#### KARADENİZ İHRACATÇI BİRLİKLERİ GENEL SEKRETERLİĞİ



Savi : 35649853-TİM.KİB.GSK.UYG.2024/214-1416 Giresun, 29/04/2024

Konu: Sri Lanka / İhale Belgeleri

**E-POSTA** 

# KARADENİZ İHRACATÇI BİRLİKLERİ ÜYELERİNE SİRKÜLER <a href="2024/262">2024/262</a>

Sayın üyemiz,

T.C. Ticaret Bakanlığının bir yazısına atfen, Türkiye İhracatçılar Meclisinin 24/04/2024 tarih 360-1049 sayılı yazısı ekinde alınan Sri Lanka Dışişleri Bakanlığı Notaları ve ihale duyuruları ilişik bulunmaktadır.

Bilgilerinize sunarız.

e-imzalıdır Şahin KURUL Genel Sekreter a. Şube Müdürü

#### **EKLER:**

Ek.1- Sri Lanka Dışişleri Bakanlığı Notaları (2 sayfa)

**Ek.2-** İhale Duyuruları (33 Sayfa)

ahin KURUL tarafından 5070 sayılı kanun gere ince güvenli elektronik imza ile imzelenek tır

Ayrıntılı bilgi için: Şahin KURUL – Şube Müdürü

Karadeniz İhracatçı Birlikleri Genel Sekreterliği

Atatürk Bulvarı No:19/E PK.51 28200 GİRESUN

Telefon: 0.454.2162426 (PBX) Faks: 0.454.2164842-2168890

e-posta: kib@kib.org.tr Kep: kib@hs01.kep.tr

Web: www.kib.org.tr



Note No: EA/182/2024 Ref: EA/GEN/560/WWT

The Ministry of Foreign Affairs of the Democratic Socialist Republic of Sri Lanka presents its compliments to all Diplomatic Missions and Honorary Consulates in Sri Lanka and has the honor to inform that the State Pharmaceuticals Corporation of Sri Lanka has invited bids to supply following surgical items.

No	Item description	Bid Number
01	100,000 Tablets of Clomifene Tablet 50mg.	DHS/P/WW/143/24
02	500 vials of Pamidronate Disodium IV infusion 30mg vial	DHS/P/WW/144/24
03	18,000 vials of Ketorolac Tromethamine 0.4% sterile ophthalmic solution 5ml	DHS/P/WW/43/23

The Ministry of Foreign Affairs would highly appreciate if the attached three Procurement Notices and the three Bid Documents could be shared with the interested parties in the respective countries enabling them to submit the bids **on or before 14.05.2024.** 

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

03 April 2024, Colombo විදේශ පුමාතනාංශය

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Foreign Ministry
Democratic Socialist Republic
of Sri Lanka.

All Diplomatic Missions and Honorary Consulates in Colombo



**Note No:** EA/171/2024 **Ref:** EA/GEN/560/WWT

The Ministry of Foreign Affairs of the Democratic Socialist Republic of Sri Lanka presents its compliments to all Diplomatic Missions and Honorary Consulates in Sri Lanka and has the honor to inform that the Ministry of Ports, Shipping & Aviation of Sri Lanka has invited bids to the following two procurements.

No	Procurement Name	Closing Date		
01	Invitation for Offers for "Time Chartering" or "Commercial Management" of Vessels Owned by Ceylon Shipping Corporation Ltd.			
	<ul><li>– from 2024/2025 to 2026/2027 (Mv. Ceylon Princess)</li></ul>			
02	Lightering (Barging) for Discharging of Coal from the Mother Ships to Jetty of the Lakvijaya Power Stations – Season 2024/25 and 2025/26			

The Ministry of Foreign Affairs would highly appreciate if the attached two Paper Advertisements could be shared with the interested parties in the respective countries enabling them to submit the proposals.

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

28 March 2024, Colombo

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Foreign Ministry

Democratic Socialist Republic
of Sri Lanka.

