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.**

Note : A certified copy of Business registration Certificate (by an Attorney at law) should be submitted with the offer

BID NO: DHS/SA/WW/73/25 CLOSING ON : 01.10.2024 at 9.00 a.m.

ORDER LIST NUMBER: 2025/SPC/N/R/S/00156

(A) ITEM NO	(B) SR NO	(C) ITEM	(D) QTY	(E) DELIVERY	(F) Bid Bond value (LKR)
1.	13401101	Wire Reinforced Venous Return Catheter, straight, with open tapered tip, size 18Fr, sterile.	160 Nos	160 – Jan/2025	29,560.00
2.	13401102	Wire Reinforced Venous Return Catheter, straight, with open tapered tip, size 20Fr, sterile.	94 Nos	94 – Jan/2025	
3.	13401103	Wire Reinforced Venous Return Catheter, straight, with open tapered tip, size 22Fr, sterile.	99 Nos	99 – Jan/2025	
4.	13401104	Wire Reinforced Venous Return Catheter, straight, with open tapered tip, size 24Fr, sterile.	39 Nos	39 – Jan/2025	
5.	13402100	Atrial Vent Catheter, malleable, paediatric, with 6.3mm connector, size 10Fr, sterile.	100 Nos	100 – Jan/2025	
6.	13406705	Perfusion Tubing Connector, straight, size 9.5mm x 9.5mm, sterile.	20 Nos	20 – Jan/2025	
7.	13406801	Luer Connector, straight, 9.5mm x 6.3mm, sterile.	50 Nos	50 – Jan/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 28.04.2025 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.

ANNEX – 1

BID NO. : DHS/SA/WW/72/25
DATE OF ISSUE : 20.08.2024
CLOSING DATE & TIME : 01.10.2024 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 (m³)
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 29.03.2025

CONDITIONS FOR SUPPLY OF SURGICAL 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 and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (Total charge = $[a]+[a]\times 0.25$) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 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 at the MSD stores) 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 1/6th (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. **Standards**; 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 charge 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 & 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.

- 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 quantity in the purchase order is less than 100,000 tablets/capsules, with deliveries in one/more lots or 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 nos. of surgical items,, 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 (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.

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 Bar coded (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 30⁰c +/- 2⁰c 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. $< 25^{\circ}\text{c}$, $2-25^{\circ}\text{c}$, $15-20^{\circ}\text{c}/30^{\circ}\text{c}$, $2-8^{\circ}\text{c}$ etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at $30^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $75\% \pm 5\%$ RH for **AC stored** items and at $25^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $60\% \pm 5\%$ 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 15th 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 www.msd.gov.lk)
If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 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: SOC's 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.

(i) -

(ii) -

(iii) -

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 should also be valid until at least six (06) months after the last consignment of the products to be procured are due to be received in Sri Lanka.**

b) For products which are manufactured in Sri Lanka the registration should be valid for at least six (06) months after the last consignment of the products to be procured are received by the Procurement Entity.

(XII) Local Agent shall attend to renew the product registration with NMRA six months prior to expiration of the existing product registration.

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

(XIV) 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.

Note : A certified copy of Business registration Certificate (by an Attorney at law) should be submitted with the offer

BID NO: DHS/SA/WW/72/25 CLOSING ON : 01.10.2024 at 9.00 a.m.

ORDER LIST NUMBER: 2025/SPC/N/R/S/00149

(A) ITEM NO	(B) SR NO	(C) ITEM	(D) QTY	(E) DELIVERY	(F) Bid Bond value (LKR)
1.	14100403	Scalp Vein Set, (Infusion Needle Set), Size 25G Needle, Conforming to ISO standards, With luer lock fitting, Flexible fixation wings, with 30cm transparent tubing. Sterile, non-toxic and pyrogen free.	150,000 Nos	75,000 – Jan/2025 75,000 – Jul/2025	52,230.00

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 28.04.2025 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.

ANNEX – 1

BID NO. : DHS/SA/WW/71/25
DATE OF ISSUE : 20.08.2024
CLOSING DATE & TIME : 01.10.2024 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 (m³)
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 29.03.2025**

CONDITIONS FOR SUPPLY OF SURGICAL 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 and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (Total charge = $[a]+[a]\times 0.25$) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 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 at the MSD stores) 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 1/6th (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. **Standards**; 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 charge 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 & 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.

