ANNEX-1

BID NO.: DHS/L/WW/57/24DATE OF ISSUE: 08[™] AUGUST 2023CLOSING DATE & TIME: 18[™] SEPTEMBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

CONDITIONS FOR SUPPLY OF LABORATORY ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- **2.** All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of Registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharma & 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

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

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

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01)

Standards & Quality

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the user manual/instruction pamphlet for surgical items. With information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- **11.** Withdrawal from use of items due to quality failure found as manufacturer's fault:
 - (a). In case of batch withdrawal, **value of entire batch quantity supplied** shall be recovered from the supplier.
 - (b). In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be 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 and facilities)

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

14. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

- **16.** In respect of bulk packs (not applicable for blister/strip packs), "DHS" mark shall be;
 - (a). embossed or printed in case of tablets
 - (b), printed in case of capsules

Above condition can be waved off, if the purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots or when an exemption is notified in the special order conditions of the relevant MSD order list (This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., 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 $30^{\circ}c$ +/- $2^{\circ}c$ temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB

Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

- C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (**follow instructions in website <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website 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 condition No. 27 will not be applicable.

Common conditions

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

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

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

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

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the each item exceeds LKR 1 million. Bid Bond should be submitted with valid up to 15.04.2024 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/57/24 CLOSING ON : 18.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/C/D/00125

Item No.	SR No.	Item Specification	Quantity	Delivery	Bid Bond Value (LKR)
1	40409101	Monoclonal mouse anti human PR (Progesterone Receptor) for Immuno histochemistry 1ml Packing: 1 vial	42 vials	100%- Mar/2024	287,117.38
2	40416102	Mouse Anti-Human Terminal Deoxynucleo Transferase (TDT) 1ml/vial Packing: 1 vial	9 vials	100%- Mar/2024	29,305.81
3	40417201	Anti Human IgG (y-chain specific)-for immunodiffusion Packing: 1 ml	1 ml	100%- Mar/2024	N/A
4	40417301	Anti Human IgM (u-chain specific)-for immunodiffusion Packing: 1 ml	1ml	100%- Mar/2024	N/A
5	40419201	Monoclonal Mouse Anti-Human D2-40 for Immuno Histochemistry 1ml/vial Packing: 1 vial	5 vials	100%- Mar/2024	N/A
6	40419301	Monoclonal Mouse Anti-Human Mast Cell Triptase for Immunohistochemistry 0.2ml/vial Packing: 1 vial	7 vials	100%- Mar/2024	N/A
7	40419401	Monoclonal Mouse Anti-Human Gross Cystic Disease Fluid Protein 15 for Immunohistochemistry 1ml/vial Packing: 1 vial	3 vials	100%- Mar/2024	N/A
8	40419601	Monoclonal Mouse Anti-Human CD19 for Immunohistochemistry 1ml/vial Packing: 1 vial	5 vials	100%- Mar/2024	N/A
9	40419602	Monoclonal Mouse Anti-Human CD19 for Immunohistochemistry 0.2ml/vial Packing: 1 vial	1 vials	100%- Mar/2024	N/A
10	40420401	Monoclonal mouse anti human Alk 1 for Immunohistochemistry 1 ml/ vial Packing: 1 vial	9 vials	100%- Mar/2024	34,759.37
11	40420501	Monoclonal mouse anti human BCL 2 for Immuno histochemistry 1ml Packing: 1 vial	16 vials	100%- Mar/2024	42,340.63

12	40422201	Alfa Feto Protein for Immunohistochemistry 0.2ml Packing: 1 vial	4 vials	100%- Mar/2024	N/A
13	40422301	Polyclonlal rabbit anti human C4d complement for Immunohistochemistry 1ml Packing: 1 vial	3 vials	100%- Mar/2024	N/A
14	40422602	Polyclonal rabbit anti human MPO for Immunohistochemistry 0.2ml Packing: 1 vial	14 vials	100%- Mar/2024	N/A
15	40422801	Polyclonal rabbit anti human c-erbB-2 Oncoprotein for Immunohistochemistry 1ml Packing: 1 vial	14 vials	100%- Mar/2024	N/A
16	40423102	Polyclonal rabbit anti human Cacitonin for immunohistochemistry 0.2ml Packing: 1 vial	6 vials	100%- Mar/2024	N/A
17	40424103	Polyclonal rabbit anti human thyroglobulin for Immunohistochemistry 2ml Packing: 1 vial	2 vials	100%- Mar/2024	N/A
18	40424201	Polyclonal rabbit anti human HCG for Immuno histochemistry 1ml Packing: 1 vial	3 vials	100%- Mar/2024	N/A
19	40424202	Polyclonal rabbit anti human HCG for Immuno histochemistry 2ml Packing: 1 vial	1 vials	100%- Mar/2024	N/A
20	40424302	Polyclonal rabbit anti Terminal Deoxynucleatidyl Transferase (TDT) for Immuno histochemistry 0.5ml Packing: 1 vial	2 vials	100%- Mar/2024	N/A
21	40424901	Rabbit anti human Thyroglobulin for Immunohistochemistry 2ml Packing: 1 vial	1 vials	100%- Mar/2024	N/A
22	40428001	Monoclonal mouse anti human Bcl 6 protein for Immuno histochemistry 1ml Packing: 1 vial	12 vials	100%- Mar/2024	46,345.83
23	40428101	Monoclonal mouse anti human Caldesmon for Immuno histochemistry 1ml Packing: 1 vial	5 vials	100%- Mar/2024	N/A
24	40430001	Target Retrieval Solution pH 6.1 (Concentrate) for Immuno histochemistry 1 L	155 L	100%- Mar/2024	N/A

25	40440002	Antibody diluent for Immunohistochemistry 125 ml Packing: 1 pack	102 pack	100%- Mar/2024	50,157.28
26	40449901	Gold coated slides for Immunohistochemistry Packing: 1 Nos.	18,000 Nos.	100%- Mar/2024	100,962.00
27	40450102	Monoclonal mouse anti human CD 4 for Immunohistochemistry 1ml Packing: 1 vial	19 vials	100%- Mar/2024	56,240.00
28	40451301	Monoclonal mouse anti human CD 64 for Immunocytochemistry 1ml Packing: 1 vial	1 vials	100%- Mar/2024	N/A
29	40470101	Glycergel Mounting Medium Packing: 1 ml	200 ml	100%- Mar/2024	32,184.60
30	40480201	Myosin Heavy Chain (neonatal) 1ml/vial Packing: 1 vial	2 vials	100%- Mar/2024	N/A
31	40480701	Dystrophin (Rod domain) mouse monoclonal antibody for muscle biopsy (2.5 ml/vial) Packing: 1 vial	2 vials	100%- Mar/2024	N/A
32	40480901	Mouse monoclonal Antibody Spectrin 1ml/vial Packing: 1 vial	2 vials	100%- Mar/2024	N/A
33	40481001	Monoclonal mouse anti human Beta catenin for Immunocytochemistry 1ml Packing: 1 vial	6 vials	100%- Mar/2024	21,136.70
34	40481201	Monoclonal mouse anti human Napsin-A for Immunocytochemistry 1ml Packing: 1 vial	8 vials	100%- Mar/2024	N/A
35	40481301	Monoclonal mouse anti human OCT 2 for Immunocytochemistry 1ml Packing: 1 vial	2 vials	100%- Mar/2024	N/A
36	40481901	Monoclonal mouse anti human PAX 8 for Immunocytochemistry 1ml Packing: 1 vial	8 vials	100%- Mar/2024	N/A
37	40482001	Monoclonal mouse anti human Uroplakin 3 for Immunocytochemistry 1ml Packing: 1 vial	2 vials	100%- Mar/2024	N/A
38	40482101	Monoclonal mouse anti human Androgen Receptor for Immunocytochemistry 1ml Packing: 1 vial	3 vials	100%- Mar/2024	N/A

39	40482201	Monoclonal mouse anti human CDX 2 for Immunocytochemistry 1ml Packing: 1 vial	 100%- Mar/2024	38,750.60
40	40482301	Monoclonal mouse anti human HBME 1 for Immunocytochemistry 1ml Packing: 1 vial	 100%- Mar/2024	N/A

The offer should be valid till 180 days from closing of bid. (16.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 12,500.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX – 1	
			ANNE
BID NO/]	BID REFERENCE :		
(TENDER	NO)		
DATE OF	ISSUE :		
CLOSING	G DATE & TIME :		
	$\mathbf{KAN TIME}$		
	<u>IST NO :</u>		
SR No	IST NO : Item Description/ Specifications	Quantity	Delivery Schedule
		Quantity	Delivery Schedule
		Quantity	Delivery Schedule
		Quantity	Delivery Schedule
SR No	Item Description/ Specifications		
SR No	f Bid Bond : LKR or USD		
SR No	Item Description/ Specifications		

Bid Document Fee : (should be paid in cash to SPC for each set of Bid Documents)

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
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2	

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ANNEX-1

BID NO.: DHS/L/WW/58/24DATE OF ISSUE: 08[™] AUGUST 2023CLOSING DATE & TIME: 18[™] SEPTEMBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

CONDITIONS FOR SUPPLY OF LABORATORY ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- **2.** All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of Registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharma & 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

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

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

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01)

Standards & Quality

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the user manual/instruction pamphlet for surgical items. With information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- **11.** Withdrawal from use of items due to quality failure found as manufacturer's fault:
 - (a). In case of batch withdrawal, **value of entire batch quantity supplied** shall be recovered from the supplier.
 - (b). In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be 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 and facilities)

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

14. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

- **16.** In respect of bulk packs (not applicable for blister/strip packs), "DHS" mark shall be;
 - (a). embossed or printed in case of tablets
 - (b), printed in case of capsules

Above condition can be waved off, if the purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots or when an exemption is notified in the special order conditions of the relevant MSD order list (This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., 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 $30^{\circ}c$ +/- $2^{\circ}c$ temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB

Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

- C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (**follow instructions in website <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website 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 condition No. 27 will not be applicable.

Common conditions

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

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

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

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

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the each item exceeds LKR 1 million. Bid Bond should be submitted with valid up to 15.04.2024 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

8

BID NO: DHS/L/WW/58/24 CLOSING ON : 18.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/C/D/00123

Item No.	SR No.	Item Specification	Quantity vials	Delivery	Bid Bond Value (LKR)
1	40400101	Monoclonal mouse anti human CD 1 a for Immunohistochemistry 1ml	7	100%- Mar/2024	27,860.56
2	40400301	Monoclonal mouse anti human CD 3 T cell for Immuno histochemistry 1ml	30	100%- Mar/2024	109,829.95
3	40400401	Monoclonal mouse anti human CD 5 for Immunohistochemistry 0.2ml	6	100%- Mar/2024	28,724.76
4	40400402	Monoclonal mouse anti human CD5 for immunohistochemistry 1ml	for 9 100%- Mar/2024		35,143.26
5	40400501	Monoclonal mouse anti human CD 7 for Immuno histochemistry 1ml	3	100%- Mar/2024	N/A
6	40400601	Monoclonal mouse anti human CD 8 for Immunohistochemistry 1ml	8	100%- Mar/2024	35,724.91
7	40400701	01 Monoclonal mouse anti human CD 10 for Immunohistochemistry 0.2ml		100%- Mar/2024	N/A
8	40400702	0702 Monoclonal mouse anti human CD 10 (formalin fixed paraffin embeded) for Immuno histochemistry 1ml		100%- Mar/2024	41,630.02
9	40400801	Monoclonal mouse anti human CD 14 for Immunohistochemistry 1ml	1	100%- Mar/2024	N/A
10	40400901	01 Monoclonal mouse anti human CD 15 for Immuno histochemistry 1ml		100%- Mar/2024	84,823.70
11	40401002	Monoclonal mouse anti human CD 20 for Immuno histochemistry 1ml	21	100%- Mar/2024	34,845.94
12	40401101	Monoclonal mouse anti human CD 21 for Immuno histochemistry 1ml	2	100%- Mar/2024	N/A
13	40401201	Monoclonal mouse anti human CD 23 for Immuno histochemistry 1ml	11	100%- Mar/2024	40,157.39
14	40401202	Monoclonal mouse anti human CD 235a Glycophorin A for Immunohistochemistry 1ml	1	100%- Mar/2024	N/A
15	40401301	Monoclonal mouse anti human CD 30 for Immunohistochemistry 0.2ml	1	100%- Mar/2024	N/A
16	40401302	Monoclonal mouse anti human CD 30 for Immuno histochemistry 1ml	18	100%- Mar/2024	21,407.53