All Diplomatic Missions and Honorary Consulates in Colombo

#### MINISTRY OF PORTS, SHIPPING AND AVIATION



#### AIRPORT & AVIATION SERVICES (SRI LANKA) PRIVATE LIMITED

#### **REQUEST FOR PROPOSAL (RFP)**

#### **FOR**

# PREPARATION OF MASTER PLAN FOR BANDARANAIKE INTERNATIONAL AIRPORT AT KATUNAYAKE, SRI LANKA

Bid No.: 100/T/2023

The Chairman, Ministry Consultants Procurement Committee (CPCM) invites Proposals for the preparation and provision of a Master Plan for Bandaranaike International Airport, Katunayake, Sri Lanka from reputed Airport Consultancy Firms/Joint Ventures fulfilling following minimum requirements.

- (i) The Airport Consultants should have prepared satisfactorily (accepted for implementation / implementing) at least Three Airport Master Plan studies for operational international airports with minimum target passenger capacity of 30 million passengers per annum within immediate past 08 years. Further, 02 out of these airports shall not be in the Consultants Country.
- (ii) The Consultancy firm shall not be based / origin in Asian continent to avoid conflict of interest.
- (iii) The Airport Consultant should have provided design consultancy services for the development works of at least 02 International Airports having annual passenger capacity of 20 Million or more. At least one of these shall be out of the Consultants Country

In case of joint ventures, all parties are jointly and severally liable for the execution and completion of the works.

RFP Document in English Language can be purchased from **04.03.2024** between 0900 hrs. to 1500 hrs. on working days up to **19.04.2024** from the Supply Chain Management Division, Airport & Aviation Services (Sri Lanka) (Private) Limited, Bandaranaike International Airport, Katunayake, Sri Lanka on payment of a non-refundable fee equivalent to Two Hundred (200) US Dollars in Sri Lankan Rupees. In addition the document can be down loaded from the web www.airport.lk making an on line payment of 200 US Dollars. RFP Document could be inspected free of charge at the above address.

Bids will be closed at **1400 hrs.** on **24.04.2024** and will be opened immediately thereafter in the presence of the Bidders or their authorized representatives at the Aviation Division, Ministry of Ports, Shipping and Aviation, Level 30, West Tower, WTC, Colombo 01, Sri Lanka.

Therefore, duly completed RFP documents to be returned to reach the above address not later than **14.00 hrs.** on **24.04.2024**. Late submissions will be rejected.

All Bidders and their designated Representatives are invited to attend **Pre-Bid Meeting (physical) at 10.00 hrs.** on **26.03.2024** at the Conference Room, 4th Floor, New Administration Building, Airport & Aviation Services (Sri Lanka) Private Limited, Bandaranaike International Airport, Katunayake, Sri Lanka. Bidders have an option of participating for virtual meeting and link will be informed to bidders who purchase the RFP document

Further information could be obtained from the Head Civil Engineering (P&D), Airport & Aviation Services (Sri Lanka) (Private) Limited, Bandaranaike International Airport, Katunayake on Telephone Nos. 011-2263500/011-2263502 and email pd@airport.lk

All times indicated above are local times (Sri Lanka Time: GMT + 5.30hrs.)

Chairman,
Consultant Procurement Committee (CPCM),
Ministry of Ports, Shipping and Aviation
Level 30, West Tower, WTC,
Colombo 01, Sri Lanka.

## **Notice of Extension of the Closing Date**



#### DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

## **CEYLON SHIPPING CORPORATION LTD**





# **Invitation for Bids (IFB)**

# International Competitive Bidding for Partnering with CSC in Lightering of Coal in the Port of Puttalam 2024/25 and 2025/26

This refers to the Advertisement published in "Sunday Observer" on 17<sup>th</sup> March, 2024 on the above Tender.

The "Biding Documents purchasing & Closing/Opening Time" are hereby amended to read as follows;

Accordingly, the Bidding documents can be purchased until 3.00 p.m. on 26<sup>th</sup> April, 2024 and bids will be closed/opened at 14.00 hrs. Sri Lanka Standard Time on 30th April, 2024.

All other terms and conditions in the advertisement published in "Sunday Observer" on 17<sup>th</sup> March, 2024 and the Bidding Document shall remain unchanged. Any Bids received after the Closing Time will be rejected.

Chairperson,

Standing Cabinet Appointed Procurement Committee,
Ministry of Ports, Shipping and Aviation,
Colombo 00100,
Sri Lanka.