- 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 quantity in the purchase order is less than 100,000 tablets/capsules, with deliveries in one/more lots or 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 nos. of surgical items,, 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 (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.

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 Bar coded (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 30⁰c +/- 2⁰c 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. $< 25^{\circ}\text{c}$, $2-25^{\circ}\text{c}$, $15-20^{\circ}\text{c}/30^{\circ}\text{c}$, $2-8^{\circ}\text{c}$ etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at $30^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $75\% \pm 5\%$ RH for **AC stored** items and at $25^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $60\% \pm 5\%$ 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 15th 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 www.msd.gov.lk)
If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 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: SOC's 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.

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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 should also be valid until at least six (06) months after the last consignment of the products to be procured are due to be received in Sri Lanka.**

b) For products which are manufactured in Sri Lanka the registration should be valid for at least six (06) months after the last consignment of the products to be procured are received by the Procurement Entity.

(XII) Local Agent shall attend to renew the product registration with NMRA six months prior to expiration of the existing product registration.

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

(XIV) 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.

Note : A certified copy of Business registration Certificate (by an Attorney at law) should be submitted with the offer

BID NO: DHS/SA/WW/71/25 CLOSING ON : 01.10.2024 at 9.00 a.m.

ORDER LIST NUMBER: 2025/SPC/N/R/S/00133

(A) ITEM NO	(B) SR NO	(C) ITEM	(D) QTY	(E) DELIVERY	(F) Bid Bond value (LKR)
1.	12000101	Prejelled E.C.G. Electrodes Silver/Silver Chloride for Adult Disposable.	5,292,000 Nos	2,792,000 – Jan/2025 2,500,000 – 4 months after 1 st lot	925,040.00

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 28.04.2025 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. 12,500/ + taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

ANNEX – 1

BID NO. : DHS/SA/WW/69/25
DATE OF ISSUE : 20.08.2024
CLOSING DATE & TIME : 01.10.2024 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 (m³)
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 29.03.2025**

CONDITIONS FOR SUPPLY OF SURGICAL 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 and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (Total charge = $[a]+[a]\times 0.25$) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 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 at the MSD stores) 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 1/6th (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. **Standards**; 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 charge 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 & 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.

- 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 quantity in the purchase order is less than 100,000 tablets/capsules, with deliveries in one/more lots or 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 nos. of surgical items,, 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 (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.

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 Bar coded (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 30⁰c +/- 2⁰c 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. $< 25^{\circ}\text{c}$, $2-25^{\circ}\text{c}$, $15-20^{\circ}\text{c}/30^{\circ}\text{c}$, $2-8^{\circ}\text{c}$ etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at $30^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $75\% \pm 5\%$ RH for **AC stored** items and at $25^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $60\% \pm 5\%$ 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 15th 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 www.msd.gov.lk)
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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.*

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Note: SOC's 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.

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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.
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- (XI) a) for products which are imported to Sri Lanka the registration should also be valid until at least six (06) months after the last consignment of the products to be procured are due to be received in Sri Lanka.**

b) For products which are manufactured in Sri Lanka the registration should be valid for at least six (06) months after the last consignment of the products to be procured are received by the Procurement Entity.

(XII) Local Agent shall attend to renew the product registration with NMRA six months prior to expiration of the existing product registration.

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

(XIV) 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.

Note : A certified copy of Business registration Certificate (by an Attorney at law) should be submitted with the offer

BID NO: DHS/SA/WW/69/25 CLOSING ON : 01.10.2024 at 9.00 a.m.