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17	40401401	Monoclonal mouse anti human CD 31 for Immunohistochemistry 1ml	6	100%- Mar/2024	N/A
18	40401601	Monoclonal mouse anti human CD 34 (Class II) for Immunohistochemistry 0.2ml	3	100%- Mar/2024	N/A
19	40401602	Monoclonal mouse anti human CD 34 (Class II) for Immunohistochemistry 1ml	13	100%- Mar/2024	24,929.66
20	40401801	Monoclonal mouse anti human CD 45 (LCA) for Immuno histochemistry 1ml	15	100%- Mar/2024	24,473.71
21	40401901	Monoclonal mouse anti human CD 45 RO for Immunohistochemistry 1ml	N/A		
22	40402201	Monoclonal mouse anti human CD 56 (purified) for Immuno histochemistry 1ml	100%- Mar/2024	36,288.14	
23	40402301	Monoclonal mouse anti human CD 57 for Immuno histochemistry 1ml	4	100%- Mar/2024	N/A
24	40402401	Monoclonal mouse anti human CD 61 Platelet Glycoprotein 111a for Immuno histochemistry 1ml	2	100%- Mar/2024	N/A
25	40402501	Monoclonal mouse anti human CD 68 for Immuno histochemistry 1ml	11	100%- Mar/2024	29,109.18
26	40402602	Monoclonal mouse anti human CD 79 alpha B cell for Immunohistochemistry 1ml	2	100%- Mar/2024	N/A
27	40402701	Monoclonal mouse anti human CD 99 for Immuno histochemistry 1ml	10	100%- Mar/2024	N/A
28	40403001	Monoclonal mouse anti human CD 117 1ml	34	100%- Mar/2024	24,290.33
29	40403002	Monoclonal mouse anti human CD 117 0.2ml	9	100%- Mar/2024	N/A
30	40403101	Monoclonal mouse anti human CA 125 for Immunohistochemistry 1ml	6	100%- Mar/2024	N/A
31	40403201	Monoclonal mouse anti human CD 138 for Immuno histochemistry 1ml	27	100%- Mar/2024	25,568.76
32	40404101	Monoclonal mouse anti human CEA for Immuno histochemistry 1ml	10	100%- Mar/2024	20,961.48
33	40404201	Monoclonal mouse anti human Chromogranin A for Immunohistochemistry 0.2ml	7	100%- Mar/2024	N/A
34	40404202	Monoclonal mouse anti human Chromogranin A for Immuno histochemistry 1ml	22	100%- Mar/2024	84,374.14

35	40404301	Monoclonal mouse anti human Cyclin D1 for Immuno histochemistry 1ml	10	100%- Mar/2024	47,412.41
36	40404401	Monoclonal mouse anti human CK 19 for Immunohistochemistry 1ml	11	100%- Mar/2024	29,510.49
37	40404501	Monoclonal mouse anti human CK 5/6 for Immuno histochemistry 1ml	15	100%- Mar/2024	49,868.21
38	40404601	Monoclonal mouse anti human Cytokeratin (AE1/AE3) for Immuno histochemistry 1ml	17	100%- Mar/2024	26,509.56
39	40404602	Monoclonal mouse anti human Cytokeratin 20 for Immuno histochemistry 1ml	33	100%- Mar/2024	153,212.58
40	40404604	Monoclonal mouse anti human Cytokeratin 7 for Immuno histochemistry 1ml	35	100%- Mar/2024	93,897.01

Packing: 1 vial

The offer should be valid till 180 days from closing of bid. (16.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 20,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX – 1	
			ANNE
BID NO/]	BID REFERENCE :		
(TENDER	NO)		
DATE OF	ISSUE :		
CLOSING	G DATE & TIME :		
	KAN TIME)		
<u>OKDEK L</u>	<u>IST NO:</u>		
SR No	IST NO : Item Description/ Specifications	Quantity	Delivery Schedule
		Quantity	Delivery Schedule
		Quantity	Delivery Schedule
		Quantity	Delivery Schedule
SR No	Item Description/ Specifications		
SR No	f Bid Bond : LKR or USD		
SR No	Item Description/ Specifications		

Bid Document Fee : (should be paid in cash to SPC for each set of Bid Documents)

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
1. õõõõõõõõõõõõõ.	$\tilde{0} \ \tilde{0} \ $
$2. \ \ \tilde{o} \ o$	$\tilde{o}\ \tilde{o}\ \tilde$

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President/Managing Director/C.E.O.

 $\tilde{0} \ \tilde{0} \$

Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.								
1. õõõõõõõõõõõõ.	$\tilde{0}$								
2. õõõõõõõõõõõõ.	õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ								

CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
1	
2	



<u>ANNEX-1</u>

BID NO.: DHS/L/WW/59/24DATE OF ISSUE: 08[™] AUGUST 2023CLOSING DATE & TIME: 21ST SEPTEMBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

CONDITIONS FOR SUPPLY OF LABORATORY ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- **2.** All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of Registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharma & 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

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

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

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01)

Standards & Quality

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the user manual/instruction pamphlet for surgical items. With information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- **11.** Withdrawal from use of items due to quality failure found as manufacturer's fault:
 - (a). In case of batch withdrawal, **value of entire batch quantity supplied** shall be recovered from the supplier.
 - (b). In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be 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 and facilities)

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

14. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

- **16.** In respect of bulk packs (not applicable for blister/strip packs), "DHS" mark shall be;
 - (a). embossed or printed in case of tablets
 - (b), printed in case of capsules

Above condition can be waved off, if the purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots or when an exemption is notified in the special order conditions of the relevant MSD order list (This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., 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 $30^{\circ}c$ +/- $2^{\circ}c$ temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB

Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

- C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (**follow instructions in website <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website 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 condition No. 27 will not be applicable.

Common conditions

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

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

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

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

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the each item exceeds LKR 1 million. Bid Bond should be submitted with valid up to 18.04.2024 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

8

BID NO: DHS/L/WW/59/24 CLOSING ON : 21.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/R/D/00087

Item No.	SR No.	Item Specification	Quantity vials	Delivery	Bid Bond Value (LKR)
1	45200103	Quality Control serum for clinical chemistry, assayed, freeze dried: normal range 5ml/vial (pathological and normal should be in same source)	900	300-Jan/2024 300-May/2024 300-Oct/2024	50,555.52
2	45200203	Quality Control serum for clinical chemistry, assayed, freeze dried: pathological range 5ml/vial (pathological and normal should be in same source)	900	300-Jan/2024 300-May/2024 300-Oct/2024	50,555.52

Packing: 1 vial

The offer should be valid till 180 days from closing of bid. (19.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX – 1	
			ANNE
BID NO/ I (TENDER	BID REFERENCE : NO)		
DATE OF	ISSUE :		
	G DATE & TIME : KAN TIME)		
ORDER L	IST NO :		
SR No	Item Description/ Specifications	Quantity	Delivery Schedule
	f Bid Bond : LKR or USD . nd valid till (date)	to	be submitted along
Bid vəlidit	y period : Bid should be valid till	(date)	

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

 $\mathsf{M}/\mathsf{s}\,\,\tilde{\mathsf{o}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
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2	

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ANNEX-1

BID NO.: DHS/L/WW/60/24DATE OF ISSUE: 08^{TH} AUGUST 2023CLOSING DATE & TIME: 21^{ST} SEPTEMBER 2023at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

GENERAL CONDITIONS OF SUPPLY FOR SPC ORDERS óApplicable for Laboratory Items

- 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, manufacturerøs name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

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

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

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

Shelf life & Warrantees

- 7. In the supply of all Non consumables; Manufacturer or supplier or local agent shall provide a minimum of 02 year warranty period or as specified in the specification, for each such item or ites sub components supplied (through the local agent), unless otherwise agreed upon with MSD, prior to awarding the tender. Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repairs & spares, when necessary.
- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores in case of local supplies) of the product, shall be 85% of the shelf life requested (specified in order/Indent/PO). In respect of the items with requested shelf life equal or more than 24 months, any deficit between the residual shelf life and requested shelf, shall not be more than 04 months.

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

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

Standards & Quality

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

- 10. Any product deficient of its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 11. Withdrawal from use of items due to quality failure found as manufacturerøs fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total **cost involved for MSD**, of the quality failed supplies with 25% administrative surcharge of the same.
- **12.** The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

- **13.** Immediately after delivery at MRI, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities) If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
- 14. Consignments supplied to MRI violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

16. In respect of bulk packs (not applicable for blister/strip packs), õDHSö mark shall be;
 (a). embossed or printed in case of tablets

(b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

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 õSTATE LOGOö of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as

it is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as õYear & Monthö or õNo Exp.ö), in the innermost pack and suppliers invoice.

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and õSTATE LOGOö 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 $30^{0}c$ +/- $2^{0}c$ 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 manufacturerøs 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 WDNor copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until -observed cold chain breakø is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- **24.** In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or itsølatest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/itsøamended; 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 suppliers fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/Cøs overstepping delivery schedules in the Indent/PO/itsø 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/itsøamendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- **32.** MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- **33.** One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The images of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided within 14 days of releasing the indent by SPC.
- **34.** The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website <u>www.msd.gov.lk</u>), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- **35.** After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD⁶ by the supplier.(follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 27 will not be applicable.

Common conditions

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

Special Conditions

38. Items to be delivered at Laboratory Stores, Medical Supplies Division, Colombo 10

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

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the each item exceeds LKR 1 million. Bid Bond should be submitted with valid up to 18.04.2024 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/60/24 CLOSING ON : 21.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/R/D/00058

Item No.	SR No.	Item Specification	Quantity	Delivery	Bid Bond Value (LKR)
1	1/51601101	pH indicator strips, scale pH 6-8, narrow range (size- 5mm x 7mm) well protected against moisture & light. Packing: 1 Nos.	200 Nos.	200-Jan/2024	N/A
2	2/51601201	pH indicator strips, scale pH 5-9, narrow range (size- 5mm x 7mm) well protected against moisture & light. Packing: 1 Nos.	1,000 Nos.	1000-Jan/2024	N/A
3	3/51601301	pH indicator strips, scale pH 1-14, narrow range (size- 5mm x 7mm) well protected against moisture & light. Packing: 1 Nos.	1,000 Nos.	1000-Jan/2024	30,653.40
4	4/51602101	Aluminium Foil, Length – 75m, width- 500mm Packing: 1 Roll	80 Rolls	80-Jan/2024	67,025.92
5	5/51602401	Nickel chromium wire 80%/20%, SWG 24, 0.56mm, rolls, approximately 100g/pack Packing: 1 pack	70 packs	70-Jan/2024	N/A
6	7/51603006	Weighing boat, Diamond shaped, disposable, made of high impact polystyrene designed to be bent between the fingers to give a funnel shape to facilitate pouring size 30ml Packing: 1 Nos.	1,000 Nos.	1000-Jan/2024	N/A
7	8/51611201	Parafilm-M (4" -250') Laboratory film, double size roll Packing: 1 Nos.	20 Nos.	20-Jan/2024	N/A

The offer should be valid till 180 days from closing of bid. (19.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SPECIMEN OF A	ANNEX – 1	
			ANNE
BID NO/]	BID REFERENCE :		
(TENDER	NO)		
DATE OF	ISSUE :		
CLOSING	G DATE & TIME :		
(SRI LAN	KAN TIME)		
ONDEN L	IST NO :		
SR No	IST NO : Item Description/ Specifications	Quantity	Delivery Schedul
		Quantity	Delivery Schedul
		Quantity	Delivery Schedul
		Quantity	Delivery Schedul
SR No	Item Description/ Specifications		
SR No			

Bid Document Fee : (should be paid in cash to SPC for each set of Bid Documents)

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

 $\mathsf{M}/\mathsf{s}\,\,\tilde{\mathsf{o}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
1	
2	

/ns	
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<u>ANNEX-1</u>

BID NO.: DHS/L/WW/61/24DATE OF ISSUE: 08[™] AUGUST 2023CLOSING DATE & TIME: 21ST SEPTEMBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

CONDITIONS FOR SUPPLY OF LABORATORY ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- **2.** All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of Registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharma & 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

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

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

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01)

Standards & Quality

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the user manual/instruction pamphlet for surgical items. With information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- **11.** Withdrawal from use of items due to quality failure found as manufacturer's fault:
 - (a). In case of batch withdrawal, **value of entire batch quantity supplied** shall be recovered from the supplier.
 - (b). In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be 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 and facilities)

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

14. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

- **16.** In respect of bulk packs (not applicable for blister/strip packs), "DHS" mark shall be;
 - (a). embossed or printed in case of tablets
 - (b), printed in case of capsules

Above condition can be waved off, if the purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots or when an exemption is notified in the special order conditions of the relevant MSD order list (This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., 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 $30^{\circ}c$ +/- $2^{\circ}c$ temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB

Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

- C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (**follow instructions in website <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website 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 condition No. 27 will not be applicable.

Common conditions

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

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

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

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

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the each item exceeds LKR 1 million. Bid Bond should be submitted with valid up to 18.04.2024 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

8

BID NO: DHS/L/WW/61/24 CLOSING ON : 21.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/R/D/00084

Item	SR No.	Item Specification	Quantity	Delivery	Bid Bond
No.			strips		Value (LKR)
1	43033602	Urine strips -2 parameters with high sensitivity & high specificity for Glucose & Protein with a desiccant to eliminate negative effects of moisture to strip (supply of positive & negative controls are preferable)		800,000- Jan/2024 700,000- May/2024 700,000- Oct/2024	183,920.00

Packing: 50 strips

The offer should be valid till 180 days from closing of bid. (19.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

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CLOSING DA (SRI LANKAI	ATE & TIME : N TIME)		
(SRI LANKAN	N TIME)		
	<u>NO :</u>		
SR No I	Item Description/ Specifications	Quantity	Delivery Schedule
	id Bond : LKR or USD . valid till (date)	t	o be submitted along

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
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<u>ANNEX-1</u>

BID NO.: DHS/L/WW/62/24DATE OF ISSUE: 08[™] AUGUST 2023CLOSING DATE & TIME: 21ST SEPTEMBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

CONDITIONS FOR SUPPLY OF LABORATORY ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- **2.** All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of Registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharma & 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

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

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

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01)

Standards & Quality

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the user manual/instruction pamphlet for surgical items. With information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- **11.** Withdrawal from use of items due to quality failure found as manufacturer's fault:
 - (a). In case of batch withdrawal, **value of entire batch quantity supplied** shall be recovered from the supplier.
 - (b). In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be 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 and facilities)

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

14. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

- **16.** In respect of bulk packs (not applicable for blister/strip packs), "DHS" mark shall be;
 - (a). embossed or printed in case of tablets
 - (b), printed in case of capsules

Above condition can be waved off, if the purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots or when an exemption is notified in the special order conditions of the relevant MSD order list (This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., 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 $30^{\circ}c$ +/- $2^{\circ}c$ temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB

Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

- C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (**follow instructions in website <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website 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 condition No. 27 will not be applicable.

Common conditions

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

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

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

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

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the each item exceeds LKR 1 million. Bid Bond should be submitted with valid up to 18.04.2024 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/62/24 CLOSING ON : 21.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/R/D/00085

Item	SR No.	Item Specification	Quantity	Delivery	Bid Bond
No.			ml		Value (LKR)
1	43410103	Sodium hypochlorite solution 10 - 20%	16,000,000	8,000,000-Jan/2024 8,000,000-Jun/2024	1,398,400.00
2	43410201	Multipurpose detergent/disinfectant for hospital/laboratory use - Teepol or similar property to Teepol with not remaining residuals at glassware	8,500,000	4,500,000-Jan/2024 4,000,000-Jun/2024	486,200.00

Packing: 1000 ml

The offer should be valid till 180 days from closing of bid. (19.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 20,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

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	<u>NO :</u>		
SR No I	Item Description/ Specifications	Quantity	Delivery Schedule
	id Bond : LKR or USD . valid till (date)	t	o be submitted along

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
1	
2	

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<u>ANNEX-1</u>

BID NO.: DHS/L/WW/63/24DATE OF ISSUE: 08[™] AUGUST 2023CLOSING DATE & TIME: 21ST SEPTEMBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

CONDITIONS FOR SUPPLY OF LABORATORY ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- **2.** All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of Registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharma & 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

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

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

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01)

Standards & Quality

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the user manual/instruction pamphlet for surgical items. With information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- **11.** Withdrawal from use of items due to quality failure found as manufacturer's fault:
 - (a). In case of batch withdrawal, **value of entire batch quantity supplied** shall be recovered from the supplier.
 - (b). In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be 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 and facilities)

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

14. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

- **16.** In respect of bulk packs (not applicable for blister/strip packs), "DHS" mark shall be;
 - (a). embossed or printed in case of tablets
 - (b), printed in case of capsules

Above condition can be waved off, if the purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots or when an exemption is notified in the special order conditions of the relevant MSD order list (This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., 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 $30^{\circ}c$ +/- $2^{\circ}c$ temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB

Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

- C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (**follow instructions in website <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website 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 condition No. 27 will not be applicable.

Common conditions

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

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

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

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

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the each item exceeds LKR 1 million. Bid Bond should be submitted with valid up to 18.04.2024 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/63/24 CLOSING ON : 21.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/C/D/00124

Item No.	SR No.	Item Specification	Quantity vials	Delivery	Bid Bond Value (LKR)		
1	40404801	Monoclonal mouse anti human Desmin for Immunohistochemistry 0.2ml	2	100%- Mar/2024	N/A		
2	40404802	Monoclonal mouse anti human Desmin for Immuno histochemistry 1ml	14	100%- Mar/2024	25,126.34		
3	40405001	Monoclonal mouse anti human E Cadherin for Immuno histochemistry 1ml	11	100%- Mar/2024	25,903.41		
4	40405101	Monoclonal mouse anti human Epithelial Membrane Antigen (EMA) for Immunohistochemistry 0.2ml	100%- Mar/2024	N/A			
5	40405102	Monoclonal mouse anti human Epithelial Membrane Antigen for Immuno histochemistry 1ml	N/A				
6	40405201	01 Monoclonal mouse anti human Epstein Barr virus 4 100%- LMP for Immunohistochemistry 1ml Mar/2024					
7	40405302	Monoclonal mouse anti human Estrogen Receptor for Immuno histochemistry 1ml					
8	40405402	Monoclonal mouse anti human Follicle Stimulating Hormon (FSH) for immunohistochemistry 0.2ml	1	100%- Mar/2024	N/A		
9	40405502	Monoclonal mouse anti human GFAP for Immuno histochemistry 1ml	11	100%- Mar/2024	30,818.63		
10	40405601	Monoclonal mouse anti human Hepatocyte (HEPPAR 1)for Immunohistochemistry 1 ml	8	100%- Mar/2024	N/A		
11	40405702	Monoclonal mouse anti human HER 2 New for Immuno histochemistry 1ml	34	100%- Mar/2024	36,902.34		
12	40405801	Monoclonal mouse anti human HMB 45 for Immuno histochemistry 1ml	10	100%- Mar/2024	26,704.13		
13	40405901	Monoclonal mouse anti human Inhibin for Immunohistochemistry 1ml	8	100%- Mar/2024	N/A		
14	40406001	Monoclonal mouse anti human Kappa Light chains for Immuno histochemistry 1ml	16	100%- Mar/2024	22,457.70		
15	40406101	Monoclonal mouse anti human Lambda Light chains for Immuno histochemistry 1ml	16	100%- Mar/2024	22,457.70		
16	40406201	Monoclonal mouse anti human Ki 67 antigen for Immunohistochemistry 0.2ml	10	100%- Mar/2024	N/A		

17	40406202	Monoclonal mouse anti human Ki 67 antigen for Immunohistochemistry 1ml	39	100%- Mar/2024	130,690.68
18	40406302	Monoclonal mouse anti human Luteinizing Hormon (LH) for immunohistochemistry 0.2ml	6	100%- Mar/2024	N/A
19	40406401	Monoclonal mouse anti human Mammaglobin for Immuno histochemistry 1ml	10	100%- Mar/2024	47,219.01
20	40406402	Monoclonal mouse anti human Mammaglobin for Immunohistochemistry 0.2ml	5	100%- Mar/2024	29,149.71
21	40406501	Monoclonal mouse anti human MB 45 for Immuno histochemistry 1ml	2	100%- Mar/2024	N/A
22	40406601	Monoclonal mouse anti human Melan A for Immunohistochemistry 1ml	8	100%- Mar/2024	24,392.67
23	40406701	Monoclonal mouse anti human MNF 116 for Immuno histochemistry 1ml	6	100%- Mar/2024	N/A
24	40406801	Monoclonal mouse anti human MUM 1 protein for Immuno histochemistry 1ml	8	100%- Mar/2024	29,536.27
25	40406901	Monoclonal mouse anti human MYO D1 for Immuno histochemistry 1ml	9	100%- Mar/2024	22,315.49
26	40407002	Monoclonal mouse anti human NSE (Neuro Specific Enclose) for Immuno histochemistry 1ml	10	100%- Mar/2024	42,649.41
27	40407101	Monoclonal mouse anti human NF for Immuno histochemistry 1ml	5	100%- Mar/2024	N/A
28	40407102	Monoclonal mouse anti human NF for Immuno Histochemistry (0.2ml/vial)	1	100%- Mar/2024	N/A
29	40407201	Monoclonal mouse anti human Oestrogen for Immunohistochemistry 1ml	7	100%- Mar/2024	50,224.11
30	40407401	Monoclonal mouse anti human P 53 protein for Immunohistochemistry 1ml	11	100%- Mar/2024	25,686.46
31	40407501	Monoclonal mouse anti human P 63 for Immunohistochemistry 1ml	13	100%- Mar/2024	62,149.24
32	40407601	Monoclonal mouse anti human PLAP for Immuno histochemistry 1ml	7	100%- Mar/2024	20,588.02
33	40407702	Monoclonal mouse anti human Prostate Specific Antigen for Immunohistochemistry 0.2ml	13	100%- Mar/2024	N/A
34	40407703	Monoclonal mouse anti human PSA for Immunohistochemistry 1ml	6	100%- Mar/2024	N/A

35	40407901	Monoclonal mouse anti human S 100 for Immuno histochemistry 1ml	25	100%- Mar/2024	29,307.47
36	40408001	Monoclonal mouse anti human smooth muscle actine for Immuno histochemistry 1ml	24	100%- Mar/2024	28,896.81
37	40408101	Monoclonal mouse anti human Synaptophysin for Immuno histochemistry 1ml	15	100%- Mar/2024	88,623.33
38	40408202	Monoclonal mouse anti human Thyroid Stimulating Hormon (TSH) for immunohistochemistry 0.2ml	8	100%- Mar/2024	N/A
39	40408401	Monoclonal mouse anti human WTI for Immunohistochemistry 1ml	14	100%- Mar/2024	32,461.04
40	40408502	Monoclonal mouse anti Adrenocorticotropin (ACTH) for immunohistochemistry 0.2ml	8	100%- Mar/2024	N/A
41	40408701	Monoclonal mouse anti human Calretinin for Immunohistochemistry 1ml	9	100%- Mar/2024	27,441.75

Packing: 1 vial

The offer should be valid till 180 days from closing of bid. (19.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 20,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX – 1	
			ANNE
BID NO/ 1	BID REFERENCE :		
(TENDER	NO)		
DATE OF	ISSUE :		
CLOSING	G DATE & TIME :		
(SRI LAN	KAN TIME)		
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SR No	IST NO : Item Description/ Specifications	Quantity	Delivery Schedul
		Quantity	Delivery Schedul
		Quantity	Delivery Schedul
		Quantity	Delivery Schedule
SR No	Item Description/ Specifications		
SR No			

Bid Document Fee : (should be paid in cash to SPC for each set of Bid Documents)

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

 $\mathsf{M}/\mathsf{s}\,\,\tilde{\mathsf{o}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
1	
2	



<u>ANNEX-1</u>

BID NO.: DHS/L/WW/64/24DATE OF ISSUE: 15^{TH} AUGUST 2023CLOSING DATE & TIME: 25^{TH} SEPTEMBE 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

GENERAL CONDITIONS OF SUPPLY FOR SPC ORDERS óApplicable for Laboratory Items

- 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, manufacturerøs name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- **2.** All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

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

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

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

Shelf life & Warrantees

- 7. In the supply of all Non consumables; Manufacturer or supplier or local agent shall provide a minimum of 02 year warranty period or as specified in the specification, for each such item or ites sub components supplied (through the local agent), unless otherwise agreed upon with MSD, prior to awarding the tender. Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repairs & spares, when necessary.
- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores in case of local supplies) of the product, shall be 85% of the shelf life requested (specified in order/Indent/PO). In respect of the items with requested shelf life equal or more than 24 months, any deficit between the residual shelf life and requested shelf, shall not be more than 04 months.

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

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

Standards & Quality

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

- 10. Any product deficient of its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 11. Withdrawal from use of items due to quality failure found as manufacturerøs fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total **cost involved for MSD**, of the quality failed supplies with 25% administrative surcharge of the same.
- **12.** The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

- **13.** Immediately after delivery at MRI, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities) If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
- 14. Consignments supplied to MRI violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

16. In respect of bulk packs (not applicable for blister/strip packs), õDHSö mark shall be;
 (a). embossed or printed in case of tablets

(b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

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 õSTATE LOGOö of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as

it is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as õYear & Monthö or õNo Exp.ö), in the innermost pack and suppliers invoice.

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and õSTATE LOGOö 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 $30^{0}c$ +/- $2^{0}c$ 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 manufacturerøs 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 **WDNor copy of the delivery documents.** In such an event, the SPC shall arrange necessary cold storage for the consignment until ÷observed cold chain breakø is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

- d.The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- **24.** In respect of the products requiring controlled temperature storage (Eg. < 25^oc, 2-25^oc, 15-20^oc/30^oc, 2-8^oc etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30^oc +/- 2^oc & 75% +/- 5% RH for **AC stored** items and at 25^oc +/- 2^oc & 60% +/- 5% RH for **Cold stored** items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.12)

Delivery Requirements

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

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

- 26. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- **27.** Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below ;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or itsølatest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/itsø 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 suppliers fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/Cøs overstepping delivery schedules in the Indent/PO/itsø 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/itsøamendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- **32.** MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- **33.** One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The images of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided within 14 days of releasing the indent by SPC.
- **34.** The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website <u>www.msd.gov.lk</u>), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- **35.** After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD⁶ by the supplier.(follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 27 will not be applicable.

Common conditions

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

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

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value mentioned in the item list. Bid Bond should be submitted with valid up to 22.04.2024 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

BID NO:DHS/L/WW/64/24 CLOSING ON : 25.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/R/D/00051

Item No.	SR No.	Item Specification	Qty Nos.	Delivery	Bid Bond value (LKR)
1	1/50200202	Centifuge tube: conical, borosilicate glass, heat & vibration resistant, without graduations, with rim capacity 10ml Packing: 1 Nos.	500	100%-Jan/2024	N/A
2	2/50200301	Centrifuge tube: cylindrical, heat resistant borosilicate glass with rim without graduations, capacity 10ml Packing: 1 Nos.	2,000	100%-Jan/2024	N/A
3	4/50200901	Centrifuge tube: Conical, prolypropylene, autoclavable, screw capped, with graduation, capacity 15 ml Packing: 25 Nos.	6,000	100%-Jan/2024	N/A
4	6/50300302	Filter paper circular, qualitative, standard, medium flow rate, 11 micrometer retention, hermatically sealed (Similar to Whatman No 1) diameter 9 -11 cm Packing: 50 Nos.	10,000	100%-Jan/2024	N/A
5	7/50300901	Filter paper circular, Whatman grade-1, diameter 40 cm Packing: 50 Nos.	6,000	100%-Jan/2024	33,819.60

The offer should be valid till 180 days from closing of bid. (23.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

(1) Clause 8

- (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
- (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

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CLOSING DA (SRI LANKAI	ATE & TIME : N TIME)		
(SRI LANKAN	N TIME)		
	<u>NO :</u>		
SR No I	Item Description/ Specifications	Quantity	Delivery Schedule
	id Bond : LKR or USD . valid till (date)	t	o be submitted along

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

Date :

SPC Ref. No

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

 $\mathsf{M}/\mathsf{s}\,\,\tilde{\mathsf{o}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $\mathsf{M}/\mathsf{s}\,\,\tilde{\mathsf{o}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called % be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called %be Contract Documents+) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

The Common Seal of M/s (supplier)õõõõõõõõõõõõõõõõõõõõõõõõõõõõõõõõõõ

1. í í í í í í í í í í í í í í í .. President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
1. õõõõõõõõõõõ.	õõõõõõõõõõõõõõõõõõõõõ
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<u>Witnesses</u>

<u>Signature</u>	Name, Address and ID No./Passport No.
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CONDITIONS OF CONTRACT

3. FREE REPLACEMENT /REIMBURSEMENT

3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of

- 3.1.1 Short packing
- 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
- 3.1.3 Packs which cannot be identified due to labels falling off.
- 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or it fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharn	naceuticals Corp	oration of Sri L	anka was affixed)	
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Authorized signatory					
Authorized signatory					
<u>Witnesses</u>					
Signature Name, Address and ID No					
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ANNEX-1

BID NO.: DHS/L/WW/65/24DATE OF ISSUE: 15[™] AUGUST 2023CLOSING DATE & TIME: 25[™] SEPTEMBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

GENERAL CONDITIONS OF SUPPLY FOR SPC ORDERS óApplicable for Laboratory Items

- 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, manufacturerøs name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

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

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

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

Shelf life & Warrantees

- 7. In the supply of all Non consumables; Manufacturer or supplier or local agent shall provide a minimum of 02 year warranty period or as specified in the specification, for each such item or ites sub components supplied (through the local agent), unless otherwise agreed upon with MSD, prior to awarding the tender. Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repairs & spares, when necessary.
- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores in case of local supplies) of the product, shall be 85% of the shelf life requested (specified in order/Indent/PO). In respect of the items with requested shelf life equal or more than 24 months, any deficit between the residual shelf life and requested shelf, shall not be more than 04 months.

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

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

Standards & Quality

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

- 10. Any product deficient of its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 11. Withdrawal from use of items due to quality failure found as manufacturerøs fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total **cost involved for MSD**, of the quality failed supplies with 25% administrative surcharge of the same.
- **12.** The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

- **13.** Immediately after delivery at MRI, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities) If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
- 14. Consignments supplied to MRI violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

16. In respect of bulk packs (not applicable for blister/strip packs), õDHSö mark shall be;
 (a). embossed or printed in case of tablets

(b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

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 õSTATE LOGOö of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as

it is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as õYear & Monthö or õNo Exp.ö), in the innermost pack and suppliers invoice.

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and õSTATE LOGOö 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 $30^{0}c$ +/- $2^{0}c$ 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 manufacturerøs 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 WDNor copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until -observed cold chain breakø is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- **24.** In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or itsølatest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/itsøamended; 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 suppliers fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/Cøs overstepping delivery schedules in the Indent/PO/itsø 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/itsøamendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- **32.** MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- **33.** One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The images of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided within 14 days of releasing the indent by SPC.
- **34.** The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website <u>www.msd.gov.lk</u>), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- **35.** After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD⁶ by the supplier.(follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 27 will not be applicable.

Common conditions

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

Special Conditions

38. Items to be delivered at Laboratory Stores, Medical Supplies Division, Colombo 10

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

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the each item exceeds LKR 1 million. Bid Bond should be submitted with valid up to 22.04.2024 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/65/24 CLOSING ON : 25.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/R/D/00070

Item No.	SR No.	Item Specification	Quantity Nos.	Delivery	Bid Bond Value (LKR)
1	50400401	Sterile Vacuum tube, plastic, volume 10ml (vacutainer tube) with the cap Packing: 100 Nos.	100,000	100,000- Jan/2024	54,700.00
2	51611001	Vacuum needle (similar to vacutainer) Packing: 100 Nos.	100,000	50,000- Jan/2024 50,000- Jul/2024	31,200.00
3	56101501	Perma slides for VDRL with high walled wells. Glass microscopy slides made of soda lime glass of third hydrolytic class dimensions approximately 76 x 52mm, with 12 rings/ high walled rim, of 13-14 mm diameter for microscopic examination of VDRL test. The rim could be glass or from plastic/ similar material –beveled edges with clipped corners, pre- cleaned, ready for use, autoclavable in boxes of 10 pieces. Thickness approximately 1mm Packing: 10 Nos.	250	250-Jan/2024	N/A

The offer should be valid till 180 days from closing of bid. (23.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX – 1	
			ANNE
BID NO/ I (TENDER	BID REFERENCE : NO)		
DATE OF	ISSUE :		
	G DATE & TIME : KAN TIME)		
ORDER L	IST NO :		
SR No	Item Description/ Specifications	Quantity	Delivery Schedule
	f Bid Bond : LKR or USD . nd valid till (date)	to	be submitted along
Bid vəlidit	y period : Bid should be valid till	(date)	

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

 $\mathsf{M}/\mathsf{s}\,\,\tilde{\mathsf{o}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
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2	

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<u>ANNEX-1</u>

BID NO. : DHS/L/WW/66/24 DATE OF ISSUE : 15[™] AUGUST 2023 CLOSING DATE & TIME : 25[™] SEPTEMBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

CONDITIONS FOR SUPPLY OF LABORATORY ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- **2.** All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of Registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharma & 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

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

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

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01)

Standards & Quality

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the user manual/instruction pamphlet for surgical items. With information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- **11.** Withdrawal from use of items due to quality failure found as manufacturer's fault:
 - (a). In case of batch withdrawal, **value of entire batch quantity supplied** shall be recovered from the supplier.
 - (b). In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be 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 and facilities)

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

14. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

- **16.** In respect of bulk packs (not applicable for blister/strip packs), "DHS" mark shall be;
 - (a). embossed or printed in case of tablets
 - (b), printed in case of capsules

Above condition can be waved off, if the purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots or when an exemption is notified in the special order conditions of the relevant MSD order list (This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., 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 $30^{\circ}c$ +/- $2^{\circ}c$ temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB

Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

- C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (**follow instructions in website <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website 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 condition No. 27 will not be applicable.

Common conditions

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

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

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

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

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/66/24 CLOSING ON : 25.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/R/D/00083

Item	SR No.	Item Specification	Quantity	Delivery	Bid Bond Value
No.					(LKR)
1	1/43009502	Trichloroacetic acid AR Packing: 500g	15,000 g	5000-Jan/2024 5000-May/2024 5000-Oct/2024	N/A
2	2/43009602	Tris (hydroxy methyl amino methane) AR Packing: 100g	4,000 g	2000-Jan/2024 2000-Jun/2024	N/A
3	3/43009801	Urea 40% solution Packing: 100ml	2000 ml	1000-Jan/2024 1000-Jun/2024	N/A
4	4/43009803	Urea AR Packing: 100g	6,000 g	3000-Jan/2024 3000-Jun/2024	N/A
5	5/43012601	Liquid Paraffin for laboratory use Packing: 100ml	7,500 ml	4000-Jan/2024 3500-Jun/2024	N/A
6	7/43029401	Disodium hydrogen orthophosphate anhydrous AR Packing: 100g	6,000 g	3000-Jan/2024 3000-Jun/2024	N/A

The offer should be valid till 180 days from closing of bid. (23.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX – 1	
			ANNEX
	BID REFERENCE :		
(TENDER	NO)		
DATE OF	ISSUE :		
CLOSING	G DATE & TIME :		
	KAN TIME)		
<u>UKDEK L</u>	<u>IST NO :</u>		
SR No	ISI NO : Item Description/ Specifications	Quantity	Delivery Schedule
		Quantity	Delivery Schedule
SR No	Item Description/ Specifications		
SR No Amount o			
SR No Amount o the Bid Bo	f Bid Bond : LKR or USD		

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

 $\mathsf{M}/\mathsf{s}\,\,\tilde{\mathsf{o}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
1	
2	

/ns	
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ANNEX-1

BID NO.: DHS/L/WW/67/24DATE OF ISSUE: 15[™] AUGUST 2023CLOSING DATE & TIME: 25[™] SEPTEMBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

CONDITIONS FOR SUPPLY OF LABORATORY ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- **2.** All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of Registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharma & 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

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

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

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01)

Standards & Quality

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the user manual/instruction pamphlet for surgical items. With information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- **11.** Withdrawal from use of items due to quality failure found as manufacturer's fault:
 - (a). In case of batch withdrawal, **value of entire batch quantity supplied** shall be recovered from the supplier.
 - (b). In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be 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 and facilities)

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

14. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

- **16.** In respect of bulk packs (not applicable for blister/strip packs), "DHS" mark shall be;
 - (a). embossed or printed in case of tablets
 - (b), printed in case of capsules

Above condition can be waved off, if the purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots or when an exemption is notified in the special order conditions of the relevant MSD order list (This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., 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 $30^{\circ}c$ +/- $2^{\circ}c$ temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB

Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

- C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (**follow instructions in website <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website 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 condition No. 27 will not be applicable.

Common conditions

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

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

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

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

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/67/24 CLOSING ON : 25.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/R/D/00081

Item No.	SR No.	Item Specification	Quantity	Delivery	Bid Bond Value (LKR)
1	1/43000401	Acetone Packing: 500ml	43,000 ml	43,000-Oct/2024	N/A
2	2/43000402	Acetone AR in amber colour glass bottles Packing: 500ml	71,000 ml	71,000-Jun/2024	N/A
3	3/43004801	Lithium carbonate AR Packing: 50g	2200 g	1100-Jan/2024 1100-Jun/2024	N/A
4	4/43006201	Picric acid Packing: 500g	16,000 g	6000-Jan/2024 5000-May/2024 5000-Oct/2024	N/A
5	5/43006202	Picric acid (2,4,6-trinitrophenol) AR Packing: 100g	1,000 g	1000-Jun/2024	N/A
6	7/43008201	Sodium carbonate anhydrous AR Packing: 1000g	80,000 g	40,000-Jan/2024 40,000-Jun/2024	N/A
7	8/43008802	Sodium Metabisulphite AR Packing: 100g	3,000 g	1,500-Jan/2024 1,500-Jun/2024	N/A
8	9/43009002	Sodium nitroprusside AR Packing: 100g	3,000 g	1,500-Jan/2024 1,500-Jun/2024	N/A
9	10/43005501	Nitric acid Packing: 500ml	15,000 ml	15,000-Jun/2024	N/A

The offer should be valid till 180 days from closing of bid. (23.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX – 1	
			ANNEX
	BID REFERENCE :		
(TENDER	NO)		
DATE OF	ISSUE :		
CLOSING	G DATE & TIME :		
	KAN TIME)		
<u>UNDEN L</u>	<u>IST NO :</u>		
SR No	ISI NO : Item Description/ Specifications	Quantity	Delivery Schedule
		Quantity	Delivery Schedule
SR No	Item Description/ Specifications		
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SR No Amount o the Bid Bo	f Bid Bond : LKR or USD		

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

<u>Signature</u>	Name, Address and ID No./Passport No.
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
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2	

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ANNEX-1

BID NO.: DHS/L/WW/68/24DATE OF ISSUE: 15[™] AUGUST 2023CLOSING DATE & TIME: 25[™] SEPTEMBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

CONDITIONS FOR SUPPLY OF LABORATORY ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- **2.** All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of Registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharma & 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

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

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

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01)

Standards & Quality

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the user manual/instruction pamphlet for surgical items. With information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- **11.** Withdrawal from use of items due to quality failure found as manufacturer's fault:
 - (a). In case of batch withdrawal, **value of entire batch quantity supplied** shall be recovered from the supplier.
 - (b). In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be 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 and facilities)

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

14. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

- **16.** In respect of bulk packs (not applicable for blister/strip packs), "DHS" mark shall be;
 - (a). embossed or printed in case of tablets
 - (b), printed in case of capsules

Above condition can be waved off, if the purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots or when an exemption is notified in the special order conditions of the relevant MSD order list (This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., 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 $30^{\circ}c$ +/- $2^{\circ}c$ temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB

Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

- C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (**follow instructions in website <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website 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 condition No. 27 will not be applicable.

Common conditions

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

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

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

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

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/68/24 CLOSING ON : 25.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/C/D/00119

Item No.	SR No.	Item Specification	Quantity	Delivery	Bid Bond Value (LKR)
1	40101102	Anti Xa assay Packing: 1 kit	3 kit	100%-Mar/2024	N/A
2	40102304	Fibrinogen Functional Assay(2ml/vial) Packing: 1 vial	300 vial	100%-Mar/2024	N/A

The offer should be valid till 180 days from closing of bid. (23.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX - 1	
			ANNE
BID NO/]	BID REFERENCE :		
(TENDER	NO)		
DATE OF	ISSUE :		
CLOSING	GDATE & TIME :		
	KAN TIME)		
	<u>IST NO :</u>		
SR No	Item Description/ Specifications	Quantity	Delivery Schedule
		Quantity	Delivery Schedule
SR No	f Bid Bond : LKR or USD		
SR No	Item Description/ Specifications		

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
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2	

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ANNEX-1

BID NO.: DHS/L/WW/69/24DATE OF ISSUE: 15[™] AUGUST 2023CLOSING DATE & TIME: 25[™] SEPTEMBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

CONDITIONS FOR SUPPLY OF LABORATORY ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- **2.** All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of Registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharma & 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

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

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

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01)

Standards & Quality

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the user manual/instruction pamphlet for surgical items. With information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- **11.** Withdrawal from use of items due to quality failure found as manufacturer's fault:
 - (a). In case of batch withdrawal, **value of entire batch quantity supplied** shall be recovered from the supplier.
 - (b). In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be 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 and facilities)

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

14. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

- **16.** In respect of bulk packs (not applicable for blister/strip packs), "DHS" mark shall be;
 - (a). embossed or printed in case of tablets
 - (b), printed in case of capsules

Above condition can be waved off, if the purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots or when an exemption is notified in the special order conditions of the relevant MSD order list (This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., 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 $30^{\circ}c$ +/- $2^{\circ}c$ temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB

Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

- C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (**follow instructions in website <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website 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 condition No. 27 will not be applicable.

Common conditions

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

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

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

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

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/69/24 CLOSING ON : 25.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/C/D/00137

Item No.	SR No.	Item Specification	Quantity	Delivery	Bid Bond Value (LKR)
1	2/43013103	Napthol AS-D Chloroacetate Packing: 1 g	100 g	100%-Mar/2024	N/A
2	4/43014001	Rubeanic acid Packing: 1 g	40 g	100%-Mar/2024	N/A

The offer should be valid till 180 days from closing of bid. (23.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX – 1	
			ANNE
BID NO/ I (TENDER	BID REFERENCE : NO)		
DATE OF	ISSUE :		
	G DATE & TIME : KAN TIME)		
ORDER L	IST NO :		
SR No	Item Description/ Specifications	Quantity	Delivery Schedule
	f Bid Bond : LKR or USD . nd valid till (date)	to	be submitted along
Rid validit	y period : Bid should be valid till	(date)	

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.				
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.			
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
1	
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<u>ANNEX-1</u>

BID NO.: DHS/L/WW/70/24DATE OF ISSUE: 15TH AUGUST 2023CLOSING DATE & TIME: 25TH SEPTEMBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

GENERAL CONDITIONS OF SUPPLY FOR SPC ORDERS óApplicable for Laboratory Items

- 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, manufacturerøs name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

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

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

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

Shelf life & Warrantees

- 7. In the supply of all Non consumables; Manufacturer or supplier or local agent shall provide a minimum of 02 year warranty period or as specified in the specification, for each such item or ites sub components supplied (through the local agent), unless otherwise agreed upon with MSD, prior to awarding the tender. Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repairs & spares, when necessary.
- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores in case of local supplies) of the product, shall be 85% of the shelf life requested (specified in order/Indent/PO). In respect of the items with requested shelf life equal or more than 24 months, any deficit between the residual shelf life and requested shelf, shall not be more than 04 months.

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

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

Standards & Quality

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

- 10. Any product deficient of its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 11. Withdrawal from use of items due to quality failure found as manufacturerøs fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total **cost involved for MSD**, of the quality failed supplies with 25% administrative surcharge of the same.
- **12.** The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

- **13.** Immediately after delivery at MRI, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities) If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
- 14. Consignments supplied to MRI violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

16. In respect of bulk packs (not applicable for blister/strip packs), õDHSö mark shall be;
 (a). embossed or printed in case of tablets

(b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

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 õSTATE LOGOö of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as

it is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as õYear & Monthö or õNo Exp.ö), in the innermost pack and suppliers invoice.

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and õSTATE LOGOö 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 $30^{0}c$ +/- $2^{0}c$ 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 manufacturerøs 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 **WDNor copy of the delivery documents.** In such an event, the SPC shall arrange necessary cold storage for the consignment until ÷observed cold chain breakø is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

- d.The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- **24.** In respect of the products requiring controlled temperature storage (Eg. < 25^oc, 2-25^oc, 15-20^oc/30^oc, 2-8^oc etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30^oc +/- 2^oc & 75% +/- 5% RH for **AC stored** items and at 25^oc +/- 2^oc & 60% +/- 5% RH for **Cold stored** items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.12)

Delivery Requirements

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

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

- 26. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- **27.** Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below ;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or itsølatest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/itsø 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 suppliers fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/Cøs overstepping delivery schedules in the Indent/PO/itsø 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/itsøamendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- **32.** MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- **33.** One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The images of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided within 14 days of releasing the indent by SPC.
- **34.** The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website <u>www.msd.gov.lk</u>), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- **35.** After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD⁶ by the supplier.(follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 27 will not be applicable.

Common conditions

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

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

Sufficient quantity of samples should be forwarded for evaluation.

BID NO:DHS/L/WW/70/24 CLOSING ON : 25.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/C/D/00108

	Item Specification	Qty	Delivery	Bid Bond
				value (LKR)
4/45500501	Propane 2-ol HPLC grade	7,500	100%-Jan/2024	N/A
	Packing: 1 ml	ml		
8/45501701	Acetic acid Glacial HPLC grade	10,200	100%-Jan/2024	N/A
	Packing: 1 ml	ml		
9/45501801	Acetonitrile HPLC	122,500	100%-Jan/2024	N/A
	Packing: 1 ml	ml		
11/45502001	Methanol HPLC grade	212,500	100%-Jan/2024	N/A
	Packing: 1 ml	ml		
	8/45501701 9/45501801	Packing: 1 ml 8/45501701 Acetic acid Glacial HPLC grade Packing: 1 ml 9/45501801 Acetonitrile HPLC Packing: 1 ml 11/45502001 Methanol HPLC grade	Packing: 1 mlml8/45501701Acetic acid Glacial HPLC grade Packing: 1 ml10,200 ml9/45501801Acetonitrile HPLC Packing: 1 ml122,500 ml11/45502001Methanol HPLC grade212,500	Packing: 1 ml ml 8/45501701 Acetic acid Glacial HPLC grade Packing: 1 ml 10,200 9/45501801 Acetonitrile HPLC Packing: 1 ml 122,500 100%-Jan/2024 ml 100%-Jan/2024 11/45502001 Methanol HPLC grade

The offer should be valid till 180 days from closing of bid. (23.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

(1) Clause 8

- (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
- (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX – 1	
			ANNE
BID NO/ I (TENDER	BID REFERENCE : NO)		
DATE OF	ISSUE :		
	G DATE & TIME : KAN TIME)		
ORDER L	IST NO :		
SR No	Item Description/ Specifications	Quantity	Delivery Schedule
	f Bid Bond : LKR or USD . nd valid till (date)	to	be submitted along
Bid vəlidit	y period : Bid should be valid till	(date)	

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

Date :

SPC Ref. No

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

 $\mathsf{M}/\mathsf{s}\,\,\tilde{\mathsf{o}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $\mathsf{M}/\mathsf{s}\,\,\tilde{\mathsf{o}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called % be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **THIRD PART**.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called %be Contract Documents+) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

1. í í í í í í í í í í í í í í í .. President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
1. õõõõõõõõõõõ.	õõõõõõõõõõõõõõõõõõõõõ
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 $\tilde{o} ~ \tilde{o} ~ . \\ President/Managing Director/C.E.O.$

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<u>Witnesses</u>

<u>Signature</u>	Name, Address and ID No./Passport No.
1. õõõõõõõõõõõõ.	$\tilde{0}$
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of

- 3.1.1 Short packing
- 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
- 3.1.3 Packs which cannot be identified due to labels falling off.
- 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharn	aceuticals Corporation of Sri	Lanka was affixed)
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Authorized signatory		
Authorized signatory		
<u>Witnesses</u>		
Signature	Name, Address	and ID No
1		
2		

/ns







ANNEX-1

BID NO.: DHS/L/WW/71/24DATE OF ISSUE: 15[™] AUGUST 2023CLOSING DATE & TIME: 25[™] SEPTEMBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

CONDITIONS FOR SUPPLY OF LABORATORY ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- **2.** All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of Registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharma & 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

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

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

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01)

Standards & Quality

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the user manual/instruction pamphlet for surgical items. With information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- **11.** Withdrawal from use of items due to quality failure found as manufacturer's fault:
 - (a). In case of batch withdrawal, **value of entire batch quantity supplied** shall be recovered from the supplier.
 - (b). In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be 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 and facilities)

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

14. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

- **16.** In respect of bulk packs (not applicable for blister/strip packs), "DHS" mark shall be;
 - (a). embossed or printed in case of tablets
 - (b), printed in case of capsules

Above condition can be waved off, if the purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots or when an exemption is notified in the special order conditions of the relevant MSD order list (This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., 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 $30^{\circ}c$ +/- $2^{\circ}c$ temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB

Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

- C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (**follow instructions in website <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website 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 condition No. 27 will not be applicable.

Common conditions

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

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

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

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

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the each item exceeds LKR 1 million. Bid Bond should be submitted with valid up to 22.04.2024 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/71/24 CLOSING ON : 25.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/C/D/00072

Item No.	SR No.	Item Specification	Quantity Nos.	Delivery	Bid Bond Value (LKR)
1	2/50240101	Micro centrifuge tubes for amplification; Dome-shaped lids,size 0.2 ml individual tubes, sterile,(PCR grade) Packing: 500 Nos.	24,000 Nos.	100%- Jan/2024	N/A
2	3/50240301	Micro centrifuge tubes for amplification; Flat-shaped lids, size 0.2 ml individual tubes, sterile, (PCR grade) Packing: 500 Nos.	15000 Nos.	100%- Jan/2024	N/A
3	4/50605601	Bottles, media-Lab (Schott Bottle) borosilicate glass, graduated,conical shoulders,ISO screw thread and with blue poly propylene screw cap and fitted pouring ring Sterilizable at 140 C capacity 1000 ml Packing: 1 Nos.	100 Nos.	100%- Jan/2024	N/A
4	9/51602304	Syringe filter units, pore size 0.22um, individually packed, sterile Packing: 50 Nos.	800 Nos.	100%- Jan/2024	N/A
5	14/51611602	Polypropylene storage box withstand temperature down to -80C).1.8 ml, 9x9 vials Packing: 1 Nos.	145 Nos.	100%- Jan/2024	N/A
6	16/51630001	Lab coats, disposable Packing: 1 Nos.	10,000 Nos.	100%- Jan/2024	69,884.00

The offer should be valid till 180 days from closing of bid. (23.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX – 1	
			ANNE
BID NO/ I (TENDER	BID REFERENCE : NO)		
DATE OF	ISSUE :		
	G DATE & TIME : KAN TIME)		
ORDER L	IST NO :		
SR No	Item Description/ Specifications	Quantity	Delivery Schedule
	f Bid Bond : LKR or USD . nd valid till (date)	to	be submitted along
Bid vəlidit	y period : Bid should be valid till	(date)	

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

 $\mathsf{M}/\mathsf{s}\,\,\tilde{\mathsf{o}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
1. õõõõõõõõõõõõ.	$\tilde{0}$
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President/Managing Director/C.E.O.

 $\tilde{\mathbf{0}} ~ \tilde{\mathbf{0}} ~$

Director

<u>Witnesses</u>

<u>Signature</u>	Name, Address and ID No./Passport No.
1. õõõõõõõõõõõõ.	õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
1	
2	

/ns	
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ANNEX-1

BID NO.: DHS/L/WW/72/24DATE OF ISSUE: 22ND AUGUST2023CLOSING DATE & TIME: 02ND OCTOBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

GENERAL CONDITIONS OF SUPPLY FOR SPC ORDERS óApplicable for Laboratory Items

- 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, manufacturerøs name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

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

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

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

Shelf life & Warrantees

- 7. In the supply of all Non consumables; Manufacturer or supplier or local agent shall provide a minimum of 02 year warranty period or as specified in the specification, for each such item or ites sub components supplied (through the local agent), unless otherwise agreed upon with MSD, prior to awarding the tender. Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repairs & spares, when necessary.
- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores in case of local supplies) of the product, shall be 85% of the shelf life requested (specified in order/Indent/PO). In respect of the items with requested shelf life equal or more than 24 months, any deficit between the residual shelf life and requested shelf, shall not be more than 04 months.

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

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

Standards & Quality

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

- 10. Any product deficient of its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 11. Withdrawal from use of items due to quality failure found as manufacturerøs fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total **cost involved for MSD**, of the quality failed supplies with 25% administrative surcharge of the same.
- **12.** The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

- **13.** Immediately after delivery at MRI, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities) If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
- 14. Consignments supplied to MRI violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

16. In respect of bulk packs (not applicable for blister/strip packs), õDHSö mark shall be;
 (a). embossed or printed in case of tablets

(b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

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 õSTATE LOGOö of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as

it is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as õYear & Monthö or õNo Exp.ö), in the innermost pack and suppliers invoice.

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and õSTATE LOGOö 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 $30^{0}c$ +/- $2^{0}c$ 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 manufacturerøs 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 WDNor copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until -observed cold chain breakø is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- **24.** In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or itsølatest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/itsøamended; 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 suppliers fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/Cøs overstepping delivery schedules in the Indent/PO/itsø 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/itsøamendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- **32.** MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- **33.** One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The images of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided within 14 days of releasing the indent by SPC.
- **34.** The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website <u>www.msd.gov.lk</u>), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- **35.** After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD⁶ by the supplier.(follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 27 will not be applicable.

Common conditions

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

Special Conditions

38. Items to be delivered at Medical Research Institute, Colombo 8

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

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the each item exceeds LKR 1 million. Bid Bond should be submitted with valid up to 29.04.2024 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/72/24 CLOSING ON : 02.10.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/C/D/00013

Item No.	SR No.	Item Specification	Quantity kit	Delivery	Bid Bond Value (LKR)
1	4/42700702	Mycoplasma Antibody Particle Agglutination Test kit	100	50-Jan/2024 50-Jul/2024	35,860.00
2	7/42701703	Helicobacter pylori stool antigen ELISA kit	3	3-Jan/2024	N/A
3	8/42701801	Cryptococcus Antigen Latex Agglutination Test kit, 50 tests/kit	40	20-Jan/2024 20-Jul/2024	60,610.00

Packing: 1 kit

The offer should be valid till 180 days from closing of bid. (30.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX - 1	
			ANNE
BID NO/]	BID REFERENCE :		
(TENDER	NO)		
DATE OF	ISSUE :		
CLOSING	GDATE & TIME :		
	KAN TIME)		
	<u>IST NO :</u>		
SR No	Item Description/ Specifications	Quantity	Delivery Schedule
		Quantity	Delivery Schedule
SR No	f Bid Bond : LKR or USD		
SR No	Item Description/ Specifications		

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
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2	

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ANNEX-1

BID NO.: DHS/L/WW/73/24DATE OF ISSUE: 22ND AUGUST 2023CLOSING DATE & TIME: 02ND OCTOBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

CONDITIONS FOR SUPPLY OF LABORATORY ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- **2.** All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of Registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharma & 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

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

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

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01)

Standards & Quality

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the user manual/instruction pamphlet for surgical items. With information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- **11.** Withdrawal from use of items due to quality failure found as manufacturer's fault:
 - (a). In case of batch withdrawal, **value of entire batch quantity supplied** shall be recovered from the supplier.
 - (b). In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be 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 and facilities)

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

14. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

- **16.** In respect of bulk packs (not applicable for blister/strip packs), "DHS" mark shall be;
 - (a). embossed or printed in case of tablets
 - (b), printed in case of capsules

Above condition can be waved off, if the purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots or when an exemption is notified in the special order conditions of the relevant MSD order list (This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., 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 $30^{\circ}c$ +/- $2^{\circ}c$ temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB

Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

- C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (**follow instructions in website <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website 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 condition No. 27 will not be applicable.

Common conditions

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

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

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

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

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the each item exceeds LKR 1 million. Bid Bond should be submitted with valid up to 29.04.2024 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/73/24 CLOSING ON : 02.10.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/C/D/00132

Item No.	SR No.	Item Specification	Quantity	Delivery	Bid Bond Value (LKR)
1	1/43002804	Sodium dihydrogen orthophosphste AR 12 hydrate Packing: 1 g	130,000 g	100%- Mar/2024	72,510.00
2	2/43005503	Nitric acid - heavy metal free Packing: 1 ml	70,000 ml	100%- Mar/2024	38,120.00
3	3/43011701	Diacetyl monoxime AR Packing: 1 g	300 g	100%- Mar/2024	N/A
4	4/43014401	Sodium sulphate Anhydrous AR Packing: 1 g	3,000 g	100%- Mar/2024	N/A
5	12/43014401	Sodium Citrate AR Packing: 1 g	700 g	100%- Mar/2024	N/A

The offer should be valid till 180 days from closing of bid. (30.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX - 1	
			ANNE
BID NO/]	BID REFERENCE :		
(TENDER	NO)		
DATE OF	ISSUE :		
CLOSING	GDATE & TIME :		
	KAN TIME)		
	<u>IST NO :</u>		
SR No	Item Description/ Specifications	Quantity	Delivery Schedule
		Quantity	Delivery Schedule
SR No	f Bid Bond : LKR or USD		
SR No	Item Description/ Specifications		

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
1. õõõõõõõõõõõ.	$\tilde{0}$
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
1. õõõõõõõõõõõõ.	õõõõõõõõõõõõõõõõõõõõõõõõõõ
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
1	
2	

/ns	
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ANNEX-1

BID NO.: DHS/L/WW/74/24DATE OF ISSUE: 22ND AUGUST 2023CLOSING DATE & TIME: 02ND OCTOBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

CONDITIONS FOR SUPPLY OF LABORATORY ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- **2.** All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of Registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharma & 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

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

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

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01)

Standards & Quality

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the user manual/instruction pamphlet for surgical items. With information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- **11.** Withdrawal from use of items due to quality failure found as manufacturer's fault:
 - (a). In case of batch withdrawal, **value of entire batch quantity supplied** shall be recovered from the supplier.
 - (b). In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be 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 and facilities)

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

14. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

- **16.** In respect of bulk packs (not applicable for blister/strip packs), "DHS" mark shall be;
 - (a). embossed or printed in case of tablets
 - (b), printed in case of capsules

Above condition can be waved off, if the purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots or when an exemption is notified in the special order conditions of the relevant MSD order list (This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., 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 $30^{\circ}c$ +/- $2^{\circ}c$ temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB

Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

- C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (**follow instructions in website <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website 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 condition No. 27 will not be applicable.

Common conditions

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

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

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

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

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/74/24 CLOSING ON : 02.10.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/C/D/00118

Item No.	SR No.	Item Specification	Quantity vial	Delivery	Bid Bond Value (LKR)
1	40100701	Clotting factor VII deficient plasma (1ml/vial)	2	100%-Mar/2024	N/A
2	40100801	Clotting factor VIII deficient plasma (1ml/vial)	81	100%-Mar/2024	N/A
3	40100901	Clotting factor IX defficient plasma(1ml/vial)	66	100%-Mar/2024	N/A
4	40101101	Clotting factor XI defficient plasma(1ml/vial)	6	100%-Mar/2024	N/A
5	40102201	Coagulation Calibration plasma 1ml/vial	53	100%-Mar/2024	N/A

Packing: 1 vial

The offer should be valid till 180 days from closing of bid. (30.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

(TENDER NO DATE OF ISS	SUE : ATE & TIME : N TIME)		ANNE
(TENDER NO DATE OF ISS CLOSING DA (SRI LANKAI	D) SUE : ATE & TIME : N TIME)		
CLOSING DA (SRI LANKAI	ATE & TIME : N TIME)		
(SRI LANKAN	N TIME)		
	<u>NO :</u>		
SR No I	Item Description/ Specifications	Quantity	Delivery Schedule
	id Bond : LKR or USD . valid till (date)	t	o be submitted along

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

 $\mathsf{M}/\mathsf{s}\,\,\tilde{\mathsf{o}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
1	
2	

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ANNEX-1

BID NO.: DHS/L/WW/75/24DATE OF ISSUE: 22ND AUGUST 2023CLOSING DATE & TIME: 02ND OCTOBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

CONDITIONS FOR SUPPLY OF LABORATORY ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- **2.** All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of Registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharma & 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

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

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

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01)

Standards & Quality

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the user manual/instruction pamphlet for surgical items. With information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- **11.** Withdrawal from use of items due to quality failure found as manufacturer's fault:
 - (a). In case of batch withdrawal, **value of entire batch quantity supplied** shall be recovered from the supplier.
 - (b). In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be 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 and facilities)

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

14. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

- **16.** In respect of bulk packs (not applicable for blister/strip packs), "DHS" mark shall be;
 - (a). embossed or printed in case of tablets
 - (b), printed in case of capsules

Above condition can be waved off, if the purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots or when an exemption is notified in the special order conditions of the relevant MSD order list (This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., 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 $30^{\circ}c$ +/- $2^{\circ}c$ temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB

Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

- C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (**follow instructions in website <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website 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 condition No. 27 will not be applicable.

Common conditions

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

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

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

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

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the each item exceeds LKR 1 million. Bid Bond should be submitted with valid up to 29.04.2024 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/75/24 CLOSING ON : 02.10.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/C/D/00121

Item No.	SR No.	Item Specification	Quantity	Delivery	Bid Bond Value (LKR)
1		Dithiothreitol (sputalysin) 0.1% solution for sputum culture Packing: 1 g	680 g	100%-Mar/2024	26,910.00

The offer should be valid till 180 days from closing of bid. (30.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SI ECHVIEN OF A	NNEX - 1	
			ANNEX
BID NO/ B (TENDER]	ID REFERENCE : NO)		
DATE OF 1	ISSUE :		
	DATE & TIME : (AN TIME)		
	CT NO		
<u>ORDER LI</u>	<u>SI NO :</u>		
SR No	Item Description/ Specifications	Quantity	Delivery Schedule
		Quantity	Delivery Schedule
		Quantity	Delivery Schedule

Bid Document Fee : (should be paid in cash to SPC for each set of Bid Documents)

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

 $\mathsf{M}/\mathsf{s}\,\,\tilde{\mathsf{o}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No		
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ANNEX-1

BID NO.: DHS/L/WW/76/24DATE OF ISSUE: 22ND AUGUST 2023CLOSING DATE & TIME: 02ND OCTOBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

CONDITIONS FOR SUPPLY OF LABORATORY ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- **2.** All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of Registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharma & 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

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

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

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01)

Standards & Quality

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the user manual/instruction pamphlet for surgical items. With information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- **11.** Withdrawal from use of items due to quality failure found as manufacturer's fault:
 - (a). In case of batch withdrawal, **value of entire batch quantity supplied** shall be recovered from the supplier.
 - (b). In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be 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 and facilities)

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

14. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

- **16.** In respect of bulk packs (not applicable for blister/strip packs), "DHS" mark shall be;
 - (a). embossed or printed in case of tablets
 - (b), printed in case of capsules

Above condition can be waved off, if the purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots or when an exemption is notified in the special order conditions of the relevant MSD order list (This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., 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 $30^{\circ}c$ +/- $2^{\circ}c$ temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB

Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

- C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (**follow instructions in website <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website 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 condition No. 27 will not be applicable.

Common conditions

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

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

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

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

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the each item exceeds LKR 1 million. Bid Bond should be submitted with valid up to 29.04.2024 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

8

BID NO: DHS/L/WW/76/24 CLOSING ON : 02.10.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/C/D/00028

Item No.	SR No.	Item Specification	Quantity	Delivery	Bid Bond Value (LKR)
1	1/41200502	Brain heart infusion agar Packing: 500g	1000 g	100%-Jan/2024	N/A
2	3/41201502	Mueller Hinton Broth Packing: 500g	1000 g	100%-Jan/2024	N/A
3	4/41201701	Oxidation fermentation medium (Hugh Leifson agar) Packing: 500g	1000 g	100%-Jan/2024	N/A
4	6/41202701	Chromogenic candida agar Packing: 500g	2000 g	100%-Jan/2024	N/A
5	15/41204101	Leptospira Enrichment broth EMJH Packing: 500 ml	7500 ml	100%-Jan/2024	36,450.00
6	16/41204103	Leptospira medium agar base EMJH Packing: 500g	500 g	100%-Jan/2024	N/A
7	23/41205501	Thioglycholate Broth Packing: 500g	500 g	100%-Jan/2024	N/A
8	30/41205807	Supplement to Listeria Selective agar Packing: 1 vial	25 vials	100%-Jan/2024	N/A
9	41/41211201	Nutrient broth No 2 Packing: 500g	2500 g	100%-Jan/2024	N/A
10	43/41212101	Tryptone Soya agar Packing: 500g	10000 g	100%-Jan/2024	N/A
11	44/41212301	Mannitol salt agar Packing: 500g	2000 g	100%-Jan/2024	N/A
12	48/41213902	Fraser Selective Supplement Packing: 1 vial	60 vial	100%-Jan/2024	N/A
13	49/41213903	Half Fraser Selective Supplement Packing: 1 vial	60 vial	100%-Jan/2024	N/A

The offer should be valid till 180 days from closing of bid. (30.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

(TENDER NO DATE OF ISS	SUE : ATE & TIME : N TIME)		ANNE
(TENDER NO DATE OF ISS CLOSING DA (SRI LANKAI	D) SUE : ATE & TIME : N TIME)		
CLOSING DA (SRI LANKAI	ATE & TIME : N TIME)		
(SRI LANKAN	N TIME)		
	<u>NO :</u>		
SR No I	Item Description/ Specifications	Quantity	Delivery Schedule
	id Bond : LKR or USD . valid till (date)	t	o be submitted along

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

 $\mathsf{M}/\mathsf{s}\,\,\tilde{\mathsf{o}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
1	
2	

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ANNEX-1

BID NO.: DHS/L/WW/77/24DATE OF ISSUE: 22ND AUGUST 2023CLOSING DATE & TIME: 02ND OCTOBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

GENERAL CONDITIONS OF SUPPLY FOR SPC ORDERS óApplicable for Laboratory Items

- 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, manufacturerøs name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

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

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

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

Shelf life & Warrantees

- 7. In the supply of all Non consumables; Manufacturer or supplier or local agent shall provide a minimum of 02 year warranty period or as specified in the specification, for each such item or ites sub components supplied (through the local agent), unless otherwise agreed upon with MSD, prior to awarding the tender. Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repairs & spares, when necessary.
- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores in case of local supplies) of the product, shall be 85% of the shelf life requested (specified in order/Indent/PO). In respect of the items with requested shelf life equal or more than 24 months, any deficit between the residual shelf life and requested shelf, shall not be more than 04 months.

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

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

Standards & Quality

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

- 10. Any product deficient of its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 11. Withdrawal from use of items due to quality failure found as manufacturerøs fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total **cost involved for MSD**, of the quality failed supplies with 25% administrative surcharge of the same.
- **12.** The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

- **13.** Immediately after delivery at MRI, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities) If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
- 14. Consignments supplied to MRI violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

16. In respect of bulk packs (not applicable for blister/strip packs), õDHSö mark shall be;
 (a). embossed or printed in case of tablets

(b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

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 õSTATE LOGOö of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as

it is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as õYear & Monthö or õNo Exp.ö), in the innermost pack and suppliers invoice.

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and õSTATE LOGOö 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 $30^{0}c$ +/- $2^{0}c$ 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 manufacturerøs 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 WDNor copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until -observed cold chain breakø is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- **24.** In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or itsølatest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/itsøamended; 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 suppliers fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/Cøs overstepping delivery schedules in the Indent/PO/itsø 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/itsøamendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- **32.** MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- **33.** One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The images of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided within 14 days of releasing the indent by SPC.
- **34.** The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website <u>www.msd.gov.lk</u>), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- **35.** After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD⁶ by the supplier.(follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 27 will not be applicable.

Common conditions

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

Special Conditions

38. Items to be delivered at Laboratory Stores, Medical Supplies Division, Colombo 10

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

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the each item exceeds LKR 1 million. Bid Bond should be submitted with valid up to 29.04.2024 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

8

BID NO: DHS/L/WW/77/24 CLOSING ON : 02.10.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/C/D/00097

Item	SR No.	Item Specification	Quantity	Delivery	Bid Bond Value
No.					(LKR)
1	1/45403201	Amonium acetate AR	750g	750-Jan/2024	N/A
		Packing: 1 g			
2	16/45428101	5-Hydroxymethyl furfural AR	250ml	250-Jan/2024	N/A
		Packing: 1 ml			
3	17/45428601	Ammonia 13.5m AR	15,000ml	15,000-	N/A
		Packing: 1ml		Jan/2024	
4	21/45430701	Diethyl ether peroxide free AR	35,000ml	35,000-	21,000.00
		Packing: 1ml		Jan/2024	
5	22/45431601	Ethanol (96%) AR	150,000ml	150,000-	117,000.00
		Packing: 1ml		Jan/2024	
6	24/45432904	Hydrogen peroxide solution (30vol) AR	5,250ml	5,250-	N/A
		Packing: 1 ml		Jan/2024	
7	26/45437601	N-Hexane AR	12,500ml	12,500-	N/A
		Packing: 1ml		Jan/2024	

The offer should be valid till 180 days from closing of bid. (30.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX – 1	
			ANNE
BID NO/ I (TENDER	BID REFERENCE : NO)		
DATE OF	ISSUE :		
	G DATE & TIME : KAN TIME)		
ORDER L	IST NO :		
SR No	Item Description/ Specifications	Quantity	Delivery Schedule
	f Bid Bond : LKR or USD . nd valid till (date)	to	be submitted along
Bid vəlidit	y period : Bid should be valid till	(date)	

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

 $\mathsf{M}/\mathsf{s}\,\,\tilde{\mathsf{o}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
1. õõõõõõõõõõõõ.	õõõõõõõõõõõõõõõõõõõõõõõõõõ
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
1	
2	

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ANNEX-1

BID NO.: DHS/L/WW/78/24DATE OF ISSUE: 22ND AUGUST 2023CLOSING DATE & TIME: 02ND OCTOBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

GENERAL CONDITIONS OF SUPPLY FOR SPC ORDERS óApplicable for Laboratory Items

- 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, manufacturerøs name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

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

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

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

Shelf life & Warrantees

- 7. In the supply of all Non consumables; Manufacturer or supplier or local agent shall provide a minimum of 02 year warranty period or as specified in the specification, for each such item or ites sub components supplied (through the local agent), unless otherwise agreed upon with MSD, prior to awarding the tender. Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repairs & spares, when necessary.
- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores in case of local supplies) of the product, shall be 85% of the shelf life requested (specified in order/Indent/PO). In respect of the items with requested shelf life equal or more than 24 months, any deficit between the residual shelf life and requested shelf, shall not be more than 04 months.

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

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

Standards & Quality

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

- 10. Any product deficient of its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 11. Withdrawal from use of items due to quality failure found as manufacturerøs fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total **cost involved for MSD**, of the quality failed supplies with 25% administrative surcharge of the same.
- **12.** The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

- **13.** Immediately after delivery at MRI, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities) If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
- 14. Consignments supplied to MRI violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

16. In respect of bulk packs (not applicable for blister/strip packs), õDHSö mark shall be;
 (a). embossed or printed in case of tablets

(b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

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 õSTATE LOGOö of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as

it is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as õYear & Monthö or õNo Exp.ö), in the innermost pack and suppliers invoice.

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and õSTATE LOGOö 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 $30^{0}c$ +/- $2^{0}c$ 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 manufacturerøs 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 WDNor copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until -observed cold chain breakø is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- **24.** In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or itsølatest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/itsøamended; 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 suppliers fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/Cøs overstepping delivery schedules in the Indent/PO/itsø 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/itsøamendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- **32.** MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- **33.** One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The images of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided within 14 days of releasing the indent by SPC.
- **34.** The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website <u>www.msd.gov.lk</u>), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- **35.** After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD⁶ by the supplier.(follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 27 will not be applicable.

Common conditions

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

Special Conditions

38. Items to be delivered at Laboratory Stores, Medical Supplies Division, Colombo 10

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

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/78/24 CLOSING ON : 02.10.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/R/D/00063

Item No.	SR No.	Item Specification	Quantity Nos.	Delivery	Bid Bond Value (LKR)
1	1/55501001	Thermometer; Celcius, general purpose, 1C divisions 0-100C (Non Mercury) for laboratory purpose	110	60-Jan/2024 50-Jul/2024	N/A
2	14/56603501	Slide forceps (Forcep to hold glass slides with teeth)	70	70-Jan/2024	N/A
3	18/56607501	Timer 1hr, mechanical spring driven, activated by easy to read dial with audible alarm	50	50-Jan/2024	N/A
4	19/56607601	Digital stop clock-multi function, quartz, clip, magnetic attachments, LCD display, 1.5V	90	90-Jan/2024	N/A

Packing: 1 Nos.

The offer should be valid till 180 days from closing of bid. (30.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX - 1	
			ANNE
BID NO/]	BID REFERENCE :		
(TENDER	NO)		
DATE OF	ISSUE :		
CLOSING	G DATE & TIME :		
	KAN TIME)		
ORDER L	<u>IST NO :</u>		
ORDER L SR No	IST NO : Item Description/ Specifications	Quantity	Delivery Schedule
		Quantity	Delivery Schedule
		Quantity	Delivery Schedule
		Quantity	Delivery Schedule
SR No	Item Description/ Specifications		
SR No	f Bid Bond : LKR or USD		
SR No	Item Description/ Specifications		

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

 $\mathsf{M}/\mathsf{s}\,\,\tilde{\mathsf{o}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
1	
2	

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ANNEX-1

BID NO.: DHS/L/WW/79/24DATE OF ISSUE: 22ND AUGUST 2023CLOSING DATE & TIME: 02ND OCTOBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

GENERAL CONDITIONS OF SUPPLY FOR SPC ORDERS óApplicable for Laboratory Items

- 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, manufacturerøs name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

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

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

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

Shelf life & Warrantees

- 7. In the supply of all Non consumables; Manufacturer or supplier or local agent shall provide a minimum of 02 year warranty period or as specified in the specification, for each such item or ites sub components supplied (through the local agent), unless otherwise agreed upon with MSD, prior to awarding the tender. Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repairs & spares, when necessary.
- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores in case of local supplies) of the product, shall be 85% of the shelf life requested (specified in order/Indent/PO). In respect of the items with requested shelf life equal or more than 24 months, any deficit between the residual shelf life and requested shelf, shall not be more than 04 months.

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

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

Standards & Quality

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

- 10. Any product deficient of its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 11. Withdrawal from use of items due to quality failure found as manufacturerøs fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total **cost involved for MSD**, of the quality failed supplies with 25% administrative surcharge of the same.
- **12.** The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

- **13.** Immediately after delivery at MRI, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities) If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
- 14. Consignments supplied to MRI violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

16. In respect of bulk packs (not applicable for blister/strip packs), õDHSö mark shall be;
 (a). embossed or printed in case of tablets

(b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

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 õSTATE LOGOö of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as

it is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as õYear & Monthö or õNo Exp.ö), in the innermost pack and suppliers invoice.

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and õSTATE LOGOö 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 $30^{0}c$ +/- $2^{0}c$ 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 manufacturerøs 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 WDNor copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until -observed cold chain breakø is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- **24.** In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or itsølatest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/itsøamended; 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 suppliers fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/Cøs overstepping delivery schedules in the Indent/PO/itsø 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/itsøamendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- **32.** MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- **33.** One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The images of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided within 14 days of releasing the indent by SPC.
- **34.** The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website <u>www.msd.gov.lk</u>), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- **35.** After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD⁶ by the supplier.(follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 27 will not be applicable.

Common conditions

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

Special Conditions

38. Items to be delivered at Laboratory Stores, Medical Supplies Division, Colombo 10

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

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/79/24 CLOSING ON : 02.10.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/R/D/00061

Item No.	SR No.	Item Specification	Quantity Nos.	Delivery	Bid Bond Value (LKR)
1	1/51618902	Sterile Polythene bags (12cm x 18cm with zip seal) Packing: 10 Nos.	2,000	2,000- Jan/2024	N/A
2	5/51650001	Slide folder-stiff past board, gate fold covers, for 10 slides Packing: 1 Nos.	300	300-Jan/2024	N/A

The offer should be valid till 180 days from closing of bid. (30.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX – 1	
			ANNE
BID NO/ I (TENDER	BID REFERENCE : NO)		
DATE OF	ISSUE :		
	G DATE & TIME : KAN TIME)		
ORDER L	IST NO :		
SR No	Item Description/ Specifications	Quantity	Delivery Schedule
	f Bid Bond : LKR or USD . nd valid till (date)	to	be submitted along
Bid vəlidit	y period : Bid should be valid till	(date)	

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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President/Managing Director/C.E.O.

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Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
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2	

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<u>ANNEX-1</u>

BID NO.: DHS/L/WW/80/24DATE OF ISSUE: 22ND AUGUST2023CLOSING DATE & TIME: 02ND OCTOBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

GENERAL CONDITIONS OF SUPPLY FOR SPC ORDERS óApplicable for Laboratory Items

- 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, manufacturerøs name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

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

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

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

Shelf life & Warrantees

- 7. In the supply of all Non consumables; Manufacturer or supplier or local agent shall provide a minimum of 02 year warranty period or as specified in the specification, for each such item or ites sub components supplied (through the local agent), unless otherwise agreed upon with MSD, prior to awarding the tender. Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repairs & spares, when necessary.
- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores in case of local supplies) of the product, shall be 85% of the shelf life requested (specified in order/Indent/PO). In respect of the items with requested shelf life equal or more than 24 months, any deficit between the residual shelf life and requested shelf, shall not be more than 04 months.

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

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

Standards & Quality

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

- 10. Any product deficient of its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 11. Withdrawal from use of items due to quality failure found as manufacturerøs fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be surcharged the total **cost involved for MSD**, of the quality failed supplies with 25% administrative surcharge of the same.
- **12.** The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

- **13.** Immediately after delivery at MRI, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities) If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
- 14. Consignments supplied to MRI violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

16. In respect of bulk packs (not applicable for blister/strip packs), õDHSö mark shall be;
 (a). embossed or printed in case of tablets

(b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

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 õSTATE LOGOö of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as

it is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as õYear & Monthö or õNo Exp.ö), in the innermost pack and suppliers invoice.

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and õSTATE LOGOö 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 $30^{0}c$ +/- $2^{0}c$ 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 manufacturerøs 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 **WDNor copy of the delivery documents.** In such an event, the SPC shall arrange necessary cold storage for the consignment until ÷observed cold chain breakø is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

- d.The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- **24.** In respect of the products requiring controlled temperature storage (Eg. < 25^oc, 2-25^oc, 15-20^oc/30^oc, 2-8^oc etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30^oc +/- 2^oc & 75% +/- 5% RH for **AC stored** items and at 25^oc +/- 2^oc & 60% +/- 5% RH for **Cold stored** items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.12)

Delivery Requirements

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

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

- 26. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- **27.** Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below ;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or itsølatest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/itsø 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 suppliers fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/Cøs overstepping delivery schedules in the Indent/PO/itsø 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/itsøamendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

- **32.** MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- **33.** One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The images of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided within 14 days of releasing the indent by SPC.
- **34.** The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website <u>www.msd.gov.lk</u>), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- **35.** After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD⁶ by the supplier.(follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 27 will not be applicable.

Common conditions

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

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

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value mentioned in the item list. Bid Bond should be submitted with valid up to 29.04.2024 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

BID NO:DHS/L/WW/80/24 CLOSING ON : 02.10.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/R/D/00050

Item No.	SR No.	Item Specification	Qty Nos.	Delivery	Bid Bond value (LKR)
1	50100101	Brushes for khan tubes with a cotton wool tip	3,500	100%-Jan/2024	20,980.00
2	50100301	Brushes for test tubes, size of the head 16- 25mm,length 240mm with cotton wool tip	2,000	100%-Jan/2024	N/A
3	50100401	Brushes for test tubes, size of the head 12.5- 16mm, overall length 185mm with cotton wool tip	1500	100%-Jan/2024	N/A

Packing: 1 Nos.

The offer should be valid till 180 days from closing of bid. (30.03.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

(1) Clause 8

- (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
- (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

ERENCE : : : TIME : <u>1</u> E) <u>:</u>		ANNE
: t TIME : 1E)		
1E)		
1E)		
Description/ Specifications	Quantity	Delivery Schedule
		to be submitted along
	nd : LKR or USD till (date)	nd : LKR or USD till (date)

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called % be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

1. The following documents:

- (a) Conditions of Contract marked . Annex 1
- (b) Bid Documents marked . Annex 2
- (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

1. í í í í í í í í í í í í í í í ... President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director <u>Witnesses</u>

<u>Signature</u>	Name, Address and ID No./Passport No.			
1. õõõõõõõõõõõ.	õõõõõõõõõõõõõõõõõõõõ			
2. õõõõõõõõõõõõ.	õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ			
The Common Seal of M/s. õ õ õ õ õ õ õ õ õ õ õ	õõõõõõ (Local Agent) herein.			

 $\tilde{o} \ \tilde{o} \$

 $\tilde{o}\ \tilde{o}\ \tilde{o}\$. Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.			
1. õõõõõõõõõõõõ.	õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ			
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or it fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed						
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	õõõõõõõõ õõõõõõõõ	õõõõõõ õõõõõõ	õõõõõõõõõõ õõõõõõõõõ	õ.) õ.)		
Authorized signatory						
Authorized signatory						
<u>Witnesses</u>						
Signature	Name	, Address a	ind ID No			
1						
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/ns





ANNEX-1

BID NO.: DHS/L/WW/81/24DATE OF ISSUE: 22ND AUGUST 2023CLOSING DATE & TIME: 05TH OCTOBER 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

- 1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
- 2. Offered item should bear both our SR number and the Item number.
- 3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 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.
- 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 Bids" of the bid document in this regard.
- 6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 7. 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
- 8. The volume of the total quantity of each item should be given in cubic meters (m³)
- 9. Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.
- 10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.
- 11. We reserve the right to reject offers which do not comply above.

CONDITIONS FOR SUPPLY OF LABORATORY ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- **2.** All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of Registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharma & 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

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

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

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
 - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01)

Standards & Quality

- **9.** <u>Standards</u>; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.
- **10.** As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the user manual/instruction pamphlet for surgical items. With information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

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

- **11.** Withdrawal from use of items due to quality failure found as manufacturer's fault:
 - (a). In case of batch withdrawal, **value of entire batch quantity supplied** shall be recovered from the supplier.
 - (b). In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be 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 and facilities)

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

14. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

- **16.** In respect of bulk packs (not applicable for blister/strip packs), "DHS" mark shall be;
 - (a). embossed or printed in case of tablets
 - (b), printed in case of capsules

Above condition can be waved off, if the purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots or when an exemption is notified in the special order conditions of the relevant MSD order list (This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., 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 $30^{\circ}c$ +/- $2^{\circ}c$ temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB

Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

- C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25°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 15th December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- **30.** The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- **31.** When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (**follow instructions in website <u>www.msd.gov.lk</u>**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website 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 condition No. 27 will not be applicable.

Common conditions

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

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

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

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

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the each item exceeds LKR 1 million. Bid Bond should be submitted with valid up to 02.05.2024 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/81/24 CLOSING ON : 05.10.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/R/D/00055

Item No.	SR No.	Item Specification	Quantity Disc	Delivery	Bid Bond Value (LKR)
1	2/40601103	Cefoperazone/sulbactam 75/30 mic.g	23,000	8,000-Jan/2024 8,000-May/2024 7,000-Oct/2024	N/A
2	3/40601301	Cefoxitin 30 mic.g	110,000	40,000-Jan/2024 40,000-May/2024 30,000-Oct/2024	N/A
3	4/40601501	Ceftriaxone 30 mic.g	60,000	20,000-Jan/2024 20,000-May/2024 20,000-Oct/2024	N/A
4	6/40601901	Ciprofloxacin 1 mic.g	35,000	12,000-Jan/2024 12,000-May/2024 11,000-Oct/2024	N/A
5	7/40602101	Clindamycin 2 mic.g	85,000	30,000-Jan/2024 30,000-May/2024 25,000-Oct/2024	N/A
6	8/40602502	Chloramphenicol 30 mic.g	44,000	15,000-Jan/2024 15,000-May/2024 14,000-Oct/2024	N/A
7	9/40602601	Cefuroxime 30 mic.g	200,000	50,000-Jan/2024 50,000-Mar/2024 50,000-Jun/2024 50,000-Sep/2024	35,600.00
8	10/40602701	Nalidixic acid 30 mic.g	93,000	33,000-Jan/2024 30,000-May/2024 30,000-Oct/2024	N/A
9	12/40603701	Piperacillin/ tazobactam 100/10 mic.g	45,000	45,000-Aug/2024	N/A
10	13/40603902	Penicillin 2 Units	11,000	4,000-Jan/2024 4,000-May/2024 3,000-Oct/2024	N/A
11	14/40604401	Imipenem 10 mic.g	92,000	25,000-Mar/2024 25,000-Jun/2024 25,000-Sep/2024 17,000-Jan/2025	N/A
12	16/40604702	Furazolidone 50 mic.g	1,500	1,500-Jun/2024	N/A
13	17/40604903	Mecillinam 10 mic.g	6,000	3,000-Jun/2024 3,000-Oct/2024	N/A

N/	30,000-Jun/2024 30,000-Oct/2024	60,000	Vancomycin 30 mic.g	18/40605101	14
N/	9,000-Apr/2024 9,000-Oct/2024	18,000	Nitrofurantoin 50 mic.g	19/40605201	15
20,130.0	35,000-Jan/2024 35,000-May/2024 34,000-Oct/2024	104,000	Nitrofurantoin 300 mic.g	20/40605303	16
N/	20,000-Jan/2024 20,000-May/2024 10,000-Oct/2024	50,000	Fusidic acid 10 mic.g	21/40605401	17
20,360.0	35,000-Jan/2024 35,000-May/2024 34,000-Oct/2024	104,000	Erythromycin 15 mic.g	23/40605602	18
N/	5,000-Jan/2024 5,000-May/2024 4,000-Oct/2024	14,000	Tetracycline 30 mic.g	24/40606102	19
N/	500-Jan/2024 500-May/2024	1,000	Ertapenem 10 mic.g	25/40606201	20
N/	12,000-Jun/2024 12,000-Oct/2024	24,000	Netilmicin 30 mic.g	27/40606502	21
31,900.0	60,000-Jan/2024 50,000-May/2024 50,000-Oct/2024	160,000	Norfloxacin 10 mic.g	28/40606601	22
N/	13,000-Jan/2024 13,000-May/2024 12,000-Oct/2024	38,000	Linezolid 30 mic.g	34/40608501	23
N/	15,000-Jun/2024	15,000	Ticarcillin /clavulanic acid 75/10 mic.g	35/40608601	24
N/	5,000-Jan/2024 5,000-Jun/2024	10,000	Levofloxacin 5 mic.g	36/40608701	25
44,055.0	75,000-Jan/2024 75,000-May/2024 75,000-Oct/2024	225,000	Amoxycillin/clavulanic acid 20/10 mic.g	37/40650101	26
N/	2,500-Jun/2024	2,500	Bacitracin 10 Units	38/40650201	27
N/	3,000-Jan/2024 3,000-May/2024 3,000-Oct/2024	9,000	Bacitracin 0.04 Unit	39/40650202	28
N/	5,000-Jan/2024 5,000-May/2024 5,000-Oct/2024	15,000	Furazolidone 100 mic.g	41/40650401	29
N/	9,000-Jan/2024 9,000-May/2024 8,000-Oct/2024	26,000	Optochin 5 mic.g	42/40650501	30

31	43/40655001	XV-factor	2,500	1,000-Jan/2024 1,000-May/2024 500-Oct/2024
32	44/40655101	X-factor	2,500	1,000-Jan/2024 1,000-May/2024 500-Oct/2024
33	45/40655201	V-factor	2,500	1,000-Jan/2024 1,000-May/2024 500-Oct/2024

Pack Size: 250 Discs

The offer should be valid till 180 days from closing of bid. (02.04.2024)

Amendment to the Bid Document

Page 9 condition No 19.b

Contract:

The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

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

A non refundable fee of Rs. 12,500.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

- (1) Clause 8
 - (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
 - (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) Clause 12

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) Clause 16.6

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) Clause 28.0

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in <u>www.spc.lk</u> Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX – 1	
			ANNE
BID NO/	BID REFERENCE :		
(TENDER	NO)		
DATE OF	ISSUE :		
CLOSING	G DATE & TIME :		
	KAN TIME)		
ORDER L	<u>IST NO :</u>		
		Quantity	Delivery Schedule
ORDER L SR No	IST NO : Item Description/ Specifications	Quantity	Delivery Schedule
		Quantity	Delivery Schedule
		Quantity	Delivery Schedule
		Quantity	Delivery Schedule
SR No Amount o	f Bid Bond : LKR or USD		
SR No	Item Description/ Specifications		

Bid Document Fee : (should be paid in cash to SPC for each set of Bid Documents)

MSD CONDITIONS OF SUPPLY

1.

2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) %Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka. Telephone (00)94-1-2335008 Fax: (00)94-11-2582495 E-mail: <u>dgmsurgical@spc.lk</u> or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No

Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at Mehewara Piyasa+, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the %PC+which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

 $\mathsf{M}/\mathsf{s}\,\,\tilde{\mathsf{o}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,\tilde{\mathsf{o}}\,\,$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be supplier+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART**.

AND

 $M/s \ \tilde{o} \ \tilde$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %be Local Agent+and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the THIRD PART.

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s $\tilde{0} \ \tilde{0} \ \tilde{0$

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents:
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called % be Contract Documents-) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and $\tilde{o} \ \tilde{o} \ \tilde{o$

$1. \quad \acute{1} \quad \acute{$

President/Managing Director/C.E.O.

2. í í í í í í í í í í í í í í í ... Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.
1. õõõõõõõõõõõõõ.	$\tilde{0} \ \tilde{0} \ $
$2. \ \ \tilde{o} \ o$	$\tilde{o}\ \tilde{o}\ \tilde$

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President/Managing Director/C.E.O.

 $\tilde{0} \ \tilde{0} \$

Director

<u>Witnesses</u>

Signature	Name, Address and ID No./Passport No.									
1. õõõõõõõõõõõõ.	$\tilde{0}$									
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CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

- 3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of
 - 3.1.1 Short packing
 - 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
 - 3.1.3 Packs which cannot be identified due to labels falling off.
 - 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.
- 3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

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Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature	Name, Address and ID No
1	
2	

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