THE SELACINE

## **Notice of Extension of the Closing Date**



#### **DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA**

### **CEYLON SHIPPING CORPORATION LTD**





Invitation for Offers for "Time Chartering" or 
"Commercial Management"
of Vessels Owned by Ceylon Shipping Corporation Ltd.
from 2024/2025 to 2026/27

(Mv. Ceylon Breeze & Mv. Ceylon Princess)

This refers to the Advertisement published in "Sunday Observer" on 17th March, 2024 on the above Tender.

The "Biding Receiving Period & Opening Time" are hereby amended to read as follows;

Accordingly, the Bids will be closed/opened at 3.00 p.m. on 29<sup>th</sup> April, 2024. The Bids should be submitted between 10.00 am on 19<sup>th</sup> April, 2024 to 03.00 pm on 29<sup>th</sup> April, 2024 Indian Standard Time.

All other terms and conditions in the advertisement published in "Sunday Observer" on 17<sup>th</sup> March, 2024 and the Bidding Document shall remain unchanged. Any Bids received after the Closing Time will be rejected.

Chairperson,

Standing Cabinet Appointed Procurement Committee,
Ministry of Ports, Shipping and Aviation,
Colombo 00100,
Sri Lanka.

THE SELACINE



#### DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

#### CEYLON SHIPPING CORPORATION LTD





Invitation for Offers for "Time Chartering" or "Commercial Management" of Vessels Owned by Ceylon Shipping Corporation Ltd. from 2024/2025 to 2026/27

(Mv. Ceylon Breeze & Mv. Ceylon Princess)

The Chairman, Standing Cabinet Appointed Procurement Committee (SCAPC) of the Ministry of Ports, Shipping and Aviation of Sri Lanka, on behalf of Ceylon Shipping Corporation Ltd. (CSC) invites reputed "Charterers" and "Commercial Management Companies" (hereinafter referred to as the "Bidders" also) to submit their bids for "Time Chartering" (IFB No. CSC/2024-25/T/TC/CB&CP) or "Commercial Management" (IFB No. CSC/2024-25/T/CM/CB&CP) of one or both ships (Mv. Ceylon Breeze - IMO No. 9734563 and Mv. Ceylon Princess - IMO No. 9734575).

#### Conditions:

- 1. The vessels will be open with following approx. delivery laycans for deployments (to be narrowed down after selection):
  - a. Mv. Ceylon Princess ...... June, 2024
  - b. Mv. Ceylon Breeze ...... June, 2024
- Preferred place of delivery: Indian or Singapore region for both Vessels
- 3. Preferred redelivery ranges:

My, Ceylon Breeze - India or Singapore region Mv. Ceylon Princess - India or Singapore region

- Deployment period for both vessels will be up to June of 2027.
- Remittances of the charter hires shall be made for 15 days in advance to CSC's nominated bank account/s in United States Dollars direct by the charterers.
- The selected Bidder/s shall enter into mutually agreed Implementation Agreement/s ("Commercial Management Agreement" or "Charterparty Agreement," as applicable). In either case, charterparty agreements shall be as per NYPE93 charterparty format as amended with Rider Clauses subject to trading and cargo exclusions.
- 7. SCAPC reserves the right to select the Bids received for the option of "Time Chartering" or "Commercial Management" for one ship or both ships, depending on the net highest economic benefit that will be accrued to CSC. Therefore, the Bids received for "Time Chartering" and then for "Commercial Management" will be evaluated in that order.

#### **Eligibility Criteria:**

- 1. The Bidders should be registered entities in Sri Lanka or any other country and be a member of the Baltic & International Maritime Council (BIMCO) or The Baltic Exchange etc., With an compulsory experience of at least four (04) years in shipping/chartering and operations of ships / Commercial Management, in the Supramax / Ultramax / Panamax dry bulk categories.
- Bidders should submit at least 03 Service Letters as References signed by a CEO/GM/ Director of the client company, as applicable for Time Chartering or Commercial Management).

#### Place of obtaining of Bidding Documents:

The time charter Specifications of the ships and the Bidding Documents (Common Invitation for Bids including General Terms & Conditions and two separate Instructions to the Bidders) could be downloaded from CSC website: www.cscl.lk (free of charge).