ORDER LIST NUMBER: 2025/SPC/N/R/S/00138

(A) ITEM NO	(B) SR NO	(C) ITEM	(D) QTY	(E) DELIVERY	(F) Bid Bond value (LKR)
1.	15307607	ERCP Pancreatic Drainage Plastic Stent 7Fr x 10cm : stent diameter 7Fr, stent length 10cm, single end pigtail shape, proximal RO marker, distal endoscopic marker, multiple holes on the proximal side of the stent with flap, 0.035" guide wire compatibility, hydrophilic coated stent, sterile.	220 Nos	70 – Feb/2025 70 – May/2025 80 – Aug/2025	38,350.00
2.	15308002	ERCP Pancreatic Drainage Plastic Stent pushing catheter: 7 Fr pushing catheter, 170cm (approx.) working length, minimum accessory channel 3.2mm, sterile.	100 Nos	50 – Feb/2025 50 – Jun/2025	20,180.00
3.	15307608	ERCP Pancreatic Drainage Plastic Stent 7Fr x 12cm : stent diameter 7Fr, stent length 12cm, single end pigtail shape, proximal RO marker, distal endoscopic marker, multiple holes on the proximal side of the stent with flap, 0.035" guide wire compatibility, hydrophilic coated stent, sterile.	200 Nos	100 – Feb/2025 100 – Jun/2025	35,360.00

4.	15308201	ERCP Billiary stent introducer with pushing catheter: 7-11Fr Pushing catheter with compatible guiding catheter and guide wire. 2.8-4.2mm Minimum accessory channel, sterile.	120 Nos	60 – Jan/2025 60 – May/2025	46,180.00
5.	15307603	ERCP Pancreatic Drainage Plastic Stent 5Fr x 10cm : stent diameter 5Fr, stent length 10cm, single end pigtail shape, proximal RO marker, distal endoscopic marker, multiple holes on the proximal side of the stent with flap, 0.035" guide wire compatibility, hydrophilic coated stent, sterile.	400 Nos	150 – Jan/2025 150 – Apr/2025 100 – Aug/2025	68,510.00
6.	15307601	ERCP Pancreatic Drainage Plastic Stent 5Fr x 5cm : stent diameter 5Fr, stent length 5cm, single end pigtail shape, proximal RO marker, distal endoscopic marker, multiple holes on the proximal side of the stent with flap, 0.035" guide wire compatibility, hydrophilic coated stent, sterile.	250 Nos	80 – Jan/2025 80 – Apr/2025 90 – Jul/2025	44,200.00
7.	15307602	ERCP Pancreatic Drainage Plastic Stent 5Fr x 7cm : stent diameter 5Fr, stent length 7cm, single end pigtail shape, proximal RO marker, distal endoscopic marker, multiple holes on the proximal side of the stent with flap, 0.035" guide wire compatibility, hydrophilic coated stent, sterile.	250 Nos	80 – Jan/2025 80 – Apr/2025 90 – Jul/2025	43,800.00
8.	15307604	ERCP Pancreatic Drainage Plastic Stent 5Fr x 12cm : stent diameter 5Fr, stent length 12cm, single end pigtail shape, proximal RO marker, distal endoscopic marker, multiple holes on the proximal side of the stent with flap, 0.035" guide wire compatibility, hydrophilic coated stent, sterile.	300 Nos	100 – Feb/2025 100 – May/2025 100 – Aug/2025	51,200.00

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 28.04.2025 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. 12,500/ + taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

ANNEX – 1

BID NO. : DHS/SA/WW/68/25
DATE OF ISSUE : 20.08.2024
CLOSING DATE & TIME : 01.10.2024 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 (m³)
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 29.03.2025

CONDITIONS FOR SUPPLY OF SURGICAL 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 and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (Total charge = $[a]+[a]\times 0.25$) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 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 at the MSD stores) 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 1/6th (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. Standards; 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 charge 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 & 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.

- 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 quantity in the purchase order is less than 100,000 tablets/capsules, with deliveries in one/more lots or 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 nos. of surgical items,, 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 (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.

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 Bar coded (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 30⁰c +/- 2⁰c 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. $< 25^{\circ}\text{c}$, $2-25^{\circ}\text{c}$, $15-20^{\circ}\text{c}/30^{\circ}\text{c}$, $2-8^{\circ}\text{c}$ etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at $30^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $75\% \pm 5\%$ RH for **AC stored** items and at $25^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $60\% \pm 5\%$ 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 15th 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 www.msd.gov.lk)
If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 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: SOC's 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.

(i) -

(ii) -

(iii) -

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 should also be valid until at least six (06) months after the last consignment of the products to be procured are due to be received in Sri Lanka.**

b) For products which are manufactured in Sri Lanka the registration should be valid for at least six (06) months after the last consignment of the products to be procured are received by the Procurement Entity.

(XII) Local Agent shall attend to renew the product registration with NMRA six months prior to expiration of the existing product registration.

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

(XIV) 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.

Note : A certified copy of Business registration Certificate (by an Attorney at law) should be submitted with the offer

BID NO: DHS/SA/WW/68/25 CLOSING ON : 01.10.2024 at 9.00 a.m.

ORDER LIST NUMBER: 2025/SPC/N/R/S/00137

(A) ITEM NO	(B) SR NO	(C) ITEM	(D) QTY	(E) DELIVERY	(F) Bid Bond value (LKR)
1.	15305003	ERCP stiff Guide Wire 0.035" x 450cm for biliary/pancreatic canulation: guide wire diameter 0.035", guide wire length 450cm (approx.), distal 7-10cm floppy tip, straight tip, Distal Hydrophilic and proximal PTFE coated wire, sterile/single use.	300 Nos	100 – Jan/2025 100 – 3 months after 1 st lot 100 – 3 months after 2 nd lot	120,120.00
2.	15304101	ERCP Triple Lumen pre cut Needle Knife Sphincterotome : triple lumen, 0.035" guide wire compatibility, Sheath distal tip OD 4-5.5Fr, Tip length 4-5mm, catheter length 200cm (approx.), sterile.	300 Nos	100 – Feb/2025 100 – 2 months after 1 st lot 100 – 3 months after 2 nd lot	173,160.00
3.	15305004	ERCP stiff Guide Wire 0.025" x 450cm for biliary/pancreatic canulation: guide wire diameter 0.025", guide wire length 450cm (approx.), distal 7-10cm floppy tip, angled tip, Distal Hydrophilic and proximal PTFE coated wire, sterile/single use.	350 Nos	120 – Jan/2025 120 – 3 months after 1 st lot 110 – 3 months after 1 st lot	234,510.00

4.	15304001	ERCP Triple Lumen Bow String Sphincterotome triple lumen, 0.035" guide wire compatibility, sheath OD 7.5Fr, Sheath distal tip OD 4-5.5Fr, cutting wire length 20-25mm with or without coating, Tip length 4-7mm, catheter length 200cm (approx.), sterile.	250 Nos	80 – Feb/2025 80 – 3 months after 1 st lot 90 – 3 months after 2 nd lot	
5.	15305501	ERCP Wire guided Stone Extraction Basket with handle : basket diameter 2cm, stainless steel/nitinol or eqv wire basket,working length 200cm (approx.), minimum working channel 3.2mm, sterile.	110 Nos	60 – Jan/2025 50 – 4 months after 1 st lot	124,350.00
6.	15304002	ERCP Triple Lumen Bow String Sphincterotome: triple lumen, 0.035" guide wire compatibility, sheath OD 7.5Fr, Sheath distal tip OD 4-5.5Fr, cutting wire length 30mm with or without coating, Tip length 4-7mm, catheter length 200cm (approx.), sterile.	400 Nos	150 – Jan/2025 150 – 2 months after 1 st lot 100 – 3 months after 2 nd lot	180,960.00

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 28.04.2025 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. 12,500/ + taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

ANNEX – 1

BID NO. : DHS/SA/WW/67/25
DATE OF ISSUE : 20.08.2024
CLOSING DATE & TIME : 01.10.2024 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 (m³)
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 29.03.2025**

CONDITIONS FOR SUPPLY OF SURGICAL 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 and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (Total charge = $[a]+[a]\times 0.25$) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 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 at the MSD stores) 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 1/6th (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. Standards; 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 charge 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 & 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.

- 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 quantity in the purchase order is less than 100,000 tablets/capsules, with deliveries in one/more lots or 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 nos. of surgical items,, 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 (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.

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 Bar coded (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 30⁰c +/- 2⁰c 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. $< 25^{\circ}\text{c}$, $2-25^{\circ}\text{c}$, $15-20^{\circ}\text{c}/30^{\circ}\text{c}$, $2-8^{\circ}\text{c}$ etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at $30^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $75\% \pm 5\%$ RH for **AC stored** items and at $25^{\circ}\text{c} \pm 2^{\circ}\text{c}$ & $60\% \pm 5\%$ 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 15th 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 www.msd.gov.lk)
If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 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: SOC's 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.

(i) -

(ii) -

(iii) -

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 should also be valid until at least six (06) months after the last consignment of the products to be procured are due to be received in Sri Lanka.**

b) For products which are manufactured in Sri Lanka the registration should be valid for at least six (06) months after the last consignment of the products to be procured are received by the Procurement Entity.

(XII) Local Agent shall attend to renew the product registration with NMRA six months prior to expiration of the existing product registration.

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

(XIV) 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.

Note : A certified copy of Business registration Certificate (by an Attorney at law) should be submitted with the offer

BID NO: DHS/SA/WW/67/25 CLOSING ON : 01.10.2024 at 9.00 a.m.

ORDER LIST NUMBER: 2025/SPC/N/R/S/00023

(A) ITEM NO	(B) SR NO	(C) ITEM	(D) QTY	(E) DELIVERY	(F) Bid Bond value (LKR)
1.	14103001	Pressure Monitoring Kit - Double Dome, Hp Intellivue Monitors compatible,comprising; Giving Set, High Pressure Monitoring Lines, Transducer Domes,Flushing Devices, Three way Stopcocks & Pressure tubes.Giving Set - Suitable for pressure monitoring, Flush device - Flush rate > 1ml/s and continuous flush rate 3ml/hr at 300mmHg, Disposable Transducer with; Accurate pressure transmission, Adapts to interface cable with plug connection, Chip technology for accurate registration of values, Pre calibrated sensor with constant electrical parameters (Sensitivity, linearity, Zero stability),Straight fluid channel for air bubble free filing with Three way stopcock (Red) arterial, (Blue) venous, Pressure tube 200 cm, Internal diameter 1.5 x2.7mm,Pressure Tube 10cm, Internal diameter1.5cm x 2.7mm. Red (Arterial), Blue(venous) lined, with colour coded (Blue & red) closed loop blood sampling kit with needleless sampling ports (blue & red colour coded) sterile.	2,200 Nos	1,100 – Feb/2025 1,100 – 5 months after 1 st lot	141,090.00

		Four Accessory Sets should be provided free of charge for each 50 Monitoring Kits. Each Accessory Set comprising; One quadruple attachment plate, Attachment plate holder, and one connecting cable, 3 meter length, reusable.			
2.	14103403	Pressure Monitoring Kit - Single Dome (Arterial), Nihon Kohden Monitors compatible, comprising; Giving Set, High Pressure Monitoring Lines, Transducer Dome, Flushing Device, Three way Stopcock & Pressure tubes. Giving Set Suitable for pressure monitoring, Flush device - Flush rate > 1ml/s and continuous flush rate 3ml/hr at 300mmHg, Disposable Transducer with; Accurate pressure transmission, Adapts to interface cable with plug connection, Chip technology for accurate registration of values, Pre calibrated sensor with constant electrical parameters (Sensitivity, linearity, Zero stability), Straight fluid channel for air bubble free filing with Three way stopcock (Red) arterial, Pressure tube 200cm, Internal diameter 1.5 x2.7mm, Pressure Tube 10cm, Internal diameter1.5cm x 2.7mm. Red (Arterial), lined, with colour coded (red) closed loop blood sampling kit with needleless sampling ports (red colour coded)sterile. Two Accessory Set should be provided free of charge for each 50 Monitoring Kits. Each Accessory Set comprising; One quadruple attachment plate, Attachment plate holder, and One connecting cable, 3 meter length, reusable.	1,250 Nos	1,250 – Jun/2025	93,600.00
3.	14103404	Pressure Monitoring Kit - Single Dome (Venous), Nihon Kohden Monitors compatible, comprising; Giving Set, High Pressure Monitoring Lines, Transducer Dome, Flushing Device, Three way Stopcock & Pressure tubes. Giving Set - Suitable for pressure monitoring, Flush device - Flush rate > 1ml/s and continuous flush rate 3ml/hr at 300mmHg, Disposable Transducer with; Accurate pressure transmission, Adapts to interface cable with plug connection, Chip technology for accurate registration of values, Pre calibrated sensor with constant electrical parameters (Sensitivity, linearity, Zero stability), Straight fluid channel for air bubble free filing with Three way stopcock (Blue) venous, Pressure tube 200cm, Internal diameter 1.5 x2.7mm, Pressure Tube 10cm, Internal diameter1.5cm x 2.7mm. Blue (Venous), lined, with colour coded (Blue) closed loop blood sampling kit with needleless sampling ports (blue colour coded) sterile.	550 Nos	550 – Jul/2025	41,180.00

		Two Accessory Set should be provided free of charge for each 50 Monitoring Kits. Each Accessory Set comprising; One quadruple attachment plate, Attachment plate holder, and One connecting cable, 3 meter length, reusable.			
4.	14103804	Pressure Monitoring Kit - Single Dome (Venous), Mindray Monitors compatible, comprising; Giving Set, High Pressure Monitoring Lines, Transducer Dome, Flushing Device, Three way Stopcock & Pressure tubes. Giving Set – Suitable for pressure monitoring, Flush device - Flush rate > 1ml/s and continuous flush rate 3ml/hr at 300mmHg, Disposable Transducer with; Accurate pressure transmission, Adapts to interface cable with plug connection, Chip technology for accurate registration of values, Pre calibrated sensor with constant electrical parameters (Sensitivity, linearity, Zero stability), Straight fluid channel for air bubble free filing with Three way stopcock (Blue) venous, Pressure tube 200cm, Internal diameter 1.5 x2.7mm, Pressure Tube 10cm, Internal diameter1.5cm x 2.7mm. Blue (Venous), lined, with colour coded (Blue) closed loop blood sampling kit with needleless sampling ports (blue colour coded)sterile. Two Accessory Set should be provided free of charge for each 50 Monitoring Kits. Each Accessory Set comprising; One quadruple attachment plate, Attachment plate holder, and One connecting cable, 3 meter length, reusable.	1,000 Nos	1,000 – Aug/2025	107,550.00
5.	14103902	Pressure Monitoring Kit - Double Dome, Mindray Monitors compatible, comprising; Giving Set, High Pressure Monitoring Lines, Transducer Domes, Flushing Devices, Three way Stopcocks & Pressure tubes. Giving Set - Suitable for pressure monitoring, Flush device - Flush rate > 1ml/s and continuous flush rate 3ml/hr at 300mmHg, Disposable Transducer with; Accurate pressure transmission, Adapts to interface cable with plug connection, Chip technology for accurate registration of values, Pre calibrated sensor with constant electrical parameters (Sensitivity, linearity, Zero stability), Straight fluid channel for air bubble free filing with Three way stopcock (Red) arterial, (Blue) venous, Pressure tube 200cm, Internal diameter 1.5 x2.7mm, Pressure Tube 10cm, Internal diameter1.5cm x 2.7mm. Red (Arterial), Blue (venous) lined, with colour coded (Blue & red) closed loop blood sampling kit with needleless sampling ports (blue & red colour coded)sterile.	6,000 Nos	3,000 – Jan/2025 3,000 – 5 months after 1 st lot	355,130.00

		Four Accessory Sets should be provided free of charge for each 50 Monitoring Kits. Each Accessory Set comprising; One quadruple attachment plate, Attachment plate holder, and one connecting cable, 3 meter length, reusable.			
6.	14103803	Pressure Monitoring Kit - Single Dome (Arterial), Mindray Monitors compatible, comprising; Giving Set, High Pressure Monitoring Lines, Transducer Dome, Flushing Device, Three way Stopcock & Pressure tubes. Giving Set – Suitable for pressure monitoring, Flush device - Flush rate > 1ml/s and continuous flush rate 3ml/hr at 300mmHg, Disposable Transducer with; Accurate pressure transmission, Adapts to interface cable with plug connection, Chip technology for accurate registration of values, Pre calibrated sensor with constant electrical parameters (Sensitivity, linearity, Zero stability), Straight fluid channel for air bubble free filing with Three way stopcock (Red) arterial, Pressure tube 200cm, Internal diameter 1.5 x2.7mm, Pressure Tube 10cm, Internal diameter1.5cm x 2.7mm. Red (Arterial), lined, with colour coded (red) closed loop blood sampling kit with needleless sampling ports (red -colour coded)sterile. Two Accessory Set should be provided free of charge for each 50 Monitoring Kits. Each Accessory Set comprising; One quadruple attachment plate, Attachment plate holder, and One connecting cable, 3 meter length, reusable.	5,500 Nos	3,000 – Jan/2025 2,500 – 5 months after 1 st lot	210,940.00

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 28.04.2025 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. 12,500/ + taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid,