PROCUREMENT NOTICE - GLOBAL

MINISTRY PROCUREMENT COMMITTEE, MINISTRY OF HEALTH

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

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

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

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

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

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

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter. Bidders or their authorizec representatives will be permitted to be present at the time of opening of Bids.

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

CHAIRMAN – MINISTRY PROCUREMENT COMMITTEE
MINISTRY OF HEALTH
C/O STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
"MEHEWARA PIYASA", 16TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496
TELEPHONE : 00 94-11- 2326227
E-MAIL : pharma.manager@spc.lk

ANNEX

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

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

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

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

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

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

Bid should be valid till 10.05.2025.

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

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

(a) Part A

CONDITIONS OF SUPPLY

1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable manufacturer's name, country of manufacture, country of origin, etc.) provided bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent . Purchase Order (PO), issued by State Pharmaceuticals Corporation..

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

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

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

4. If MSD decides to accept a part f full consignment, with deviations from certain tender conditions (eg. with regard labeling /packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering th total cost (a) of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost (total charge =(a) + (a) x 0.25) or 2% of the invoiced value whichever is the highest.

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

Shelf life & Warrantees

6. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores in case of local supplies) of the product , shall be 85% of the shelf life requested (specified in order/Indent/PO)
   In respect of the items with requested shelf life equals or more than 24 months, any deficit between the residual shelf life and requested shelf , shall not be more that 04 months.

   In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 30)

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

Standards & Quality

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

8. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.

9. Withdrawal from use of items due to quality failure found as manufacturer/s fault:

(a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from t supplier.

(b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from t supplier.

(c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MS of the quality failed supplies with 25% administrative charge of the same.

10. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.20)

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

11. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drav one random batch sample (Post-delivery sample) of the consignment at a government/ser government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all t batches/lots in the consignment, and entire expenses on such tests, like value of samples, transpo sampling & testing charges, etc, will be recovered from the supplier.

12. Consignments supplied to MSD violating the storage conditions indicated on product labels and/ product information leaflet (as accepted for product registration at NMRA), shall be considered quality affected consignments and quality assurance of such consignments shall be carried out post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredit laboratory (foreign/local). All the expenses on such an event, including storage cost shall be bor by the supplier. If found to be quality affected the consignment will be treated as quality failed (clause No. 9).

Pack size, Labeling & Packaging

13. Offers for pack sizes at a lower level (smaller quantity per pack) than the pack size specified in t item description/specification and MSD order List, are also acceptable, but higher level (larger quant per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accept by the procurement committee, with the concurrence of MSD.

14. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, S No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Da 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 for as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per t pack specified in the specification)

15. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name a address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on t outer covering of the individual/innermost pack containing the minimum unit of measure, includi blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM DOE shall consist of at least the year & month.

16. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., S No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. Th may be printed, stenciled or label properly affixed.

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

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

Storage Conditions & Temperature

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

19. Maintenance of Cold Chain;
    a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.

    b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized **USB Devices** for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

    c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant **WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment** until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

    d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.

    e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

20. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.10)

Delivery Requirements

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

    Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof that is delivered after the due delivery date, Condition No. 23 on delayed deliveries, shall be applied.

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

23. Defaulted consignments with respect to delivery schedule shall only be considered for acceptan subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to t weeks. Consignments delivered after that grace period shall be considered for acceptance subject 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 c up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amenc delivery schedules.

    (b). When the delay exceeds 60 days purchase order will be considered as automatically cancell on defaulted performance. In such a situation, MSD reserve the right to recover liquidat damages or to revoke the cancellation (eg. if payments have been released prior to such cancellation), and accept the consignment subject to a 25% admin surcharge.

24. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall i in any way affect the recovery of late delivery charges, as per Condition No. 23 (regarding defaul consignments) and any other direct or indirect additional costs/liquidated damag relating/consequent to extension of L/C.

25. When adequate storage space is not available at MSD, to accept a delivery defaulted consignm (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. any additional expenses caused to MSD or SPC in arranging temporary external storage and otl expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall borne by the supplier.

Documents & Information

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

27. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way B 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 da before the ETA of Air freighted consignments.

28. If it is not complied or the information so provided are found to be incomplete/false, the gra period (for supply delays) mentioned in the clause 23 will not be applicable.

Common conditions

29. In addition to the general conditions of supply given herein, item/order-list specific amendmen exclusions or additions to the same, stated in the covering letter of the order list and any oth relevant conditions as per the tender document issued by SPC, are also applicable. The order/ite specific; new conditions or amendments to General Order Conditions, will be included in the orc list itself and as a remark entry in the MSMIS order records.

30. Administrative surcharge of 25% (on the value of goods), will be applied for tender conditi violations that cause deficiencies in supply with respect to; quality, standards & specifications, sh packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions N 08,05,10,13)

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

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

Checklist for Waver of Registration,

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

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

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

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

Please refer Global Bid Document

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