#### Pre-Bid Teleconference:

A Pre-Bid teleconference will be held between 1.00 pm to 3.00 pm Indian Standard time (IST) on 18th

#### **Bid Receiving Period & Opening Time:**

Detailed Bids addressed to the Chairman, SCAPC, Ministry of Ports, Shipping and Aviation, Colombo 00100, Sri Lanka should be submitted between 10.00 am on 19th April, 2024 to 3.00 pm on 24th April, 2024 Indian Standard time by ONLY email to password protected email account of CSC chartcom@cscl.lk. The Bids will be closed and opened at the end of the Bid Receiving Period at 3.00 pm Indian Standard time on the same

The Subject of the emails should be the clearly mentioned, as relevant for the Bids being offered out of two Options, as mentioned in the Common Invitation for Bids.

Bids shall be opened in the presence of the bidders or their authorised representative/s who wish to attend, soon after the closing of Bids.

Contact details for further details / clarifications:

Contact details for further details / clarifications:

Assistant General Manager - Chartering & Agency

Acting Manager - Chartering & Agency +94715656715 Contact No:

Contact No : +94 71 021 5702 +94 11 232 8772/3

+94 11 232 8772/3

Chairman,

#### Government of the Democratic Socialist Republic of Sri Lanka

#### CEYLON SHIPPING CORPORATION LTD



(Ministry of Ports, Shipping and Aviation)

## **Invitation for Bids (IFB)**

# International Competitive Bidding for Partnering with CSC in Lightering of Coal in the Port of Puttalam – 2024/25 and 2025/26

The Chairman, Standing Cabinet Appointed Procurement Committee (SCAPC) of the Ministry of Ports, Shipping and Aviation of the Government of Democratic Socialist Republic of Sri Lanka, for and on behalf of Ceylon Shipping Corporation Ltd. (CSC), hereby invites sealed bids from the interested parties for the provision of lightering services for conveyance of coal from the Anchorage of the Port of Puttalam to the Jetty at Lakvijaya Power Station at Puttalam, Sri Lanka.

CSC has been awarded the contract by Lanka Coal Company (Pvt) Ltd. of Sri Lanka (LCC) for the provision of this service and CSC intends to sub-contract to a self - propelled barge owning and operating third - party.

- The total annual volume of coal to be lightered in this contract will be in the range of 2,250,000 MT +/- 10%. Due to South West monsoon sea conditions this operation is confined to the period from mid September to mid May following year. The scope of service also includes onboard stevedoring from mother vessels to self propelled barges and cleaning of holds of mother vessels.
- Season of 2024/25 will be commenced operations around 10 th September, 2024 and all barges with
  crew and stevedore are to be arrived in advance in order to comply with Health Guidelines issued by
  Government of Sri Lanka.
- Detailed descriptions of the service and other related details are contained in the Bidding Documents will be available at the Chartering & Agency Department of CSC (C & A) at No. 27, 1st Floor, MICH Building, Sir Razik Fareed Mawatha Colombo 00100, Sri Lanka, for reference, free of charge and on the CSC website (www.cscl.lk).
- 4. Bidders shall purchase a complete set of Bidding Documents on submission of a written application and on payment of a non-refundable fee of Rs. 100,000 + VAT in cash between 18<sup>th</sup> March 2024 to 24<sup>th</sup> April 2024 from 9.00 a.m. to 3.00 p.m. (Sri Lanka Standard Time) on working days at the above address.
- Sealed Bids marked as "Tender for the Provision of Lightering Services 2024/25 and 2025/26" accompanied by a Bid Security in the form of a Bank Guarantee shall be tendered at the address given below by not later than 1400 hrs on 25<sup>th</sup> April, 2021 (Sri Lanka Standard Time).

Chairman's Office, Ceylon Shipping Corporation, No. 27, MICH Building, Sir Razik Fareed Mawatha, Colombo 00100, Sri Lanka.

Bids will be opened immediately thereafter. Bidders or their authorized representatives may witness the opening of Bids. Late Bids will not be accepted.

- 6. Provisions of the Public Contract Act, No.3 of 1987 shall be applicable for this procurement.
- 7. Interested Bidders may obtain further information from the Assistant General Manager C & A Dept. of CSC (Tel.: +94 112436819, Mobile: +94 710215702, Fax: +94 112447547, email: dantha@cscl.lk).

Chairman,



# **PROCUREMENT NOTICE - GLOBAL**

#### STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2024.

Please note that Tender No. DHS/P/WW/40/23 (Item: Chlorpheniramine inj. 10mg/1ml (Chlorphenamine)) published "SUNDAY OBSERVER" newspaper on 24.03.2024 treat as cancelled.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/143/24	14.05.2024 at 9.00 A.M	100,000 Tablets of Clomifene Tablet 50mg.	02.04.2024	Rs. 3,000/= + Taxes

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

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

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

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

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

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

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

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

FAX : 00 94-11- 2344082 TELEPHONE : 00 94-11- 2326227 E-MAIL : pharma.manager@spc.lk TENDER NO. : DHS/P/WW/143/24

DATE OF ISSUE : 02<sup>nd</sup> April 2024

CLOSING DATE & TIME : 14th May 2024 AT 09.00 HOURS SRI LANKA TIME

#### ORDER LIST NO.: 2024/SPC/N/R/P/00089

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00702801	Clomifene tablet 50mg  Clomifene tablets BP 50mg.  Each tablet to contain 50mg of Clomiphene Citrate BP  OR  Clomifene tablets USP 50mg.  Each tablet to contain 50mg of Clomiphene.  Note:  01.The shelf life of the product should be minimum of 24 months.	100,000 Tablets	50,000 Tablets/ October 2024 50,000 Tablets/ December 2024

Representative Tender samples to be submitted for the evaluation.

Amount of Bid Bond should be 2% of the total bid value to be submitted along with the Bid, when the value exceeds LKR one million.

Bid Bond should be submitted with valid up to 10.12.2024 together with the bid

Bid should be valid till 10.11.2024

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

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

#### **CONDITIONS OF SUPPLY**

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

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

4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.

- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.
  - All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 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 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 consumable; 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 as 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 supplier of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repairs & 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/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01).

#### **Standards & Quality**

- 9. <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial 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 Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- 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 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 (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 <u>or</u> when an exemption is notified in the Conditions of the relevant MSD order list. (**This clause No. 16 is not applicable for 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., 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 (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 Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

#### **Storage Conditions & Temperature**

- 22. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of  $30\,^{\circ}\text{C}$  +/-  $2\,^{\circ}\text{C}$  temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 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 °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.12)

#### **Delivery Requirements**

- 25. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 27 on delayed deliveries, shall be applied.
- 26. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 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 additional 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 Product artwork or dimensional detail diagrams, product Catalogs 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 also 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 <a href="www.msd.gov.lk">www.msd.gov.lk</a>)

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

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.
  - Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.
  - Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.
- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.

- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.

  Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.
- 18. In case of an offer of product not registered with NMRA, bidders should submit documents in the annexure 1 (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 (<a href="www.nmra.gov.lk">www.nmra.gov.lk</a>) for more details on the documentation required.

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

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

#### STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2024.

Please note that Tender No. DHS/P/WW/40/23 (Item: Chlorpheniramine inj. 10mg/1ml (Chlorphenamine)) published "SUNDAY OBSERVER" newspaper on 24.03.2024 treat as cancelled.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/144/24	14.05.2024 at 9.00 A.M	500 vials of Pamidronate Disodium IV Infusion 30mg vial.	02.04.2024	Rs. 3,000/= + Taxes

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

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

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

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

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

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

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

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

FAX : 00 94-11- 2344082 TELEPHONE : 00 94-11- 2326227 E-MAIL : pharma.manager@spc.lk TENDER NO. : DHS/P/WW/144/24

DATE OF ISSUE : 02<sup>nd</sup> April 2024

CLOSING DATE & TIME : 14th May 2024 AT 09.00 HOURS SRI LANKA TIME

#### ORDER LIST NO.: 2024/SPC/N/R/P/00090

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00703601	Pamidronate Disodium Intravenous Infusion 30mg vial  Pamidronate disodium Injection 30mg in 10ml Vial Each vial to contain 30mg of Disodium Pamidronate as sterile dry powder for reconstitution with water for Injection BP/USP before use for intravenous infusion.		500 vials/ November 2024
	Note:  1. This injection should be stable for minimum of 02 years when stored between 30°C-35°C  2. Each vial should be labelled accordingly.		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 89,808.00 or USD 299.00

Bid Bond should be submitted with valid up to 10.12.2024 together with the bid

Bid should be valid till 10.11.2024

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

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

#### **CONDITIONS OF SUPPLY**

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

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

- 4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.
  - All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 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 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 consumable; 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 as 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 supplier of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repairs & 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/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01).

#### **Standards & Quality**

9. <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial 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 Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- 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 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 (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 <u>or</u> when an exemption is notified in the Conditions of the relevant MSD order list. (**This clause No. 16 is not applicable for 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., 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 (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 Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

#### **Storage Conditions & Temperature**

- 22. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25 °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.12)

#### **Delivery Requirements**

- 25. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 27 on delayed deliveries, shall be applied.
- 26. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 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 additional 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 Product artwork or dimensional detail diagrams, product Catalogs 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 also 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 <a href="www.msd.gov.lk">www.msd.gov.lk</a>)

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

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.
  - Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.
  - Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.
- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.

- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.

  Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.
- 18. In case of an offer of product not registered with NMRA, bidders should submit documents in the annexure 1 (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 (<a href="www.nmra.gov.lk">www.nmra.gov.lk</a>) for more details on the documentation required.

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

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

#### STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2024.

Please note that Tender No. DHS/P/WW/40/23 (Item: Chlorpheniramine inj. 10mg/1ml (Chlorphenamine)) published "SUNDAY OBSERVER" newspaper on 24.03.2024 treat as cancelled.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/43/23	14.05.2024	18,000 vials of Ketorolac	02.04.2024	Rs. 3,000/= +
	at 9.00 A.M	Tromethamine 0.4% sterile		Taxes.
		ophthalmic solution 5ml.		

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

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

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

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

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

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

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

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

FAX : 00 94-11- 2344082 TELEPHONE : 00 94-11- 2326227 E-MAIL : pharma.manager@spc.lk TENDER NO. : DHS/P/WW/43/23 DATE OF ISSUE : 02<sup>nd</sup> April 2024

CLOSING DATE & TIME : 14th May 2024 AT 09.00 HOURS SRI LANKA TIME

#### ORDER LIST NO.: 2023/SPC/N/C/P/00077

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00903302	Ketorolac Tromethamine 0.4% Sterile Oph. Sol. 5ml	18,000	9,000 vials/
		Vials.	Immediately
	Ketorolac Tromethamine Sterile Ophthalmic Solution 0.4%, 5ml		0.000 1.1.70
	dropper Bottle		9,000 vials/ 2
	Each 5ml dropper bottle to contain 0.4% of Ketorolac		months After
	Tromethamine BP/USP for Eye Drops.		the 1 <sup>st</sup> Lot
	Note:		
	1. The tamper- evident container (dropper bottle) should		
	assure the sterility of the product.		
	2. Product should be stable for minimum of 24 months when		
	stored at a temperature range of 28°C – 32°C.		
	3. Each Bottles should be labelled accordingly.		
	Packing: One vial		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 172,973.00 or USD 576.00

Bid Bond should be submitted with valid up to 10.12.2024 together with the bid

Bid should be valid till 10.11.2024

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

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

#### **CONDITIONS OF SUPPLY**

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

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 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 consumable; 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 as 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 supplier of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repairs & 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/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01).

#### **Standards & Quality**

9. <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial 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 Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- 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 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 (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 Conditions of the relevant MSD order list. (This clause No. 16 is not applicable for 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., 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 (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 Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

#### **Storage Conditions & Temperature**

- 22. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized **USB Devices** for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25 °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.12)

#### **Delivery Requirements**

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

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 27 on delayed deliveries, shall be applied.

- 26. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th **January** shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eq. 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 (eq. 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 additional 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 Product artwork or dimensional detail diagrams, product Catalogs 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 also 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.

- 36. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 37. Administrative surcharge of 25% (on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 08,05,10,13)

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

#### (b) Part B – special order conditions (SOC)of supply

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

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.
  - Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.
  - Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.
- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.

- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.

  Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.
- 18. In case of an offer of product not registered with NMRA, bidders should submit documents in the annexure 1 (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 (<a href="www.nmra.gov.lk">www.nmra.gov.lk</a>) for more details on the documentation required.

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

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC