ANNEX-1

BID NO. : DHS/L/WW/63/22 DATE OF ISSUE : 20TH JULY 2021

CLOSING DATE & TIME : 30TH AUGUST 2021 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 product/s offered in compliance with the tender specification.

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (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/Supplier'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).

15. Pack size, Labeling & Packaging

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 <u>or</u> when an exemption is notified in the special order conditions of the relevant MSD order list (**This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items**)

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

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

- **18.** Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and "STATE LOGO" of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
 - Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- **19.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- **20.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

Storage Conditions & Temperature

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

- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
 - C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
 - d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
 - e) The suppliers shall dispatch consignments of the items, which require 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 mentioned in the item list. Bid Bond should be submitted with valid up to 28.03.2022 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/63/22 CLOSING ON: 30.08.2021 at 9.00 a.m.

ORDER LIST NUMBER: 2022/SPC/N/R/D/00062

Item No.	SR No.	Item Specification	Quantity	Delivery	Bid Bond Value (LKR)		
1	43000601	Aluminium ammonium sulphate AR Packing: 500g	24,000 g	12,000-Jan/2022 12,000-Aug/2022	20,692.80		
2	43000902	Ammonia solution 35% AR Packing: 500ml	24,000 ml	12,000-Jan/2022 12,000-Aug/2022	53,760.00		
3	43001502	Barium Chloride AR Packing: 500g	8,000 g	4,000-Jan/2022 4,000-Aug/2022	N/A		
4	43002301	Chromic acid Packing: 100g	3,500 g	2,000-Jan/2022 1,500-Aug/2022	N/A		
5	43002501	Cupric sulphate Packing: 500g	180,000 g	180,000- Aug/2022	N/A		
6	43002701	D-glucose anhydrous Packing: 500g	26,000 g	13,000-Jan/2022 13,000-Aug/2022	N/A		
7	43003002	Di potassium hydrogen phosphate Packing: 100g	1,600 g	800-Jan/2022 800-Aug/2022	N/A		
8	43003204	EDTA tri potassium salt Packing: 500g	42,000 g	21,000-Jan/2022 21,000-Aug/2022	78,960.00		
9	43004001	Glycerol Packing: 1000ml	122,000 ml	61,000-Jun/2022 61,000-Oct/2022	N/A		
10	43004002	Glycerol AR Packing: 1000ml	370,000 ml	200,000- Apr/2022 170,000- Oct/2022	21,386.00		
11	43004201	Hydrochloric acid AR Packing: 1000ml	280,000 ml	140,000- Jun/2022 140,000- Oct/2022	N/A		
12	43004601	Iodine Packing: 100g	2,500 g	1,300-Jun/2022 1,200-Oct/2022	52,000.00		
13	43004801	Lithium carbonate AR Packing: 100g	1,200 g	700-Jan/2022 500-Aug/2022	N/A		

14	43005501	Nitric acid	57,000 ml	29,000-Apr/2022	N/A
		Packing: 500ml	,,,,,,,	28,000-Oct/2022	,
15	43005701	Oxalic acid AR	3,000 g	1,500-Jan/2022	N/A
		Packing: 100g		1,500-Aug/2022	
16	43005901	Phenol	296,000 ml	l '	N/A
		Packing: 500ml		Jan/2022	
				148,000- Aug/2022	
17	43005902	Phenol crystals	7,500 g	4,000-Jan/2022	N/A
		Packing: 250g		3,500-Aug/2022	·
18	43006202	Picric acid (2,4,6-trinitrophenol) AR	1,000 g	500-Jan/2022	N/A
		Packing: 100g		500-Aug/2022	
19	43006502	Potassium cyanide AR	2,500 g	1,500-Jan/2022	N/A
		Packing: 100g		1,000-Aug/2022	
20	43006701	Potassium ferricyanide AR	2,000 g	1,000-Jan/2022	N/A
		Packing: 1000g		1,000-Aug/2022	
21	43006901	Potassium dihydrogen orthophosphate	13,000 g	6,500-Jan/2022	N/A
		Packing: 250g		6,500-Aug/2022	
22	43007001	Potassium hydrogen phosphate AR	5,000 g	2,500-Jan/2022	N/A
		Packing: 250g		2,500-Aug/2022	
23	43007101	Potassium hydroxide pellets	2,800 g	1,400-Jan/2022	N/A
		Packing: 100g		1,400-Aug/2022	
24	43007102	Potassium hydroxide pellets AR	9,000 g	4,500-Jun/2022	N/A
		Packing: 500g		4,500-Oct/2022	
25	43007401	Potassium metabisulphite	2,500 g	1,500-Jan/2022	N/A
		Packing: 100g		1,000-Aug/2022	
26	43007801	Silver nitrate AR	2,000 g	1,000-Jun/2022	N/A
		Packing: 100g		1,000-Oct/2022	
27	43008102	Sodium bicarbonate AR	22,000 g	11,000-Apr/2022	N/A
		Packing: 500g		11,000-Aug/2022	
28	43008201	Sodium carbonate anhydrous AR	280,000 g	140,000-	N/A
		Packing: 1000g		Jan/2022 140,000-	
				Aug/2022	

29	43008302	Sodium chloride AR	480,000 g	240,000-	N/A
		Packing: 1000g		Jun/2022	
				240,000-	
				Oct/2022	
30	43008601	Sodium hydroxide pellets	16,000 g	8,000-Jan/2022	N/A
		Packing: 500g		8,000-Aug/2022	

The offer should be valid till 180 days from closing of bid. (26.02.2022)

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 19

19.1

(b) A Certified copy of NMRA Registration Certificate certified by Attorney-at-Law, Commissioner of Oaths of Justice of Peace should be submitted along with the bid

(5) 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 www.spc.lk Web Site)

(6) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(7) Annex – 1 to be amend as follows.

	SPECIMEN OF AN	NNEX – 1	
			<u>ANNEX – 1</u>
BID NO/ BI (TENDER N	ID REFERENCE : NO)		
DATE OF I	SSUE :		
CLOSING I	DATE & TIME : AN TIME)		
ORDER LIS	ST NO:		
SR No	Item Description/ Specifications	Quantity	Delivery Schedule
	Bid Bond : LKR or USD d valid till (date)	to	be submitted along with
Bid validity	period : Bid should be valid till	(date)	
	ent Fee : paid in cash to SPC for each set of Bid D	ocuments)	
MSD CON	DITIONS OF SUPPLY		
1. 2.			

 ${\bf Abbreviations: SPC: State\ Pharmaceuticals\ Corporation,\ MSD;\ Medical\ Supplies\ Division}$

28.1

v) The Corporation shall list out the bids which are conformed to the technical specifications as most responsive substantially responsive bids irrespective of prices they have offered as the lowest, second lowest, third lowest etc. to use in case of the lowest evaluated responsive bidder refuses to supply during the specified time frame. Please note that price quoted should be 10% range of the lowest bid. Instead of awarding 100% of quantities of respective items to be procured, the supply of quantities can be distributed among responsive bidders on a predetermined schedule Such as..

Name of the Bidder/	Rank as per the Price	Percentage of Supply of
Supplier	quoted	quantities
The lowest	1	60%
2 nd Lowest	2	30%
3 rd Lowest	3	10%

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957)

NO. 75, Sir Baron Jayatillake Mawatha, Colombo 01.Sri Lanka.

Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204

E-mail: dgmcomm@spc.lk or managerimp2spc.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 75, Sir Baron Jayatillaka Mawatha, Colombo 01, 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{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{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 $\tilde{0}$ $\tilde{0$

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} $\tilde{o$

The Common Seal of M/s (supplier) $\tilde{0}$ $\tilde{$

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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.

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ANNEX - 1

BID NO. : DHS/S/WW/97/22 DATE OF ISSUE : 20TH JULY 2021

CLOSING DATE & TIME : 03RD SEPTEMBER 2021 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering:

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka

- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. 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.
- 4. The volume of the total quantity of each item should be given in cubic meters (m³)
- 5. Foreign offers should be on C & F (CPT/CFR) 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.
- 6. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.
- 10. The offer should be valid up to 01.03.2022

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer is 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 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% 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 product/s offered in compliance with the tender specification.

Shelf life & Warrantees

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

The supplier 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 surgical consumable 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative charge of the same.
- 12. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

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

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

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

Pack size, Labeling & Packaging

- 15. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 16. In respect of bulk packs of all pharmaceuticals (not applicable for blister/strip packs),
 - · DHS mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules

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

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

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

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ·STATE LOGO, of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
 - Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- **19.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- **20.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

Storage Conditions & Temperature

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

23. Maintenance of Cold Chain;

- a.In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer 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 µbserved 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 charge.
- 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 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\same amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its¶amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)
 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for

If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the condition No. 27 will not be applicable.

Common conditions

36. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant

conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.

37. Administrative surcharge of 25% (on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 08,05,10,13)

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

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

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

- (i) -
- (ii)
- (iii) -

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 31.03.2022 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.
- In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the
 procuring of said order in any stage, if you would be placed the defaulted supplier's list due to
 quality failure found in your previous supplies made to SPC or non compliance of contractual
 agreement.
- This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- Where a purchase for a particular item is being made for the first time from a supplier, or where there are
 previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing
 the quality and standards of the goods and comparing the bulk supply with the samples provided along with
 the offer.
- Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name and designation of the signatory) or by the representative. Representatives submit offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka.
- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- All Shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely shipment of cargo. In which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.

BID NO: DHS/S/WW/97/22 CLOSING ON: 03.09.2021 at 9.00 a.m.

ORDER LIST NUMBER: 2022/SPC/N/R/S/00254

Item No	SR No	Item	Qty Nos.	Delivery	Bid Bond Value (LKR)
1	14104600	Extension Tube for IV lines, transparent, nonkinkable, 10cm length, with stopcock, male/female luer lock fitting, prime volume less than 1.5ml, sterile.	70,000	35,000- Jan/2022 35,000- Jun/2022	84,378.00
2	14104701	Extension Tube with Red line for arterial Pressure Monitoring, transparent, rigid, 150cm (approx.) length, male/female luer lock fitting, prime volume 2ml, sterile.	31,745	15,737- Jan/2022 16,008- May/2022	60,220.00
3	14104901	White Stopper/Bung, luer lock & luer slip adaptability, with male/female fittings, made of polyethylene, sterile.	14,250	7,125- Jan/2022 7,125- Apr/2022	N/A
4	14104903	Needle Free Stopper, sterile, Medical grade PVC, easy to puncture, latex free, tight-fitting adapter, transparent, with no edges or	8,700	4,350- Jan/2022 4,350-	N/A

	corners, luer connector.	Apr/2022	

Packing: 1 Nos.

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

Page 10 Condition No. 20. a
 Representative samples in respect of items offered should be submitted to reach SPC on or before the closing time on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

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.

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

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

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	19
-----	--------	----

19.1

(b) A Certified copy of NMRA Registration Certificate certified by Attorney-at-Law, Commissioner of Oaths of Justice of Peace should be submitted along with the bid

(5) 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 www.spc.lk Web Site)

(6) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(7) Annex -1 to be amend as follows.

SPECIMEN OF ANNEX - 1

ANNEX - 1

BID NO/ BID REFERENCE:

(TENDER NO)

DATE OF ISSUE :

CLOSING DATE & TIME:

(SRI LANKAN TIME)

ORDER LIST NO:

SR No	Item Description/ Specifications	Quantity	Delivery Schedule

Amount of Bid Bond: LKR or USD to be submitted along with the Bid Bond valid till (date)
Bid validity period : Bid should be valid till (date)
Bid Document Fee :

MSD CONDITIONS OF SUPPLY

1.

2.

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

28.1

v) The Corporation shall list out the bids which are conformed to the technical specifications as most responsive substantially responsive bids irrespective of prices they have offered as the lowest, second lowest, third lowest etc. to use in case of the lowest evaluated responsive bidder refuses to supply during the specified time frame. Please note that price quoted should be 10% range of the lowest bid. Instead of awarding 100% of quantities of respective items to be procured, the supply of quantities can be distributed among responsive bidders on a predetermined schedule Such as..

Name o	of	the	Bidder/	Rank	as	per	the	Price	Percentage	of	Supply	of
Supplier				quoted					quantities			
The lowest				1					60%			
2 nd Lowes	t				2				30%			
3rd Lowest	t				3				10%			

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957)
NO. 75, Sir Baron Jayatillake Mawatha, Colombo 01.Sri Lanka.
Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204
E-mail: dgmcomm@spc.lk or managerimp2spc.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 75, Sir Baron Jayatillaka Mawatha, Colombo 01, 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{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

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

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %the 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 $\tilde{0}$ $\tilde{0$

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

President/Managing Director/C.E.O.

Director

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.

n of Sri Lanka was affixed)							
0 0							
ature Name, Address and ID No							
	. ■						
	ddress and ID No						

ANNEX - 1

BID NO. : DHS/S/WW/96/22 DATE OF ISSUE : 20TH JULY 2021

CLOSING DATE & TIME : 03RD SEPTEMBER 2021 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering:

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka

- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. 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.
- 4. The volume of the total quantity of each item should be given in cubic meters (m³)
- 5. Foreign offers should be on C & F (CPT/CFR) 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.
- 6. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.
- 10. The offer should be valid up to 01.03.2022

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer is 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 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% 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 product/s offered in compliance with the tender specification.

Shelf life & Warrantees

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

The supplier 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 surgical consumable 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative charge of the same.
- 12. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

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

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

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

Pack size, Labeling & Packaging

- 15. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 16. In respect of bulk packs of all pharmaceuticals (not applicable for blister/strip packs),
 - · DHS mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules

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

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

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

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ·STATE LOGO, of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
 - Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- **19.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- **20.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

Storage Conditions & Temperature

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

23. Maintenance of Cold Chain;

- a.In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer 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 µbserved 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 charge.
- 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 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\same amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its¶amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)
 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for

If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the condition No. 27 will not be applicable.

Common conditions

36. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant

conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.

37. Administrative surcharge of 25% (on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 08,05,10,13)

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

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

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

- (i) -
- (ii)
- (iii) -

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 31.03.2022 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.
- In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the
 procuring of said order in any stage, if you would be placed the defaulted supplier's list due to
 quality failure found in your previous supplies made to SPC or non compliance of contractual
 agreement.
- This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- Where a purchase for a particular item is being made for the first time from a supplier, or where there are
 previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing
 the quality and standards of the goods and comparing the bulk supply with the samples provided along with
 the offer.
- Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name and designation of the signatory) or by the representative. Representatives submit offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka.
- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- All Shipment should be made exclusively on vessels belonging to the Ceylon Shipping
 Corporation or those chartered by CSC. Shipments on other vessels will be permitted in
 instances where vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment
 or if they are not available for timely shipment of cargo. In which event the supplier should
 attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in
 the supplier's country.

BID NO: DHS/S/WW/96/22 CLOSING ON: 03.09.2021 at 9.00 a.m.

ORDER LIST NUMBER: 2022/SPC/N/R/S/00064

Item No	SR No	Item	Qty	Delivery	Bid Bond Value (LKR)
1	14501801	Semipermiable water proof and transparent hypoallergenic adhesive film dressing, without pad, size (5cm -6cm) x 7cm Note: shelf life of the product should be minimum of 24 months Packing: 1 Nos.	16,000 Nos.	16,000- Jul/2022	26,240.00

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

Page 10 Condition No. 20. a
 Representative samples in respect of items offered should be submitted to reach SPC on or
 before the closing time on the closing date of tender and acknowledgement receipt to be
 obtained from Administration Department of SPC.

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.

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

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

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	e 19
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19.1

(b) A Certified copy of NMRA Registration Certificate certified by Attorney-at-Law, Commissioner of Oaths of Justice of Peace should be submitted along with the bid

(5) 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 www.spc.lk Web Site)

(6) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(7) Annex -1 to be amend as follows.

SPECIMEN OF ANNEX - 1

ANNEX – 1

BID NO/ BID REFERENCE:

(TENDER NO)

DATE OF ISSUE :

CLOSING DATE & TIME :

(SRI LANKAN TIME)

ORDER LIST NO:

SR No	Item Description/ Specifications	Quantity	Delivery Schedule

Amount of Bid Bond: LKR	or USD	to be submitted alor	ng with the
Bid Bond valid till	(date)		

Bid validity period : Bid should be valid till (date)
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

28.1

v) The Corporation shall list out the bids which are conformed to the technical specifications as most responsive substantially responsive bids irrespective of prices they have offered as the lowest, second lowest, third lowest etc. to use in case of the lowest evaluated responsive bidder refuses to supply during the specified time frame. Please note that price quoted should be 10% range of the lowest bid. Instead of awarding 100% of quantities of respective items to be procured, the supply of quantities can be distributed among responsive bidders on a predetermined schedule Such as..

Name of the	Bidder/	Rank	as	per	the	Price	Percentage	of	Supply	of
Supplier		quotec	l				quantities			
The lowest			1				60%			
2 nd Lowest			2				30%			
3 rd Lowest			3				10%			

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957)
NO. 75, Sir Baron Jayatillake Mawatha, Colombo 01.Sri Lanka.
Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204
E-mail: dgmcomm@spc.lk or managerimp2spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA AGREEMENT

SPC Ref. No Bid Ref. Date:

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 75, Sir Baron Jayatillaka Mawatha, Colombo 01, 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{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

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

...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{o} $\tilde{o$

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

1.	••	••			••	••	••	••	••	••	••	••		••	
Pres	sid	en	t/N	I ai	nag	gin	ıg]	Di	rec	to	r/C	c.E	O.		
2.	••													••	
	D	ire	cto	or											

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/o	ا lsapproval ا	will be notifie	d within 7 v	work-
ing days	of receipt	of same	in writing.	Parties ho	wever shall	endeavours	to remove	any
obstacles	to perform	ance (whe	en possible)	and co-ope	erate to remo	ove the harm	ful effects a	as far
as praction	cable.							

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 Pharmaceutica	als Corporation of Sri Lanka was affixed)
$ \tilde{0} \ \tilde{0} \$	$ \tilde{0} \ \tilde{0} \$.) .)
Authorized signatory		
Authorized signatory		
<u>Witnesses</u>		
Signature	Name, Address and ID No	
1		
2		

LM/ns

ANNEX - 1

BID NO. : DHS/S/WW/95/22 DATE OF ISSUE : 20TH JULY 2021

CLOSING DATE & TIME : 03RD SEPTEMBER 2021 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering:

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka

- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. 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.
- 4. The volume of the total quantity of each item should be given in cubic meters (m³)
- 5. Foreign offers should be on C & F (CPT/CFR) 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.
- 6. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.
- 10. The offer should be valid up to 01.03.2022

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer is 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 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% 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 product/s offered in compliance with the tender specification.

Shelf life & Warrantees

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

The supplier 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 surgical consumable 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative charge of the same.
- 12. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

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

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

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

Pack size, Labeling & Packaging

- 15. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 16. In respect of bulk packs of all pharmaceuticals (not applicable for blister/strip packs),
 - · DHS mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules

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

- **17.** Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Product Reference/Catalogue No.s of Surgical items), Date of Manufacture, Date of Expiry (of consumables only) and · STATE LOGO, of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (not applicable for Surgical Nonconsumables) & date of Manufacture (in any form as \cdot Year & Month, or \cdot No Exp.,), in the innermost pack and supplier invoice.
- **18.** Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ·STATE LOGO, of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
 - Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- **19.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- **20.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

Storage Conditions & Temperature

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

23. Maintenance of Cold Chain;

- a.In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer 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 µbserved 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 charge.
- 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 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\\$ overstepping delivery schedules in the Indent/PO/its\\$ amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its¶amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

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

Common conditions

36. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant

conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.

37. Administrative surcharge of 25% (on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 08,05,10,13)

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

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

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

- (i) -
- (ii)
- (iii) -

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 31.03.2022 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.
- In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the
 procuring of said order in any stage, if you would be placed the defaulted supplier's list due to
 quality failure found in your previous supplies made to SPC or non compliance of contractual
 agreement.
- This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- Where a purchase for a particular item is being made for the first time from a supplier, or where there are
 previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing
 the quality and standards of the goods and comparing the bulk supply with the samples provided along with
 the offer.
- Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name and designation of the signatory) or by the representative. Representatives submit offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka.
- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- All Shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely shipment of cargo. In which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.

BID NO: DHS/S/WW/95/22 CLOSING ON: 03.09.2021 at 9.00 a.m.

ORDER LIST NUMBER: 2022/SPC/N/R/S/00064

Item No	SR No	Item	Qty Nos.	Delivery	Bid Bond Value (LKR)
1	14500302	Open Woven Bandage 2.5cm Open Woven Bandage BP(1988), Type 2 (White Open Woven Bandage) Width: 2.5 cm Length: 5m in Roll OR Ceylon standard 172: 1999 Type 2 (for bandage cloth) Note: Shelf life of the product should be minimum of 24 months. Marks & Nos: 1.Name of manufacturer, Item Description, Batch No., SR No., State Mark, Details of manufacture and Date of expiry(Year to be marked in four digits) should be stated on individual/inner/outer pack	90,000	25,000- Jan/2022 25,000- Apr/2022 25,000- Jul/2022 15,000- Aug/2022	22,464.00

2.MSD Order No. and S	PC indent No. should		
be stated on inner/oute	r pack		

Packing: 1 Roll

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

1. Page 10 Condition No. 20. a

Representative samples in respect of items offered should be submitted to reach SPC on or before the closing time on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

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.

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

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

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	19
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19.1

(b) A Certified copy of NMRA Registration Certificate certified by Attorney-at-Law, Commissioner of Oaths of Justice of Peace should be submitted along with the bid

(5) 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 www.spc.lk Web Site)

(6) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(7) Annex – 1 to be amend as follows.

SPECIMEN OF ANNEX - 1

ANNEX - 1

BID NO/ BID REFERENCE:

(TENDER NO)

DATE OF ISSUE :

CLOSING DATE & TIME:

(SRI LANKAN TIME)

ORDER LIST NO:

SR No	Item Description/ Specifications	Quantity	Delivery Schedule

Amount of Bid Bond: LKR or USD to be submitted along with the Bid Bond valid till (date)
Bid validity period : Bid should be valid till (date)
Bid Document Fee :

MSD CONDITIONS OF SUPPLY

1.

2.

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

28.1

v) The Corporation shall list out the bids which are conformed to the technical specifications as most responsive substantially responsive bids irrespective of prices they have offered as the lowest, second lowest, third lowest etc. to use in case of the lowest evaluated responsive bidder refuses to supply during the specified time frame. Please note that price quoted should be 10% range of the lowest bid. Instead of awarding 100% of quantities of respective items to be procured, the supply of quantities can be distributed among responsive bidders on a predetermined schedule Such as..

Name of	the	Bidder/	Rank	as	per	the	Price	Percentage	of	Supply	of
Supplier			quoted			quantities					
The lowest			1			60%					
2 nd Lowest	et 2				30%						
3rd Lowest	3 rd Lowest		3			10%					

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957)
NO. 75, Sir Baron Jayatillake Mawatha, Colombo 01.Sri Lanka.
Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204
E-mail: dgmcomm@spc.lk or managerimp2spc.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 75, Sir Baron Jayatillaka Mawatha, Colombo 01, 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{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

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

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %the 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 $\tilde{0}$ $\tilde{0$

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

President/Managing Director/C.E.O.

Director

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	S Corporation of Sri Lanka was affixed)
$\tilde{\mathtt{o}}$	$ \tilde{0} \ \tilde{0} \$
Authorized signatory	
Authorized signatory	
Witnesses	
Signature	Name, Address and ID No
1	
2	

<u> ANNEX – 1</u>

BID NO. : DHS/S/WW/94/22 DATE OF ISSUE : 20TH JULY 2021

CLOSING DATE & TIME : 03RD SEPTEMBER 2021 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering:

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka

- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. 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.
- 4. The volume of the total quantity of each item should be given in cubic meters (m³)
- 5. Foreign offers should be on C & F (CPT/CFR) 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.
- 6. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.
- 10. The offer should be valid up to 01.03.2022

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

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

- 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 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% 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 product/s offered in compliance with the tender specification.

Shelf life & Warrantees

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

The supplier 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 surgical consumable 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative charge of the same.
- 12. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

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

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

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

Pack size, Labeling & Packaging

- 15. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 16. In respect of bulk packs of all pharmaceuticals (not applicable for blister/strip packs),
 - · DHS mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules

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

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

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

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ·STATE LOGO, of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
 - Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- **19.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- **20.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

Storage Conditions & Temperature

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

23. Maintenance of Cold Chain;

- a.In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer 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 µbserved 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 charge.
- 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 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\same amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its¶amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)
 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for

If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the condition No. 27 will not be applicable.

Common conditions

36. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant

conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.

37. Administrative surcharge of 25% (on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 08,05,10,13)

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

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

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

- (i) -
- (ii)
- (iii) -

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 31.03.2022 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.
- In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the
 procuring of said order in any stage, if you would be placed the defaulted supplier's list due to
 quality failure found in your previous supplies made to SPC or non compliance of contractual
 agreement.
- This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- Where a purchase for a particular item is being made for the first time from a supplier, or where there are
 previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing
 the quality and standards of the goods and comparing the bulk supply with the samples provided along with
 the offer.
- Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name and designation of the signatory) or by the representative. Representatives submit offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka.
- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- All Shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely shipment of cargo. In which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.

BID NO: DHS/S/WW/94/22 CLOSING ON: 03.09.2021 at 9.00 a.m.

ORDER LIST NUMBER: 2022/SPC/N/R/S/00064

Item No	SR No	Item	Qty Nos.	Delivery	Bid Bond Value (LKR)
1	14501101	Plaster of Paris Bandage B) (1988) (P.O.P. Bandage) Width: 7.5cm Length: 2.7m Roll Note: Shelf life of the product should be minimum of 24 months. Packing: Individually packed in moisture proof polythene wrappers and inserted into air tight tins Marks & Nos: 1.Name of manufacturer, Item Description, Batch No., SR No., State Mark, Details of manufacture and Date of expiry (Year to be marked in four digits) should be stated on individual/inner/outer pack	80,000	40,000- Apr/2022 40,000- Aug/2022	158,448.00

2.MSD Order No. and SPC indent No. should		
be stated on inner/outer pack		

Packing: 1 Roll

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

1. Page 10 Condition No. 20. a

Representative samples in respect of items offered should be submitted to reach SPC on or before the closing time on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

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.

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

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

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 19
-----	-----------

19.1

(b) A Certified copy of NMRA Registration Certificate certified by Attorney-at-Law, Commissioner of Oaths of Justice of Peace should be submitted along with the bid

(5) 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 www.spc.lk Web Site)

(6) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(7) Annex -1 to be amend as follows.

SPECIMEN OF ANNEX - 1

ANNEX - 1

BID NO/BID REFERENCE:

(TENDER NO)

DATE OF ISSUE :

CLOSING DATE & TIME:

(SRI LANKAN TIME)

ORDER LIST NO:

SR No	Item Description/ Specifications	Quantity	Delivery Schedule

Amount of Bid Bond : LKR or USD to be submitted along with the Bid Bond valid till (date)
Bid validity period : Bid should be valid till (date)
Bid Document Fee :

MSD CONDITIONS OF SUPPLY

1.

2.

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

28.1

v) The Corporation shall list out the bids which are conformed to the technical specifications as most responsive substantially responsive bids irrespective of prices they have offered as the lowest, second lowest, third lowest etc. to use in case of the lowest evaluated responsive bidder refuses to supply during the specified time frame. Please note that price quoted should be 10% range of the lowest bid. Instead of awarding 100% of quantities of respective items to be procured, the supply of quantities can be distributed among responsive bidders on a predetermined schedule Such as..

Name o	of	the	Bidder/	Rank	as	per	the	Price	Percentage	of	Supply	of
Supplier				quoted	i				quantities			
The lowes	t				1				60%			
2 nd Lowes	t				2				30%			
3rd Lowest	:				3				10%			

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957)
NO. 75, Sir Baron Jayatillake Mawatha, Colombo 01.Sri Lanka.
Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204
E-mail: dgmcomm@spc.lk or managerimp2spc.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 75, Sir Baron Jayatillaka Mawatha, Colombo 01, 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{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{o}\$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %the 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 $\tilde{0}$ $\tilde{0$

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

President/Managing Director/C.E.O.

Director

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.

	•
$ \tilde{0} \ \tilde{0} \$	$ \tilde{0} \; \tilde{0} \;$
Authorized signatory	
Authorized signatory	
<u>Witnesses</u>	
Signature	Name, Address and ID No
1	
2	

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

ANNEX - 1

BID NO. : DHS/S/WW/93/22 DATE OF ISSUE : 20TH JULY 2021

CLOSING DATE & TIME : 03RD SEPTEMBER 2021 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering:

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka

- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. 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.
- 4. The volume of the total quantity of each item should be given in cubic meters (m³)
- 5. Foreign offers should be on C & F (CPT/CFR) 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.
- 6. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.
- 10. The offer should be valid up to 01.03.2022

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer is 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 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% 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 product/s offered in compliance with the tender specification.

Shelf life & Warrantees

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

The supplier 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 surgical consumable 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative charge of the same.
- 12. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

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

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

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

Pack size, Labeling & Packaging

- 15. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 16. In respect of bulk packs of all pharmaceuticals (not applicable for blister/strip packs),
 - · DHS mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules

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

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

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

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ·STATE LOGO, of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
 - Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- **19.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- **20.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

Storage Conditions & Temperature

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

23. Maintenance of Cold Chain;

- a.In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer 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 µbserved 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 charge.
- 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 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\same amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its¶amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)
 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for

If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the condition No. 27 will not be applicable.

Common conditions

36. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant

conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.

37. Administrative surcharge of 25% (on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 08,05,10,13)

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

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

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

- (i) -
- (ii)
- (iii) -

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 31.03.2022 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.
- In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the
 procuring of said order in any stage, if you would be placed the defaulted supplier's list due to
 quality failure found in your previous supplies made to SPC or non compliance of contractual
 agreement.
- This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- Where a purchase for a particular item is being made for the first time from a supplier, or where there are
 previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing
 the quality and standards of the goods and comparing the bulk supply with the samples provided along with
 the offer.
- Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name and designation of the signatory) or by the representative. Representatives submit offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka.
- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- All Shipment should be made exclusively on vessels belonging to the Ceylon Shipping
 Corporation or those chartered by CSC. Shipments on other vessels will be permitted in
 instances where vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment
 or if they are not available for timely shipment of cargo. In which event the supplier should
 attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in
 the supplier's country.

BID NO: DHS/S/WW/93/22 CLOSING ON: 03.09.2021 at 9.00 a.m.

ORDER LIST NUMBER: 2022/SPC/N/R/S/00064

Item	SR No	Item	Qty	Delivery	Bid Bond
No			Tins		Value (LKR)
1	14501201	Paraffin Gauze Dressing BP (1993) (Sterile) Size: Width; 10cm Length; 10cm Note: Shelf life of the product should be minimum of 24 months. Packing: 30, sterile pieces to be packed in a sealed tin. Marks & Nos: 1.Name of manufacturer, Item Description, Batch No., SR No., State Mark, Details of manufacture and Date of expiry(Year to be marked in four digits) should be stated on individual lippor (outer pack)	50,000	25,000-Apr/2022 25,000-Aug/2022	71,760.00
		individual/inner/outer pack 2.MSD Order No. and SPC indent No. should			

be sta	ted on inner/outer pack		

Packing: 1Tin

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

Page 10 Condition No. 20. a
 Representative samples in respect of items offered should be submitted to reach SPC on or
 before the closing time on the closing date of tender and acknowledgement receipt to be
 obtained from Administration Department of SPC.

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.

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

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

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 19

19.1

(b) A Certified copy of NMRA Registration Certificate certified by Attorney-at-Law, Commissioner of Oaths of Justice of Peace should be submitted along with the bid

(5) 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 www.spc.lk Web Site)

(6) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(7) Annex -1 to be amend as follows.

SPECIMEN OF ANNEX - 1

ANNEX - 1

BID NO/BID REFERENCE:

(TENDER NO)

DATE OF ISSUE :

CLOSING DATE & TIME:

(SRI LANKAN TIME)

ORDER LIST NO:

SR No	Item Description/ Specifications	Quantity	Delivery Schedule

Amount of Bid Bond: LKR or USD to be submitted along with the Bid Bond valid till (date)
Bid validity period : Bid should be valid till (date)
Bid Document Fee :

MSD CONDITIONS OF SUPPLY

1.

2.

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

28.1

v) The Corporation shall list out the bids which are conformed to the technical specifications as most responsive substantially responsive bids irrespective of prices they have offered as the lowest, second lowest, third lowest etc. to use in case of the lowest evaluated responsive bidder refuses to supply during the specified time frame. Please note that price quoted should be 10% range of the lowest bid. Instead of awarding 100% of quantities of respective items to be procured, the supply of quantities can be distributed among responsive bidders on a predetermined schedule Such as..

Name	of	the	Bidder/	Rank	as	per	the	Price	Percentage	of	Supply	of	
Supplier				quoted				quantities					
The lowe	est				1				60%				
2 nd Lowest			2			30%							
3 rd Lowest			3			10%							

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957)
NO. 75, Sir Baron Jayatillake Mawatha, Colombo 01.Sri Lanka.
Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204
E-mail: dgmcomm@spc.lk or managerimp2spc.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 75, Sir Baron Jayatillaka Mawatha, Colombo 01, 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{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

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

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %the 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{o} $\tilde{o$

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 % De 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 $\tilde{0}$ $\tilde{0$

President/Managing Director/C.E.O.

Director

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 S	tate Pharmaceutical	als Corporation of Sri Lanka was affixed)	
0 0	\tilde{O}	$ \tilde{0} \ \tilde{0} \$	
Authorized signatory			
Authorized signatory			
<u>Witnesses</u>			
Signature		Name, Address and ID No	
1			••
2			

HK/ns

ANNEX - 1

BID NO. : DHS/S/WW/92/22 DATE OF ISSUE : 20TH JULY 2021

CLOSING DATE & TIME : 03RD SEPTEMBER 2021 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering:

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka

- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. 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.
- 4. The volume of the total quantity of each item should be given in cubic meters (m³)
- 5. Foreign offers should be on C & F (CPT/CFR) 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.
- 6. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.
- 10. The offer should be valid up to 01.03.2022

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer is 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 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% 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 product/s offered in compliance with the tender specification.

Shelf life & Warrantees

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

The supplier 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 surgical consumable 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative charge of the same.
- 12. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

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

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

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

Pack size, Labeling & Packaging

- 15. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 16. In respect of bulk packs of all pharmaceuticals (not applicable for blister/strip packs),
 - · DHS mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules

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

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

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

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ·STATE LOGO, of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
 - Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- **19.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- **20.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

Storage Conditions & Temperature

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

23. Maintenance of Cold Chain;

- a.In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer 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 µbserved 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 charge.
- 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 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\same amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its¶amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)
 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for

If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the condition No. 27 will not be applicable.

Common conditions

36. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant

conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.

37. Administrative surcharge of 25% (on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 08,05,10,13)

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

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

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

- (i) -
- (ii)
- (iii) -

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 31.03.2022 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.
- In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the
 procuring of said order in any stage, if you would be placed the defaulted supplier's list due to
 quality failure found in your previous supplies made to SPC or non compliance of contractual
 agreement.
- This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- Where a purchase for a particular item is being made for the first time from a supplier, or where there are
 previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing
 the quality and standards of the goods and comparing the bulk supply with the samples provided along with
 the offer.
- Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name and designation of the signatory) or by the representative. Representatives submit offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka.
- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- All Shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely shipment of cargo. In which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.

BID NO: DHS/S/WW/92/22 CLOSING ON: 03.09.2021 at 9.00 a.m.

ORDER LIST NUMBER: 2022/SPC/N/R/S/00064

Item No	SR No	Item	Qty Pies	Delivery	Bid Bond Value (LKR)
1	14501301	Absorbable Gelatine Sponge BP/USP Size: 2cm x 6cm x 7mm Packing: 10 sponges in a Hermetically sealed tin. Note: Shelf life of the product should be minimum of 24 months. Marks & Nos: 1.Name of manufacturer, Item Description, Batch No., SR No., State Mark, Details of manufacture and Date of expiry (Year to be marked in four digits) should be stated on individual/inner/outer pack 2.MSD Order No. and SPC indent No. should be stated on inner/outer pack	4,600	4,600-Jun/2022	N/A

9							
2	14501302	Absorbable Gelatine Sponge BP/USP Size: 8cm x 12.5cm x 10mm Note: Shelf life of the product should be minimum of 24 months. Packing: 10 sponges in a Hermetically sealed tin (as per the sample) Marks & Nos: 1.Name of manufacturer, Item Description, Batch No., SR No., State Mark, Details of manufacture and Date of expiry (Year to be marked in four digits) should be stated on individual/inner/outer pack 2.MSD Order No. and SPC indent No. should be stated on inner/outer pack	19,000	10,000-Jan/2022 9,000-Aug/2022	139,806.00		
3	14501303	Absorbable Gelatine Sponge BP/USP Size: 5cm x 3cm x 10mm Note: Shelf life of the product should be minimum of 24 months. Packing: 10 sponges in a Hermetically sealed tin (as per the sample) Marks & Nos: 1.Name of manufacturer, Item Description, Batch No., SR No., State Mark, Details of manufacture and Date of expiry (Year to be marked in four digits) should be stated on individual/inner/outer pack 2.MSD Order No. and SPC indent No. should be stated on inner/outer pack	5,000	2,500-Jun/2022 2,500-Oct/2022	28,151.00		
4	14501304	Absorbable Gelatine Sponge BP/USP Size 7cm x 5cm x 10mm Note: Shelf life of the product should be minimum of 24 months. Packing: 10 sponges in a Hermetically seaaled tin (as per the sample) Marks & Nos: 1.Name of manufacturer, Item Description, Batch No., SR No., State Mark, Details of manufacture and Date of expiry (Year to be marked in four digits) should be stated on individual/inner/outer pack 2.MSD Order No. and SPC indent No. should be stated on inner/outer pack	8,000	4,000-Apr/2022 4,000-Aug/2022	39,910.00		

Packing: 1Piece

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

Page 10 Condition No. 20. a
 Representative samples in respect of items offered should be submitted to reach SPC on or
 before the closing time on the closing date of tender and acknowledgement receipt to be
 obtained from Administration Department of SPC.

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.

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

A non refundable fee of Rs. 12,500/= + taxes should be paid in cash to SPC for each set of Tender Documents

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	19
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19.1

(b) A Certified copy of NMRA Registration Certificate certified by Attorney-at-Law, Commissioner of Oaths of Justice of Peace should be submitted along with the bid

(5) 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 www.spc.lk Web Site)

(6) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(7) Annex – 1 to be amend as follows.

SPECIMEN OF ANNEX - 1

ANNEX - 1

BID NO/BID REFERENCE:

(TENDER NO)

DATE OF ISSUE :

CLOSING DATE & TIME:

(SRI LANKAN TIME)

ORDER LIST NO:

SR No	Item Description/ Specifications	Quantity	Delivery Schedule

Amount of Bid Bond: LKR or USD to be submitted along with the Bid Bond valid till (date)
Bid validity period : Bid should be valid till (date)
Bid Document Fee :

MSD CONDITIONS OF SUPPLY

1.

2.

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

28.1

v) The Corporation shall list out the bids which are conformed to the technical specifications as most responsive substantially responsive bids irrespective of prices they have offered as the lowest, second lowest, third lowest etc. to use in case of the lowest evaluated responsive bidder refuses to supply during the specified time frame. Please note that price quoted should be 10% range of the lowest bid. Instead of awarding 100% of quantities of respective items to be procured, the supply of quantities can be distributed among responsive bidders on a predetermined schedule Such as..

Name o	of	the	Bidder/	Rank	as	per	the	Price	Percentage	of	Supply	of		
Supplier				quoted				quantities						
The lowes	t				1				60%					
2 nd Lowes	t				2				30%					
3 rd Lowest			3					10%						

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957)
NO. 75, Sir Baron Jayatillake Mawatha, Colombo 01.Sri Lanka.
Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204
E-mail: dgmcomm@spc.lk or managerimp2spc.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 75, Sir Baron Jayatillaka Mawatha, Colombo 01, 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

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

...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

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

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %the 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 $\tilde{0}$ $\tilde{0$

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 % De 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 $\tilde{0}$ $\tilde{0$

The Common Seal of M/s (supplier)õõõõõõõõõõõõõõõõõõõõõõ... herein.

President/Managing Director/C.E.O.

Director

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 sear of State P	narmaceuticais	s Corporation of Sri Lanka was affixed)	
	$ \tilde{0} \tilde{0} \tilde{0} \tilde{0} \tilde{0} \tilde{0} $ $ \tilde{0} \tilde{0} \tilde{0} \tilde{0} \tilde{0} \tilde{0} $	Õ Õ Õ Õ Õ Õ Õ Õ Õ Õ Õ Õ Õ Õ Õ Õ Õ Õ Õ	
Authorized signatory			
Authorized signatory			
<u>Witnesses</u>			
Signature		Name, Address and ID No	
1			
2			

HK/ns

ANNEX - 1

BID NO. : DHS/S/WW/91/22 DATE OF ISSUE : 20TH JULY 2021

CLOSING DATE & TIME : 03RD SEPTEMBER 2021 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering:

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka

- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. 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.
- 4. The volume of the total quantity of each item should be given in cubic meters (m³)
- 5. Foreign offers should be on C & F (CPT/CFR) 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.
- 6. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.
- 10. The offer should be valid up to 01.03.2022

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

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

- 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 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% 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 product/s offered in compliance with the tender specification.

Shelf life & Warrantees

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

The supplier 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 surgical consumable 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative charge of the same.
- 12. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

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

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

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

Pack size, Labeling & Packaging

- 15. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 16. In respect of bulk packs of all pharmaceuticals (not applicable for blister/strip packs),
 - · DHS mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules

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

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

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

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ·STATE LOGO, of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
 - Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- **19.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- **20.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

Storage Conditions & Temperature

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

23. Maintenance of Cold Chain;

- a.In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer 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 µbserved 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 charge.
- 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 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\same amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its¶amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)
 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for

If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the condition No. 27 will not be applicable.

Common conditions

36. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant

conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.

37. Administrative surcharge of 25% (on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 08,05,10,13)

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

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

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

- (i) -
- (ii)
- (iii) -

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 31.03.2022 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.
- In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the
 procuring of said order in any stage, if you would be placed the defaulted supplier's list due to
 quality failure found in your previous supplies made to SPC or non compliance of contractual
 agreement.
- This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- Where a purchase for a particular item is being made for the first time from a supplier, or where there are
 previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing
 the quality and standards of the goods and comparing the bulk supply with the samples provided along with
 the offer.
- Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name and designation of the signatory) or by the representative. Representatives submit offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka.
- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- All Shipment should be made exclusively on vessels belonging to the Ceylon Shipping
 Corporation or those chartered by CSC. Shipments on other vessels will be permitted in
 instances where vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment
 or if they are not available for timely shipment of cargo. In which event the supplier should
 attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in
 the supplier's country.

BID NO: DHS/S/WW/91/22 CLOSING ON: 03.09.2021 at 9.00 a.m.

ORDER LIST NUMBER: 2022/SPC/N/R/S/00064

Item No	SR No	Item	Qty Nos.	Delivery	Bid Bond Value (LKR)
1	14501701	Transparent dressing for catheter fixation (6cm-6.5cm) x7cm Moisture responsive transparent dressing for IV catheter fixation with a film coating on all pieces to provide barrier to external contaminants with an incision on an edge to fit the catheter. Size: (6cm – 6.5cm) x 7cm (Approximately)	96,000	50,000- Mar/2022 46,000- Aug/2022	153,600.00
		Note: Shelf life of the product should be minimum of 24 months.			

Packing: 1 Nos.

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

Page 10 Condition No. 20. a
 Representative samples in respect of items offered should be submitted to reach SPC on or
 before the closing time on the closing date of tender and acknowledgement receipt to be
 obtained from Administration Department of SPC.

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.

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

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

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) Claus	e 19
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19.1

(b) A Certified copy of NMRA Registration Certificate certified by Attorney-at-Law, Commissioner of Oaths of Justice of Peace should be submitted along with the bid

(5) 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 www.spc.lk Web Site)

(6) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(7) Annex -1 to be amend as follows.

SPECIMEN OF ANNEX – 1

ANNEX - 1

BID NO/ BID REFERENCE:

(TENDER NO)

DATE OF ISSUE :

CLOSING DATE & TIME :

(SRI LANKAN TIME)

ORDER LIST NO:

SR No	Item Description/ Specifications	Quantity	Delivery Schedule

Amount of Bid Bond: LKR	or USD	to be submitted	along with the
Bid Bond valid till (date)			

Bid validity period : Bid should be valid till (date)
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

28.1

v) The Corporation shall list out the bids which are conformed to the technical specifications as most responsive substantially responsive bids irrespective of prices they have offered as the lowest, second lowest, third lowest etc. to use in case of the lowest evaluated responsive bidder refuses to supply during the specified time frame. Please note that price quoted should be 10% range of the lowest bid. Instead of awarding 100% of quantities of respective items to be procured, the supply of quantities can be distributed among responsive bidders on a predetermined schedule Such as..

Name	of	the	Bidder/	Rank	as	per	the	Price	Percentage	of	Supply	of		
Supplier					1				quantities					
The lowest					1				60%					
2 nd Lowest					2				30%					
3rd Lowe	3					10%								

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957)
NO. 75, Sir Baron Jayatillake Mawatha, Colombo 01.Sri Lanka.
Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204
E-mail: dgmcomm@spc.lk or managerimp2spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA AGREEMENT

SPC Ref. No Bid Ref. Date:

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 75, Sir Baron Jayatillaka Mawatha, Colombo 01, 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{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

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

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %he 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 $\tilde{0}$ $\tilde{0$

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

The Common Seal of M/s (supplier)õõõõõõõõõõõõõõõõõõõõõõõ... herein.

1.	••	••			••	••	••	••	••	••	••	••		••	
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2.	••													••	
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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.	Approv	al/disappı	roval v	vill be ı	notified v	within 7	work-
ing days	of receipt	of same	in writing.	Parties	however	shall	endeav	vours to	remov	e any
obstacles	to performa	ance (whe	n possible)	and co-	operate to	o remo	ove the	harmful	effects	as far
as practic	able.									

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.

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ANNEX - 1

BID NO. : DHS/S/WW/90/22 DATE OF ISSUE : 20TH JULY 2021

CLOSING DATE & TIME : 31ST AUGUST 2021 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering:

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka

- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. 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.
- 4. The volume of the total quantity of each item should be given in cubic meters (m³)
- 5. Foreign offers should be on C & F (CPT/CFR) 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.
- 6. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.
- 10. The offer should be valid up to 26.02.2022

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer is 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 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% 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 product/s offered in compliance with the tender specification.

Shelf life & Warrantees

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

The supplier 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 surgical consumable 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative charge of the same.
- 12. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

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

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

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

Pack size, Labeling & Packaging

- 15. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 16. In respect of bulk packs of all pharmaceuticals (not applicable for blister/strip packs),
 - · DHS mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules

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

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

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

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ·STATE LOGO, of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
 - Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- **19.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- **20.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

Storage Conditions & Temperature

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

23. Maintenance of Cold Chain;

- a.In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer 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 µbserved 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 charge.
- 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 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\same amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its¶amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)
 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for

If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the condition No. 27 will not be applicable.

Common conditions

36. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant

conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.

37. Administrative surcharge of 25% (on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 08,05,10,13)

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

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

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

- (i) Evaluators need to have a freehand to select quality product based on the clinical applications and not necessarily consider the cheaper product.
- (ii) For large volume tenders consider several quality products rather than award for only one supplier due to supply constraints and possible non supply leading to out of stocks for longer period.
- (iii) 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 07 to 10 working days by the supplier at SPC (DHL) ware house for small volume tenders, without 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] x 0.25) or 2% of the invoiced value, whichever is the highest and implement recovery as mentioned for high volume tenders.
- (iv) Based on clinical application 1:1 needle suture ratio to be considered at evaluation for fine sutures.
- (v) For all suture material in item group 100 (SR No. start from 100) required in polyglactin 910 suture material.

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 28.03.2022 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.
- In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the
 procuring of said order in any stage, if you would be placed the defaulted supplier's list due to
 quality failure found in your previous supplies made to SPC or non compliance of contractual
 agreement.
- This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- Where a purchase for a particular item is being made for the first time from a supplier, or where there are previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing

the quality and standards of the goods and along with the offer.

comparing the bulk supply with the samples provided

- Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name and designation of the signatory) or by the representative. Representatives submit offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka.
- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- All Shipment should be made exclusively on vessels belonging to the Ceylon Shipping
 Corporation or those chartered by CSC. Shipments on other vessels will be permitted in
 instances where vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment
 or if they are not available for timely shipment of cargo. In which event the supplier should
 attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in
 the supplier's country.

BID NO: DHS/S/WW/90/22 CLOSING ON: 31.08.2021 at 9.00 a.m.

ORDER LIST NUMBER: 2022/SPC/N/R/S/00166

Item No	SR No	Item	Qty Nos.	Delivery	Bid Bond Value (LKR)
1	10000402	Absorbable Synthetic Surgical Suture for Ophthalmic use, of polyglycolic acid / polyglactin, Braided, Coated, BP/USP Standard or Equivalent standard, size 8/0, 30cm (approx.) length, each end attached to a 6mm 3/8 circle micro point Spatulated eyeless needle (double arm), sterile.	7,000	2,000- Jan/2022 2,000- Apr/2022 3,000- Jun/2022	98,379.00
2	10000403	Absorbable Synthetic Surgical Suture for Ophthalmic use, of polyglycolic acid / polyglactin, Braided, Coated, BP/USP Standard or Equivalent standard, size 6/0, 45cm (approx.) length, each end attached to a 8mm 3/8 circle spatulated eyeless needle (double arm), sterile.	2,600	1,300- Jan/2022 1,300- Apr/2022	35,540.00
3	10400101	Non Absorbable Monofilament Surgical Suture	14000	4,000-	254,444.00

Polyamide 66 (Nylon) BP/USP Standard or Equivalent Standard, size 10/0, blue/black, 30cm (approx.) length, each end attached to a 6mm 3/8 circle micro point spatulated eyeless needle (double arm), sterile.	Jan/2022 5,000- Apr/2022 5,000- Jul/2022	
eyeless needle (double arm), sterile.	Jul/2022	

Packing: 1 Nos.

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

Page 10 Condition No. 20. a
 Representative samples in respect of items offered should be submitted to reach SPC on or
 before the closing time on the closing date of tender and acknowledgement receipt to be
 obtained from Administration Department of SPC.

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.

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

A non refundable fee of Rs. 12,500/= + taxes should be paid in cash to SPC for each set of Tender Documents

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 19

19.1

(b) A Certified copy of NMRA Registration Certificate certified by Attorney-at-Law, Commissioner of Oaths of Justice of Peace should be submitted along with the bid

(5) 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 www.spc.lk Web Site)

(6) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(7) Annex -1 to be amend as follows.

SPECIMEN OF ANNEX - 1

ANNEX-1

BID NO/BID REFERENCE:

(TENDER NO)

DATE OF ISSUE :

CLOSING DATE & TIME:

(SRI LANKAN TIME)

ORDER LIST NO:

SR No	Item Description/ Specifications	Quantity	Delivery Schedule

Amount of Bid Bond : LKR or USD to be su Bid Bond valid till (date)	ıbmitted along with the
Bid validity period : Bid should be valid till (date)	
Bid Document Fee :	

MSD CONDITIONS OF SUPPLY

1.

2.

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

28.1

v) The Corporation shall list out the bids which are conformed to the technical specifications as most responsive substantially responsive bids irrespective of prices they have offered as the lowest, second lowest, third lowest etc. to use in case of the lowest evaluated responsive bidder refuses to supply during the specified time frame. Please note that price quoted should be 10% range of the lowest bid. Instead of awarding 100% of quantities of respective items to be procured, the supply of quantities can be distributed among responsive bidders on a predetermined schedule Such as..

Name	of	the	Bidder/	Rank	as	per	the	Price	Percentage	of	Supply	of		
Supplier	Supplier quoted							quantities						
The lowe	est				1				60%					
2 nd Lowe	st				2				30%					
3 rd Lowest				3					10%					

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957)
NO. 75, Sir Baron Jayatillake Mawatha, Colombo 01.Sri Lanka.
Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204
E-mail: dgmcomm@spc.lk or managerimp2spc.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 75, Sir Baron Jayatillaka Mawatha, Colombo 01, 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

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

...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{o}\$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %the 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 $\tilde{0}$ $\tilde{0$

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

President/Managing Director/C.E.O.

Director

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.

	s Corporation of Sri Lanka was affixed)	
$\tilde{\mathtt{o}}\ \tilde{\mathtt{o}}\ \tilde$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	
Authorized signatory		
Authorized signatory		
<u>Witnesses</u>		
Signature I	Name, Address and ID No	
1		
2		•••

ANNEX - 1

BID NO. : DHS/S/WW/89/22 DATE OF ISSUE : 20TH JULY 2021

CLOSING DATE & TIME : 31ST AUGUST 2021 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering:

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka

- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. 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.
- 4. The volume of the total quantity of each item should be given in cubic meters (m³)
- 5. Foreign offers should be on C & F (CPT/CFR) 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.
- 6. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.
- 10. The offer should be valid up to 26.02.2022

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer is 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 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% 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 product/s offered in compliance with the tender specification.

Shelf life & Warrantees

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

The supplier 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 surgical consumable 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative charge of the same.
- 12. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

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

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

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

Pack size, Labeling & Packaging

- 15. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 16. In respect of bulk packs of all pharmaceuticals (not applicable for blister/strip packs),
 - · DHS mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules

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

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

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

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ·STATE LOGO, of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
 - Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- **19.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- **20.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

Storage Conditions & Temperature

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

23. Maintenance of Cold Chain;

- a.In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer 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 µbserved 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 charge.
- 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 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\same amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its¶amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)
 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for

If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the condition No. 27 will not be applicable.

Common conditions

36. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant

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

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

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

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

- (i) Evaluators need to have a freehand to select quality product based on the clinical applications and not necessarily consider the cheaper product.
- (ii) For large volume tenders consider several quality products rather than award for only one supplier due to supply constraints and possible non supply leading to out of stocks for longer period.
- (iii) 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 07 to 10 working days by the supplier at SPC (DHL) ware house for small volume tenders, without 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] x 0.25) or 2% of the invoiced value, whichever is the highest and implement recovery as mentioned for high volume tenders.

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 28.03.2022 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.
- In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- Where a purchase for a particular item is being made for the first time from a supplier, or where there are
 previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing
 the quality and standards of the goods and comparing the bulk supply with the samples provided along with
 the offer.

- Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name and designation of the signatory) or by the representative. Representatives submit offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka.
- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- All Shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely shipment of cargo. In which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.

BID NO: DHS/S/WW/89/22 CLOSING ON: 31.08.2021 at 9.00 a.m.

ORDER LIST NUMBER: 2022/SPC/N/R/S/00200

Item No	SR No	Item	Qty Nos.	Delivery	Bid Bond Value (LKR)
1	10801700	Non absorbable Surgical Suture for Sternal Closure, monofilamant stainless steel wire, USP standard or equivalent standard, size 5, 45cm (approx.) length, attached to a 44mm - 48mm half circle conventional cutting needle, 4 Nos straight strands together, sterile.	3,000	1,000- Jan/2022 2,000- Apr/2022	39,338.00
2	10801800	Non absorbable Surgical Suture for Sternal Closure, monofilamant stainless steel wire, USP standard or equivalent standard, size 6, 45cm (approx.) length, attached to a 44mm - 48mm half circle conventional cutting needle, 4 Nos straight strands together, sterile.	4,800	2,000- Jan/2022 2,800- Apr/2022	62,940.00
3	10801801	Non absorbable Surgical Suture for Sternal Closure, monofilamant stainless steel wire, USP standard or equivalent standard, size 6, 45cm (approx.) length, attached to a 44mm -	660	360- Jan/2022 300-	29,780.00

48mm half circle round bodied taper cut	Apr/2022	
heavy needle, 4 Nos straight strands		
together, sterile.		

Packing: 1 Nos.

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

Page 10 Condition No. 20. a
 Representative samples in respect of items offered should be submitted to reach SPC on or
 before the closing time on the closing date of tender and acknowledgement receipt to be
 obtained from Administration Department of SPC.

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.

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

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

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 19
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19.1

(b) A Certified copy of NMRA Registration Certificate certified by Attorney-at-Law, Commissioner of Oaths of Justice of Peace should be submitted along with the bid

(5) 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 www.spc.lk Web Site)

(6) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(7) Annex -1 to be amend as follows.

SPECIMEN OF ANNEX - 1

ANNEX - 1

BID NO/BID REFERENCE:

(TENDER NO)

DATE OF ISSUE :

CLOSING DATE & TIME:

(SRI LANKAN TIME)

ORDER LIST NO:

SR No	Item Description/ Specifications	Quantity	Delivery Schedule

Amount of Bid Bond : LKR or USD to be submitted along with the Bid Bond valid till (date)
Bid validity period : Bid should be valid till (date)
Bid Document Fee :

MSD CONDITIONS OF SUPPLY

1.

2.

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

28.1

v) The Corporation shall list out the bids which are conformed to the technical specifications as most responsive substantially responsive bids irrespective of prices they have offered as the lowest, second lowest, third lowest etc. to use in case of the lowest evaluated responsive bidder refuses to supply during the specified time frame. Please note that price quoted should be 10% range of the lowest bid. Instead of awarding 100% of quantities of respective items to be procured, the supply of quantities can be distributed among responsive bidders on a predetermined schedule Such as..

Name o	of	the	Bidder/	Rank	as	per	the	Price	Percentage	of	Supply	of
Supplier				quoted	i				quantities			
The lowes	t				1				60%			
2 nd Lowes	t			2		30%						
3rd Lowest	:			3			10%					

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957)
NO. 75, Sir Baron Jayatillake Mawatha, Colombo 01.Sri Lanka.
Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204
E-mail: dgmcomm@spc.lk or managerimp2spc.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 75, Sir Baron Jayatillaka Mawatha, Colombo 01, 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{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{o}\$

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %the 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 $\tilde{0}$ $\tilde{0$

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

President/Managing Director/C.E.O.

Director

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.

	s Corporation of Sri Lanka was affixed)	
$\tilde{\mathtt{o}}\ \tilde{\mathtt{o}}\ \tilde$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	
Authorized signatory		
Authorized signatory		
<u>Witnesses</u>		
Signature I	Name, Address and ID No	
1		
2		•••

ANNEX - 1

BID NO. : DHS/S/WW/88/22 DATE OF ISSUE : 20TH JULY 2021

CLOSING DATE & TIME : 31ST AUGUST 2021 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering:

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka

- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. 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.
- 4. The volume of the total quantity of each item should be given in cubic meters (m³)
- 5. Foreign offers should be on C & F (CPT/CFR) 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.
- 6. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.
- 10. The offer should be valid up to 26.02.2022

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer is 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 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% 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 product/s offered in compliance with the tender specification.

Shelf life & Warrantees

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

The supplier 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 surgical consumable 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative charge of the same.
- 12. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

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

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

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

Pack size, Labeling & Packaging

- 15. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 16. In respect of bulk packs of all pharmaceuticals (not applicable for blister/strip packs),
 - · DHS mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules

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

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

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

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ·STATE LOGO, of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
 - Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- **19.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- **20.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

Storage Conditions & Temperature

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

23. Maintenance of Cold Chain;

- a.In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer 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 µbserved 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 charge.
- 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 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\same amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its¶amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)
 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for

If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the condition No. 27 will not be applicable.

Common conditions

36. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant

conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.

37. Administrative surcharge of 25% (on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 08,05,10,13)

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

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

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

- (i) -
- (ii) ·
- (iii) -

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 28.03.2022 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.
- In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the
 procuring of said order in any stage, if you would be placed the defaulted supplier's list due to
 quality failure found in your previous supplies made to SPC or non compliance of contractual
 agreement.
- This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- Where a purchase for a particular item is being made for the first time from a supplier, or where there are
 previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing
 the quality and standards of the goods and comparing the bulk supply with the samples provided along with
 the offer.
- Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name and designation of the signatory) or by the representative. Representatives submit offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka.
- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- All Shipment should be made exclusively on vessels belonging to the Ceylon Shipping
 Corporation or those chartered by CSC. Shipments on other vessels will be permitted in
 instances where vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment
 or if they are not available for timely shipment of cargo. In which event the supplier should
 attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in
 the supplier's country.

BID NO: DHS/S/WW/88/22 CLOSING ON: 31.08.2021 at 9.00 a.m.

ORDER LIST NUMBER: 2022/SPC/N/R/S/00064

Item No	SR No	Item	Qty Nos.	Delivery	Bid Bond Value (LKR)
1	14560003	Ophthalmic Surgical Drape with pouch size 50cm x 40cm, Sterile. Note: Shelf life of the product should be minimum of 24 months.	150,000	50,000-Jan/2022 50,000-May/2022 50,000-Sep/2022	909,840.00
2	14560004	Ophthalmic Surgical Drape with pouch size (40cm - 50cm) x 60cm, Sterile. Note: Shelf life of the product should be minimum of 24 months.	73,000	40,000-Apr/2022 33,000-Aug/2022	1,187,097.00
3	14560002	Ophthalmic Surgical Drape (10cm - 12cm) x (12cm - 15cm), Sterile. Note:	55,000	30,000-Jan/2022 25,000-Jun/2022	155,584.00

	Shelf life of the product should be minimum		
	of 24 months.		

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

Page 10 Condition No. 20. a
 Representative samples in respect of items offered should be submitted to reach SPC on or before the closing time on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

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.

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

A non refundable fee of Rs. 35,000/= + taxes should be paid in cash to SPC for each set of Tender Documents

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	19
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19.1

(b) A Certified copy of NMRA Registration Certificate certified by Attorney-at-Law, Commissioner of Oaths of Justice of Peace should be submitted along with the bid

(5) 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 www.spc.lk Web Site)

(6) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(7) Annex – 1 to be amend as follows.

SPECIMEN OF ANNEX - 1

ANNEX - 1

BID NO/ BID REFERENCE:

(TENDER NO)

DATE OF ISSUE :

CLOSING DATE & TIME:

(SRI LANKAN TIME)

ORDER LIST NO:

SR No	Item Description/ Specifications	Quantity	Delivery Schedule

Amount of Bid Bond: LKR or USD to be submitted along with the Bid Bond valid till (date)
Bid validity period : Bid should be valid till (date)
Bid Document Fee :

MSD CONDITIONS OF SUPPLY

1.

2.

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

28.1

v) The Corporation shall list out the bids which are conformed to the technical specifications as most responsive substantially responsive bids irrespective of prices they have offered as the lowest, second lowest, third lowest etc. to use in case of the lowest evaluated responsive bidder refuses to supply during the specified time frame. Please note that price quoted should be 10% range of the lowest bid. Instead of awarding 100% of quantities of respective items to be procured, the supply of quantities can be distributed among responsive bidders on a predetermined schedule Such as..

Name of	the	Bidder/	Rank	as	per	the	Price	Percentage	of	Supply	of
Supplier			quoted					quantities			
The lowest		1				60%					
2 nd Lowest			2			30%					
3rd Lowest				3				10%			

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957)
NO. 75, Sir Baron Jayatillake Mawatha, Colombo 01.Sri Lanka.
Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204
E-mail: dgmcomm@spc.lk or managerimp2spc.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 75, Sir Baron Jayatillaka Mawatha, Colombo 01, 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{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

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

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %the 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 $\tilde{0}$ $\tilde{0$

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

The Common Seal of M/s (supplier)õõõõõõõõõõõõõõõõõõõõõõ... herein.

President/Managing Director/C.E.O.

Director

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 Pharmaceutica	als Corporation of Sri Lanka was affixed	
$ \tilde{0} \ \tilde{0} \$	$ \tilde{0} \; \tilde{0} \;$	
Authorized signatory		
Authorized signatory		
<u>Witnesses</u>		
Signature	Name, Address and ID No	
1		
2		•

ANNEX - 1

BID NO. : DHS/S/WW/87/22 DATE OF ISSUE : 20TH JULY 2021

CLOSING DATE & TIME : 31ST AUGUST 2021 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering:

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka

- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. 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.
- 4. The volume of the total quantity of each item should be given in cubic meters (m³)
- 5. Foreign offers should be on C & F (CPT/CFR) 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.
- 6. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.
- 10. The offer should be valid up to 26.02.2022

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

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

- 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 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% 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 product/s offered in compliance with the tender specification.

Shelf life & Warrantees

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

The supplier 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 surgical consumable 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative charge of the same.
- 12. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

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

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

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

Pack size, Labeling & Packaging

- 15. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 16. In respect of bulk packs of all pharmaceuticals (not applicable for blister/strip packs),
 - · DHS mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules

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

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

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

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ·STATE LOGO, of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
 - Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- **19.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- **20.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

Storage Conditions & Temperature

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

23. Maintenance of Cold Chain;

- a.In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer 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 µbserved 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 charge.
- 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 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\same amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its¶amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)
 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for

If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the condition No. 27 will not be applicable.

Common conditions

36. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant

conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.

37. Administrative surcharge of 25% (on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 08,05,10,13)

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

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

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

(i) -(ii) -(iii) -

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 28.03.2022 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.
- In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the
 procuring of said order in any stage, if you would be placed the defaulted supplier's list due to
 quality failure found in your previous supplies made to SPC or non compliance of contractual
 agreement.
- This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- Where a purchase for a particular item is being made for the first time from a supplier, or where there are previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.
- Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name and designation of the signatory) or by the representative. Representatives submit offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka.
- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- All Shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely shipment of cargo. In which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.

BID NO: DHS/S/WW/87/22 CLOSING ON: 31.08.2021 at 9.00 a.m.

ORDER LIST NUMBER: 2022/SPC/N/R/S/00252

Item No	SR No	Item	Qty	Delivery	Bid Bond Value (LKR)
1	14102401	Extension Tube for use with syringe pump, universal type, 200cm (approx.) length, male/ female connectors, maximum vol 2ml, non Kinkable, transparent tubing, luer lock fitting, sterile. Packing: 1 Nos.	300,000 Nos.	150,000- Jan/2022 150,000- Apr/2022	391,080.00
2	14103001	Pressure Monitoring Kit - Double Dome, Hp Intellivue Monitors compatible, comprising; Giving Set, High Pressure Monitoring Lines, Transducer Domes, Flushing Devices, Three way Stopcocks & Pressure tubes. Giving Set - Suitable for pressure monitoring, Flush device - Flush rate > 1ml/s and continuous flush rate 3ml/hr at 300mmHg, Disposable Transducer with; Accurate pressure transmission, Adapts to interface cable with plug connection, Chip technology for accurate registration of values, Pre calibrated sensor with	2,900 Nos.	1,450- Jan/2022 1,450- Mar/2022	185,988.00

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		constant electrical parameters (Sensitivity, linearity, Zero stability),Straight fluid channel for air bubble free filing with Three way stopcock (Red) arterial, (Blue) venous, Pressure tube 200 cm, Internal diameter 1.5 x2.7mm,Pressure Tube 10cm, Internal diameter1.5cm x 2.7mm. Red (Arterial), Blue(venous) lined, with colour coded (Blue & red) closed loop blood sampling kit with needleless sampling ports (blue & red colour coded) sterile. Four Accessory Sets should be provided free of charge for each 50 Monitoring Kits. Each Accessory Set comprising; One quadruple attachment plate, Attachment plate holder, and one connecting cable, 3 meter length, reusable. Packing: 1 Nos.			
3	14103401	Pressure Monitoring Kit Paediatric - Single Dome (Arterial), Nihon Kohden Monitors compatible, comprising; Giving Set, High Pressure Monitoring Lines, Transducer Dome, Flushing Device, Three way Stopcock & Pressure tubes. Giving Set - Suitable for pressure monitoring, Flush device - Flush rate > 1ml/s and continuous flush rate 1ml/hr at 300mmHg, Disposable Transducer with; Accurate pressure transmission, Adapts to interface cable with plug connection, Chip technology for accurate registration of values, Pre calibrated sensor with constant electrical parameters (Sensitivity, linearity, Zero stability), Straight fluid channel for air bubble free filing with Three way stopcock (Red) arterial, Pressure tube 200cm, Internal diameter 1.5 x2.7mm, Pressure Tube 10cm, Internal diameter1.5cm x 2.7mm. Red (Arterial), lined, with colour coded (red) closed loop blood sampling kit with needleless sampling ports (red colour coded) sterile. Two Accessory Set should be provided free of charge for each 50 Monitoring Kits. Each Accessory Set comprising; One quadruple attachment plate, Attachment plate holder, and One connecting cable, 3 meter length, reusable. Packing: 1 kit	700 kits	350- Jan/2022 350- Apr/2022	27,760.00
4	14103402	Pressure Monitoring Kit Paediatric - Single Dome (Venous), Nihon Kohden Monitors compatible, comprising; Giving Set, High Pressure Monitoring Lines, Transducer Dome, Flushing Device, Three way Stopcock & Pressure tubes. Giving Set - Suitable for pressure monitoring, Flush device - Flush rate > 1ml/s and continuous flush rate 1ml/hr at 300mmHg, Disposable Transducer with; Accurate pressure transmission, Adapts to interface cable with plug connection, Chip technology for accurate registration of values, Pre calibrated sensor with constant electrical	1,000 kits	500- Jan/2022 500- May/2022	39,658.00

		parameters (Sensitivity, linearity, Zero stability),			
		Straight fluid channel for air bubble free filing with Three way stopcock (Blue) venous, Pressure tube 200cm, Internal diameter 1.5 x2.7mm, Pressure Tube 10cm, Internal diameter1.5cm x 2.7mm. Blue (Venous), lined, with colour coded (Blue) closed loop blood sampling kit with needleless sampling ports (blue colour coded) sterile. Two Accessory Set should be provided free of charge for each 50 Monitoring Kits. Each Accessory Set comprising; One quadruple attachment plate, Attachment plate holder, and One connecting cable, 3 meter length, reusable. Packing: 1 kit			
5	14103403	Pressure Monitoring Kit - Single Dome (Arterial), Nihon Kohden Monitors compatible, comprising; Giving Set, High Pressure Monitoring Lines, Transducer Dome, Flushing Device, Three way Stopcock & Pressure tubes. Giving Set - Suitable for pressure monitoring, Flush device - Flush rate > 1ml/s and continuous flush rate 3ml/hr at 300mmHg, Disposable Transducer with; Accurate pressure transmission, Adapts to interface cable with plug connection, Chip technology for accurate registration of values, Pre calibrated sensor with constant electrical parameters (Sensitivity, linearity, Zero stability), Straight fluid channel for air bubble free filing with Three way stopcock (Red) arterial, Pressure tube 200cm, Internal diameter 1.5 x2.7mm, Pressure Tube 10cm, Internal diameter1.5cm x 2.7mm. Red (Arterial), lined, with colour coded (red) closed loop blood sampling kit with needleless sampling ports (red colour coded)sterile. Two Accessory Set should be provided free of charge for each 50 Monitoring Kits. Each Accessory Set comprising; One quadruple attachment plate, Attachment plate holder, and One connecting cable, 3 meter length, reusable. Packing: 1 Nos.	4,000 Nos.	2,000- Jan/2022 2,000- Jun/2022	160,565.00
6	14103404	Pressure Monitoring Kit - Single Dome (Venous), Nihon Kohden Monitors compatible, comprising; Giving Set, High Pressure Monitoring Lines, Transducer Dome, Flushing Device, Three way Stopcock & Pressure tubes. Giving Set - Suitable for pressure monitoring, Flush device - Flush rate > 1ml/s and continuous flush rate 3ml/hr at 300mmHg, Disposable Transducer with; Accurate pressure transmission, Adapts to interface cable with plug connection, Chip technology for accurate registration of values, Pre calibrated sensor with constant electrical parameters (Sensitivity, linearity, Zero stability), Straight fluid channel for air bubble free filing with Three way stopcock (Blue) venous, Pressure tube	4,000 Nos.	2,000- Jan/2022 2,000- Jun/2022	270,400.00

		11	T	T	
		200cm, Internal diameter 1.5 x2.7mm, Pressure Tube 10cm, Internal diameter1.5cm x 2.7mm. Blue (Venous), lined, with colour coded (Blue) closed loop blood sampling kit with needleless sampling ports (blue colour coded) sterile. Two Accessory Set should be provided free of charge for each 50 Monitoring Kits. Each Accessory Set comprising; One quadruple attachment plate, Attachment plate holder, and One connecting cable, 3 meter length, reusable. Packing: 1 Nos.			
7	14103801	Pressure Monitoring Kit Paediatric - Single Dome (Arterial), Mindray Monitors compatible, comprising; Giving Set, High Pressure Monitoring Lines, Transducer Dome, Flushing Device, Three way Stopcock & Pressure tubes. Giving Set - Suitable for pressure monitoring, Flush device - Flush rate > 1ml/s and continuous flush rate 1ml/hr at 300mmHg, Disposable Transducer with; Accurate pressure transmission, Adapts to interface cable with plug connection, Chip technology for accurate registration of values, Pre calibrated sensor with constant electrical parameters (Sensitivity, linearity, Zero stability), Straight fluid channel for air bubble free filing with Three way stopcock (Red) arterial, Pressure tube 200cm, Internal diameter 1.5 x2.7mm, Pressure Tube 10cm, Internal diameter1.5cm x 2.7mm. Red (Arterial), lined, with colour coded (red) closed loop blood sampling kit with needleless sampling ports (red colour coded) sterile. Two Accessory Set should be provided free of charge for each 50 Monitoring Kits. Each Accessory Set comprising; One quadruple attachment plate, Attachment plate holder, and One connecting cable, 3 meter length, reusable. Packing: 1 kit	1,200 kits	600- Jan/2022 600- May/2022	66,000.00
8	14103802	Pressure Monitoring Kit Paediatric - Single Dome (Venous), Mindray Monitors compatible, comprising; Giving Set, High Pressure Monitoring Lines, Transducer Dome, Flushing Device, Three way Stopcock & Pressure tubes. Giving Set - Suitable for pressure monitoring, Flush device - Flush rate > 1ml/s and continuous flush rate 1ml/hr at 300mmHg, Disposable Transducer with; Accurate pressure transmission, Adapts to interface cable with plug connection, Chip technology for accurate registration of values, Pre calibrated sensor with constant electrical parameters (Sensitivity, linearity, Zero stability), Straight fluid channel for air bubble free filing with Three way stopcock (Blue) venous, Pressure tube 200cm, Internal diameter 1.5 x2.7mm, Pressure Tube 10cm, Internal diameter1.5cm x 2.7mm. Blue (Venous), lined, with colour coded (Blue)	900 kits	450- Jan/2022 450- May/2022	49,500.00

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		closed loop blood sampling kit with needleless sampling ports (blue colour coded) sterile. Two Accessory Set should be provided free of charge for each 50 Monitoring Kits. Each Accessory Set comprising; One quadruple attachment plate, Attachment plate holder, and One connecting cable, 3 meter length, reusable. Packing: 1 kit			
9	14103803	Pressure Monitoring Kit - Single Dome (Arterial), Mindray Monitors compatible, comprising; Giving Set, High Pressure Monitoring Lines, Transducer Dome, Flushing Device, Three way Stopcock & Pressure tubes. Giving Set – Suitable for pressure monitoring, Flush device - Flush rate > 1ml/s and continuous flush rate 3ml/hr at 300mmHg, Disposable Transducer with; Accurate pressure transmission, Adapts to interface cable with plug connection, Chip technology for accurate registration of values, Pre calibrated sensor with constant electrical parameters (Sensitivity, linearity, Zero stability), Straight fluid channel for air bubble free filing with Three way stopcock (Red) arterial, Pressure tube 200cm, Internal diameter 1.5 x2.7mm, Pressure Tube 10cm, Internal diameter1.5cm x 2.7mm. Red (Arterial), lined, with colour coded (red) closed loop blood sampling kit with needleless sampling ports (red-colour coded)sterile. Two Accessory Set should be provided free of charge for each 50 Monitoring Kits. Each Accessory Set comprising; One quadruple attachment plate, Attachment plate holder, and One connecting cable, 3 meter length, reusable. Packing: 1 Nos.	6,000 Nos.	3,000- Jan/2022 3,000- Jun/2022	230,113.00
10	14103901	Pressure Monitoring Kit Paediatric - Double Dome, Mindray Monitors compatible, comprising; Giving Set, High Pressure Monitoring Lines, Transducer Domes, Flushing Devices, Three way Stopcocks & Pressure tubes. Giving Set - Suitable for pressure monitoring, Flush device - Flush rate > 1ml/s and continuous flush rate 1ml/hr at 300mmHg, Disposable Transducer with; Accurate pressure transmission, Adapts to interface cable with plug connection, Chip technology for accurate registration of values, Pre calibrated sensor with constant electrical parameters (Sensitivity, linearity, Zero stability), Straight fluid channel for air bubble free filing with Three way stopcock (Red) arterial, (Blue) venous, Pressure tube 200cm, Internal diameter 1.5 x2.7mm, Pressure Tube 10cm, Internal diameter1.5cm x 2.7mm. Red (Arterial), Blue (venous) lined, with colour coded (Blue & red) closed loop blood sampling kit with needleless sampling ports (blue & red colour coded)sterile.Four Accessory Sets	800 kits	400- Jan/2022 400- Jun/2022	84,000.00

		13	T		
		should be provided free of charge for each 50 Monitoring Kits. Each Accessory Set comprising; One quadruple attachment plate, Attachment plate holder, and one connecting cable, 3 meter length, reusable. Packing: 1 kit			
11	14103902	Pressure Monitoring Kit - Double Dome, Mindray Monitors compatible, comprising; Giving Set, High Pressure Monitoring Lines, Transducer Domes, Flushing Devices, Three way Stopcocks & Pressure tubes. Giving Set - Suitable for pressure monitoring, Flush device - Flush rate > 1ml/s and continuous flush rate 3ml/hr at 300mmHg, Disposable Transducer with; Accurate pressure transmission, Adapts to interface cable with plug connection, Chip technology for accurate registration of values, Pre calibrated sensor with constant electrical parameters (Sensitivity, linearity, Zero stability), Straight fluid channel for air bubble free filing with Three way stopcock (Red) arterial, (Blue) venous, Pressure tube 200cm, Internal diameter 1.5 x2.7mm, Pressure Tube 10cm, Internal diameter1.5cm x 2.7mm. Red (Arterial), Blue (venous) lined, with colour coded (Blue & red) closed loop blood sampling kit with needleless sampling ports (blue & red colour coded)sterile. Four Accessory Sets should be provided free of charge for each 50 Monitoring Kits. Each Accessory Set comprising; One quadruple attachment plate, Attachment plate holder, and one connecting cable, 3 meter length, reusable. Packing: 1 Nos.	6,200 Nos.	3,100- Jan/2022 3,100- Apr/2022	398,804.00

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

Page 10 Condition No. 20. a
 Representative samples in respect of items offered should be submitted to reach SPC on or
 before the closing time on the closing date of tender and acknowledgement receipt to be
 obtained from Administration Department of SPC.

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.

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

A non refundable fee of Rs. 20,000/= + taxes should be paid in cash to SPC for each set of Tender Documents

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 19

19.1

(b) A Certified copy of NMRA Registration Certificate certified by Attorney-at-Law, Commissioner of Oaths of Justice of Peace should be submitted along with the bid

(5) 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 www.spc.lk Web Site)

(6) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(7) Annex – 1 to be amend as follows.

2.

	SPECIMEN OF	ANNEX – 1		
			AN	NEX -
	BID REFERENCE :			
(TENDER	NO)			
DATE OF	ISSUE :			
CLOSING	DATE & TIME :			
(SRI LAN	KAN TIME)			
OPDED	ICT NO .			
ORDER L	<u> 151 NO :</u>			
SR No	Item Description/ Specifications	Quantity	Delivery Schedule	
	f Bid Bond : LKR or USD valid till (date)	t	o be submitted along	with t
Bid validit	y period : Bid should be valid till	(date)		
	nent Fee :paid in cash to SPC for each set of Bid I	Documents)		
MSD CON	NDITIONS OF SUPPLY			
MSD CON	NDITIONS OF SUITE!			
1.				

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

28.1

v) The Corporation shall list out the bids which are conformed to the technical specifications as most responsive substantially responsive bids irrespective of prices they have offered as the lowest, second lowest, third lowest etc. to use in case of the lowest evaluated responsive bidder refuses to supply during the specified time frame. Please note that price quoted should be 10% range of the lowest bid. Instead of awarding 100% of quantities of respective items to be procured, the supply of quantities can be distributed among responsive bidders on a predetermined schedule Such as..

Name of	the	Bidder/	Rank	Rank as per the Price Percent			Percentage	of	Supply	of		
Supplier			quoted				quantities					
The lowest			1 60%									
2 nd Lowest				2				30%				
3rd Lowest			3 10%									

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957)
NO. 75, Sir Baron Jayatillake Mawatha, Colombo 01.Sri Lanka.
Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204
E-mail: dgmcomm@spc.lk or managerimp2spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA AGREEMENT

SPC Ref. No Bid Ref. Date:

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 75, Sir Baron Jayatillaka Mawatha, Colombo 01, 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

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

...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

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

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %he 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 $\tilde{0}$ $\tilde{0$

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 % Locuments) 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 $\tilde{0}$ $\tilde{0$

The Common Seal of M/s (supplier) $\tilde{0}$ $\tilde{$

1.	•• ••	••	• ••	••	••	••	••	••	••	••	••	••	•
Pre	siden	t/Ma	ana	gir	ıg İ	Di	rec	to	r/C	LE	O.		
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	Dire	ector											

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 itos 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.

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Authorized signatory						
Authorized signatory						
Witnesses						
Signature	Name, Address and ID No					
1						
2						

AK/ns

ANNEX - 1

BID NO. : DHS/S/WW/86/22 DATE OF ISSUE : 20TH JULY 2021

CLOSING DATE & TIME : 31ST AUGUST 2021 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering:

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka

- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. 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.
- 4. The volume of the total quantity of each item should be given in cubic meters (m³)
- 5. Foreign offers should be on C & F (CPT/CFR) 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.
- 6. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.
- 10. The offer should be valid up to 26.02.2022

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

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

- 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 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% 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 product/s offered in compliance with the tender specification.

Shelf life & Warrantees

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

The supplier 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 surgical consumable 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative charge of the same.
- 12. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

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

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

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

Pack size, Labeling & Packaging

- 15. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 16. In respect of bulk packs of all pharmaceuticals (not applicable for blister/strip packs),
 - · DHS mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules

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

- **17.** Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Product Reference/Catalogue No.s of Surgical items), Date of Manufacture, Date of Expiry (of consumables only) and · STATE LOGO, of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (not applicable for Surgical Nonconsumables) & date of Manufacture (in any form as \cdot Year & Month, or \cdot No Exp.,), in the innermost pack and supplier invoice.
- **18.** Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ·STATE LOGO, of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
 - Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- **19.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- **20.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

Storage Conditions & Temperature

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

23. Maintenance of Cold Chain;

- a.In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer 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 µbserved 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 charge.
- 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 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\\$ overstepping delivery schedules in the Indent/PO/its\\$ amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its¶amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

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

Common conditions

36. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant

conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.

37. Administrative surcharge of 25% (on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 08,05,10,13)

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

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

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

(i) -(ii) -(iii) -

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 28.03.2022 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.
- In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- Where a purchase for a particular item is being made for the first time from a supplier, or where there are
 previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing
 the quality and standards of the goods and comparing the bulk supply with the samples provided along with
 the offer.
- Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name and designation of the signatory) or by the representative. Representatives submit offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka.
- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- All Shipment should be made exclusively on vessels belonging to the Ceylon Shipping
 Corporation or those chartered by CSC. Shipments on other vessels will be permitted in
 instances where vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment
 or if they are not available for timely shipment of cargo. In which event the supplier should
 attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in
 the supplier's country.

BID NO: DHS/S/WW/86/22 CLOSING ON: 31.08.2021 at 9.00 a.m.

ORDER LIST NUMBER: 2022/SPC/N/R/S/00114

Item No	SR No	Item	Qty piece	Delivery	Bid Bond Value (LKR)
1	14501202	Paraffin Gauze Dressing BP (1993) (Sterile) Size: width: 9cm Length: 7m (to be packed as a roll) Note: Shelf life of the product should be minimum of 24 months. Packing: Each sterile roll to be packed in a sealed tin. Marks & Nos: 1.Name of manufacturer, Item Description, Batch No., SR No., State Mark, Details of manufacture and Date of expiry(Year to be marked in four digits) should be stated on individual/inner/outer pack	34,000	17,000- Jan/2022 17,000- May/2022	594,313.00
		2.MSD Order No. and SPC indent No. should be			

	stated on inner/outer pack		
			ı

Packing: 1 Pies

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

Page 10 Condition No. 20. a
 Representative samples in respect of items offered should be submitted to reach SPC on or before the closing time on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

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.

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

A non refundable fee of Rs. 12,500/= + taxes should be paid in cash to SPC for each set of Tender Documents

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 1	19
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19.1

(b) A Certified copy of NMRA Registration Certificate certified by Attorney-at-Law, Commissioner of Oaths of Justice of Peace should be submitted along with the bid

(5) 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 www.spc.lk Web Site)

(6) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(7) Annex – 1 to be amend as follows.

SPECIMEN OF ANNEX - 1

ANNEX - 1

BID NO/ BID REFERENCE:

(TENDER NO)

DATE OF ISSUE :

CLOSING DATE & TIME:

(SRI LANKAN TIME)

ORDER LIST NO:

SR No	Item Description/ Specifications	Quantity	Delivery Schedule		

Amount of Bid Bond: LKR or USD to be submitted along with the Bid Bond valid till (date)
Bid validity period : Bid should be valid till (date)
Bid Document Fee :

MSD CONDITIONS OF SUPPLY

1.

2.

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

28.1

v) The Corporation shall list out the bids which are conformed to the technical specifications as most responsive substantially responsive bids irrespective of prices they have offered as the lowest, second lowest, third lowest etc. to use in case of the lowest evaluated responsive bidder refuses to supply during the specified time frame. Please note that price quoted should be 10% range of the lowest bid. Instead of awarding 100% of quantities of respective items to be procured, the supply of quantities can be distributed among responsive bidders on a predetermined schedule Such as..

Name o	of	the	Bidder/	Rank	as	per	the	Price	Percentage	of	Supply	of
Supplier				quoted	i				quantities			
The lowes	st				1				60%			
2 nd Lowes	t				2				30%			
3rd Lowest	t				3				10%			

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957)
NO. 75, Sir Baron Jayatillake Mawatha, Colombo 01.Sri Lanka.
Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204
E-mail: dgmcomm@spc.lk or managerimp2spc.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 75, Sir Baron Jayatillaka Mawatha, Colombo 01, 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}\

...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

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

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %the 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{o} $\tilde{o$

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 % De 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 $\tilde{0}$ $\tilde{0$

President/Managing Director/C.E.O.

Director

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 S	tate Pharmaceutical	als Corporation of Sri Lanka was affixed)	
0 0	\tilde{O}	$ \tilde{0} \	
Authorized signatory			
Authorized signatory			
<u>Witnesses</u>			
Signature		Name, Address and ID No	
1			••
2			

HK/ns

ANNEX - 1

BID NO. : DHS/S/WW/85/22 DATE OF ISSUE : 20TH JULY 2021

CLOSING DATE & TIME : 31ST AUGUST 2021 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering:

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka

- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. 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.
- 4. The volume of the total quantity of each item should be given in cubic meters (m³)
- 5. Foreign offers should be on C & F (CPT/CFR) 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.
- 6. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.
- 10. The offer should be valid up to 26.02.2022

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer is 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 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% 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 product/s offered in compliance with the tender specification.

Shelf life & Warrantees

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

The supplier 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 surgical consumable 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative charge of the same.
- 12. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

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

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

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

Pack size, Labeling & Packaging

- 15. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 16. In respect of bulk packs of all pharmaceuticals (not applicable for blister/strip packs),
 - · DHS mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules

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

- **17.** Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Product Reference/Catalogue No.s of Surgical items), Date of Manufacture, Date of Expiry (of consumables only) and · STATE LOGO, of Government of Sri Lanka.
 - It is essential to include and exactly match the dates of Expiry (not applicable for Surgical Nonconsumables) & date of Manufacture (in any form as \cdot Year & Month, or \cdot No Exp.,), in the innermost pack and supplier invoice.
- **18.** Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ·STATE LOGO, of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
 - Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- **19.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- **20.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

Storage Conditions & Temperature

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

23. Maintenance of Cold Chain;

- a.In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer 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 µbserved 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 charge.
- 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 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\\$ overstepping delivery schedules in the Indent/PO/its\\$ amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its¶amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

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

Common conditions

36. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant

conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.

37. Administrative surcharge of 25% (on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 08,05,10,13)

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

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

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

(i) -(ii) -(iii) -

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 28.03.2022 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.
- In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- Where a purchase for a particular item is being made for the first time from a supplier, or where there are
 previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing
 the quality and standards of the goods and comparing the bulk supply with the samples provided along with
 the offer.
- Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name and designation of the signatory) or by the representative. Representatives submit offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka.
- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- All Shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely shipment of cargo. In which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.

BID NO: DHS/S/WW/85/22 CLOSING ON: 31.08.2021 at 9.00 a.m.

ORDER LIST NUMBER: 2022/SPC/N/R/S/00131

Item No	SR No	Item	Qty Nos.	Delivery	Bid Bond Value (LKR)
1	13200002	Aural Grommet, Shah type or similar, size 1.0mm, sterile	1,000	1,000- May/2022	27,664.00
2	13200103	Hearing Aid, for moderate to severe hearing loss, for children, behind the ear type. BTE Digital Programmable Hearing Aids with minimum of four channels. Information leaflets on the hearing aids for users should be in all three languages (Sinhala, Tamil and English) with contact details of local service centers. Supplier should provide Ear mold, should do the programming and should document the Real Ear Measurement (REM) at the first programming session free of charge. The minimum period of guarantee should be two years. The supplier should provide 12 batteries with the hearing aids. Type and the battery life should be stated. Programming software and the interface (e.g.	7,000	4,000- Mar/2022 3,000- Aug/2022	1,921,269.00

		Hippro box) should be supplied to hospitals.			
3	13200104	Hearing Aid, for profound hearing loss, behind the ear type. BTE Digital Programmable Hearing Aid with minimum of four channels. Information leaflets on the hearing aids for users should be in all three languages (Sinhala, Tamil and English) with contact details of local service centers. Supplier should provide Ear mold, should do the programming and should document the Real Ear Measurement (REM) at the first programming session free of charge. The minimum period of guarantee should be two years. The supplier should provide 12 batteries with each hearing aid. Type and the battery life should be stated. Programming software and the interface should be supplied to hospitals.	5,000	2,500- Mar/2022 2,500- Aug/2022	1,684,053.00

Packing: 1 Nos.

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

Page 10 Condition No. 20. a
 Representative samples in respect of items offered should be submitted to reach SPC on or
 before the closing time on the closing date of tender and acknowledgement receipt to be
 obtained from Administration Department of SPC.

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.

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

A non refundable fee of Rs. 35,000/= + taxes should be paid in cash to SPC for each set of Tender Documents

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 19

19.1

(b)	A	Certified	copy	of	NMRA	Registration	Certificate	certified	by	Attorney-at-Law,
	Co	mmissione	er of O	aths	of Justic	ce of Peace sho	ould be submi	tted along wi	th the b	oid

(5) 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 www.spc.lk Web Site)

(6) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(7) Annex -1 to be amend as follows.

SPECIMEN OF ANNEX - 1

ANNEX – 1

BID NO/ BID REFERENCE:

(TENDER NO)

DATE OF ISSUE :

CLOSING DATE & TIME :

(SRI LANKAN TIME)

ORDER LIST NO:

SR No	Item Description/ Specifications	Quantity	Delivery Schedule

Amount of Bid Bond: LKR	or USD	to be submitted	along with the
Bid Bond valid till (da	te)		

Bid validity period: Bid should be valid till (date)

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

28.1

v) The Corporation shall list out the bids which are conformed to the technical specifications as most responsive substantially responsive bids irrespective of prices they have offered as the lowest, second lowest, third lowest etc. to use in case of the lowest evaluated responsive bidder refuses to supply during the specified time frame. Please note that price quoted should be 10% range of the lowest bid. Instead of awarding 100% of quantities of respective items to be procured, the supply of quantities can be distributed among responsive bidders on a predetermined schedule Such as..

Name of	the	Bidder/	Rank	as	per	the	Price	Percentage	of	Supply	of		
Supplier			quoted	l				quantities					
The lowest				1				60%					
2nd Lowest				2				30%					
3 rd Lowest				3				10%					

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957)

NO. 75, Sir Baron Jayatillake Mawatha, Colombo 01.Sri Lanka.

Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204

E-mail: dgmcomm@spc.lk or managerimp2spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA AGREEMENT

SPC Ref. No Date :

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 75, Sir Baron Jayatillaka Mawatha, Colombo 01, 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

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

...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

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

...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 õõõõõõõ

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

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

The Common Seal of M/s (supplier) $\tilde{0}$ $\tilde{$

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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.

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<u> ANNEX – 1</u>

BID NO. : DHS/S/WW/84/22 DATE OF ISSUE : 20TH JULY 2021

CLOSING DATE & TIME : 31ST AUGUST 2021 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering:

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka

- 2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
- 3. 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.
- 4. The volume of the total quantity of each item should be given in cubic meters (m³)
- 5. Foreign offers should be on C & F (CPT/CFR) 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.
- 6. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Bids" of the bid document in this regard.
- 7. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
- 9. We reserve the right to reject offers which do not comply above.
- 10. The offer should be valid up to 26.02.2022

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer is 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 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% 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 product/s offered in compliance with the tender specification.

Shelf life & Warrantees

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

The supplier 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 surgical consumable 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 charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative charge of the same.
- 12. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

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

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

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

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

Pack size, Labeling & Packaging

- 15. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 16. In respect of bulk packs of all pharmaceuticals (not applicable for blister/strip packs),
 - · DHS mark shall be;
 - (a). embossed or printed in case of tablets
 - (b). printed in case of capsules

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

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

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

- 18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ·STATE LOGO, of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
 - Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- **19.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- **20.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

Storage Conditions & Temperature

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

23. Maintenance of Cold Chain;

- a.In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer 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 µbserved 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 charge.
- 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 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\same amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its¶amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

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

- 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)
 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for

If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the condition No. 27 will not be applicable.

Common conditions

36. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant

conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.

37. Administrative surcharge of 25% (on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 08,05,10,13)

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

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

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

(i) -(ii) -(iii) -

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 28.03.2022 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.
- In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the
 procuring of said order in any stage, if you would be placed the defaulted supplier's list due to
 quality failure found in your previous supplies made to SPC or non compliance of contractual
 agreement.
- This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- Where a purchase for a particular item is being made for the first time from a supplier, or where there are previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.
- Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name and designation of the signatory) or by the representative. Representatives submit offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka.
- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- All Shipment should be made exclusively on vessels belonging to the Ceylon Shipping
 Corporation or those chartered by CSC. Shipments on other vessels will be permitted in
 instances where vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment
 or if they are not available for timely shipment of cargo. In which event the supplier should
 attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in
 the supplier's country.

BID NO: DHS/S/WW/84/22 CLOSING ON: 31.08.2021 at 9.00 a.m.

ORDER LIST NUMBER: 2022/SPC/N/R/S/00073

Item No	SR No	Item	Qty Rolls	Delivery	Bid Bond Value (LKR)
1	14501102	Plaster of Paris Bandage BP (1988) (P.O.P. Bandage) Width: 10cm Length: 2.7m Note: Shelf life of the product should be minimum of 24 months. Packing: Individual packed in moisture proof polythene wrappers and inserted into airtight tins Marks & Nos: 1.Name of manufacturer, Item Description, Batch No., SR No., State Mark, Details of manufacture and Date of expiry (Year to be marked in four digits) should be stated on individual/inner/outer pack	190,000	100,000- Jul/2022 90,000- Oct/2022	517,256.00

	2.MSD Order No. and SPC indent No. should be		
	stated on inner/outer pack		

Packing: 1 Roll

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

Page 10 Condition No. 20. a
 Representative samples in respect of items offered should be submitted to reach SPC on or
 before the closing time on the closing date of tender and acknowledgement receipt to be
 obtained from Administration Department of SPC.

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.

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

A non refundable fee of Rs. 12,500/= + taxes should be paid in cash to SPC for each set of Tender Documents

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 19
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19.1

(b) A Certified copy of NMRA Registration Certificate certified by Attorney-at-Law, Commissioner of Oaths of Justice of Peace should be submitted along with the bid

(5) 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 www.spc.lk Web Site)

(6) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(7) Annex -1 to be amend as follows.

SPECIMEN OF ANNEX - 1

ANNEX - 1

BID NO/BID REFERENCE:

(TENDER NO)

DATE OF ISSUE :

CLOSING DATE & TIME:

(SRI LANKAN TIME)

ORDER LIST NO:

SR No	Item Description/ Specifications	Quantity	Delivery Schedule

Amount of Bid Bond : LKR or USD to be submitted along with the Bid Bond valid till (date)
Bid validity period : Bid should be valid till (date)
Bid Document Fee :

MSD CONDITIONS OF SUPPLY

1.

2.

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

28.1

v) The Corporation shall list out the bids which are conformed to the technical specifications as most responsive substantially responsive bids irrespective of prices they have offered as the lowest, second lowest, third lowest etc. to use in case of the lowest evaluated responsive bidder refuses to supply during the specified time frame. Please note that price quoted should be 10% range of the lowest bid. Instead of awarding 100% of quantities of respective items to be procured, the supply of quantities can be distributed among responsive bidders on a predetermined schedule Such as..

Name o	of	the	Bidder/	Rank	as	per	the	Price	Percentage	of	Supply	of
Supplier				quoted	i				quantities			
The lowes	st				1				60%			
2 nd Lowes	t				2				30%			
3rd Lowest	t				3				10%			

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957)
NO. 75, Sir Baron Jayatillake Mawatha, Colombo 01.Sri Lanka.
Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204
E-mail: dgmcomm@spc.lk or managerimp2spc.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 75, Sir Baron Jayatillaka Mawatha, Colombo 01, 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}\

...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}\

...business under the time, style and firm of a company duly registered and carrying business (hereinafter called %the 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 $\tilde{0}$ $\tilde{0$

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

President/Managing Director/C.E.O.

Director

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.

	•
$ \tilde{0} \	$ \tilde{0} \;
Authorized signatory	
Authorized signatory	
<u>Witnesses</u>	
Signature	Name, Address and ID No
1	
2	

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

ANNEX - 1

BID NO. : DHS/M/SS/WW/1/22

DATE OF ISSUE : 19TH JULY 2021

CLOSING DATE & TIME : 31ST AUGUST 2021 AT 11.00 A.M. SRI LANKA TIME

ORDER LIST NUMBER: 2022/SPC/N/C/S/00024

ITEM NO	SR NO	ITEM	QUANTITY SETS	DELIVERY
1	12704100	TKR Implant Component for Total Knee Replacement (TKR) System of Mobile Bearing, Higher Flexion Knee Type, Per patient basis. Free instrumentation (SR 21200123) to be supplied for each 100 sets of implants. Packing: 1 Nos.	3,000	1,500-Jan/2022 1,500-Apr/2022

ONE (01) set of TKR Implant Component for Total Knee Replacement (TKR) System of Mobile Bearing, Higher flexion Knee Type as a Representative tender sample and Samples Catalogue/Literature should be submitted for bid evaluation.

Bid Bond value Rs. 6,694,527.00 or USD 33,489.00

Valid up to 28th March 2022 has to be submitted with the bid.

The Bid should be valid till 26th February 2022.

Non - refundable Bid fee - Rs. 60,000.00 + taxes

N.B.

If Local Agent Commission to be paid the percentage should be clearly indicate in annex 11B.

Special Conditions for this item of the tender

- 1. All the bidders should provide details on different available implant sizes with the bid for bid evaluation.
- 2. Successful bidder should agree to supply the items of required sizes in requested proportions, at the time of awarding the tender.
- 3. If there is excess stocks of slow moving sizes of this tender, the successful bidder should agree to exchange those to the fast moving sizes, one year prior to its expiry date, irrespective of the current supplier at that time.

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

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

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer sample, 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 from NMRA.

3. Maintaining the validity of the product registration during the period of supply (delivery schedule), obtaining import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical 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 copy 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. 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 unless otherwise mentioned in this document.

Shelf life & Warrantees

6. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods 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 36 months, any deficit between the residual shelf life and requested shelf life, shall not be more than 04 months.

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

Standards & Quality

- 7. <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.
- **8.** 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.
- **9.** Withdrawal from use of items due to quality failure found as manufacturer \$\s\Supplier \\$ fault:
 - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
 - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be charged the total **cost involved for MSD**, of the **quality failed supplies** with 25% administrative charge of the same.
- **10.** The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration.

The bidder must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.

- 11. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. 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.
- 12. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.09).

13. Pack size, Labeling & Packaging

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

- **14.** Each innermost pack shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue No., Date of Manufacture, Date of Expiry and · STATE LOGO, of Government of Sri Lanka. Product information Leaflet (PIL) to be included with each pack.
 - It is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as \cdot Year & Month, or \cdot No Exp.,), in the innermost pack and supplier invoice.
- **15.** Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ·STATE LOGO, of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
 - The format of Date of Manufacture / Date of Expiry should be declared in the offer and it shall consist at least the YEAR & MONTH.
- **16.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 17. 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).

18. 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

- 19. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30°c +/- 2°c temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- **20.** In respect of the products requiring controlled temperature storage (Eg. < 25°c, 2-25°c, 15-20°c/30°c, 2-8°c etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30°c +/- 2°c & 75% +/- 5% RH for **AC stored** items and at 25°c +/- 2°c & 60% +/- 5% RH for **Cold stored** items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.10)

Delivery Requirements

- 21. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD & SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
 - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 24 on delayed deliveries, shall be applied.
- **22.** 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.
- 23. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below:
 - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its¶latest amended delivery schedules.
 - (b). When the delay exceeds 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 charge.
- **24.** (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.

- 25. 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 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. 24 (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.
- **26.** The extension of L/C\\$ 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. 24 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 27. 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. 24, 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

- **28.** 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.
- 29. 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.
 - 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. Reference sample to be sent by Procurement Entity to MSD.
 - 34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
 - 35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)
 If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the condition No. 24 will not be applicable.

Common conditions

- 36. In addition to the general conditions of supply given herein, any other relevant conditions as per the tender document issued by SPC, are also applicable.
- **Abbreviations :**NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka, WDN; Wharf Delivery Note

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.
- In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the

procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.

- Where a purchase for a particular item is being made for the first time from a supplier, or where there are
 previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing the
 quality and standards of the goods and comparing the bulk supply with the samples provided along with the
 offer.
- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- All Shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation
 or those chartered by CSC. Shipments on other vessels will be permitted in instances where
 vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not
 available for timely shipment of cargo. In which event the supplier should attach a waiver
 certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's
 country.

(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 Nos. shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

BS/ns

ANNEX-1

BID NO. : DHS/L/WW/65/22 DATE OF ISSUE : 20TH JULY 2021

CLOSING DATE & TIME : 30TH AUGUST 2021 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 product/s offered in compliance with the tender specification.

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (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/Supplier'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).

15. Pack size, Labeling & Packaging

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 <u>or</u> when an exemption is notified in the special order conditions of the relevant MSD order list (**This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items**)

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

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

- **18.** Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and "STATE LOGO" of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
 - Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- **19.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- **20.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

Storage Conditions & Temperature

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

- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
 - C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
 - d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
 - e) The suppliers shall dispatch consignments of the items, which require 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 mentioned in the item list. Bid Bond should be submitted with valid up to 28.03.2022 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/65/22 CLOSING ON: 30.08.2021 at 9.00 a.m.

ORDER LIST NUMBER: 2022/SPC/N/C/D/00096

Item No.	SR No.	Item Specification	Quantity	Delivery	Bid Bond Value
			Strips		(LKR)
1	43033603	Urine strips 10 parameters with high sensitivity & high specificity with a desiccant to eliminate negative effects of moisture to strip (supply of positive & negative controls are preferable)	280,000	140,000- Jan/2022 140,000- Jul/2022	136,864.00
2	43075501	Fecal Occult Blood (FOB) Rapid test strips with high sensitivity & high specificity, individually sealed with a desiccant to eliminate negative effects of moisture to strip with positive & negative controls samples	35,000	15,000-Jan/2022 20,000-Jul/2022	123,760.00

Packing: 1 Strp

The offer should be valid till 180 days from closing of bid. (26.02.2022)

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 19

19.1

(b) A Certified copy of NMRA Registration Certificate certified by Attorney-at-Law, Commissioner of Oaths of Justice of Peace should be submitted along with the bid

(5) 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 www.spc.lk Web Site)

(6) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(7) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX – 1	
			<u>ANNEX – 1</u>
BID NO/ BI (TENDER N	D REFERENCE : NO)		
DATE OF IS	SSUE :		
CLOSING I	DATE & TIME : AN TIME)		
ORDER LIS	ST NO:		
SR No	Item Description/ Specifications	Quantity	Delivery Schedule
	Bid Bond : LKR or USD d valid till (date)	to	be submitted along with
Bid validity	period : Bid should be valid till	(date)	
	ent Fee : paid in cash to SPC for each set of Bid D	Oocuments)	
MSD CONI	DITIONS OF SUPPLY		
1. 2.			

 ${\bf Abbreviations: SPC: State\ Pharmaceuticals\ Corporation,\ MSD;\ Medical\ Supplies\ Division}$

28.1

v) The Corporation shall list out the bids which are conformed to the technical specifications as most responsive substantially responsive bids irrespective of prices they have offered as the lowest, second lowest, third lowest etc. to use in case of the lowest evaluated responsive bidder refuses to supply during the specified time frame. Please note that price quoted should be 10% range of the lowest bid. Instead of awarding 100% of quantities of respective items to be procured, the supply of quantities can be distributed among responsive bidders on a predetermined schedule Such as..

Name of the Bidder/	Rank as per the Price	Percentage of Supply of
Supplier	quoted	quantities
The lowest	1	60%
2 nd Lowest	2	30%
3 rd Lowest	3	10%

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957) NO. 75, Sir Baron Jayatillake Mawatha, Colombo 01.Sri Lanka. Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204 E-mail: dgmcomm@spc.lk or managerimp2spc.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 75, Sir Baron Jayatillaka Mawatha, Colombo 01, 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

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

...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

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

...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 $\tilde{0}$ $\tilde{0}$ $\tilde{0}$ $\tilde{0}$ $\tilde{0}$ $\tilde{0}$ õõõõõõõõõõõõõõõõõõõõõõõõõõõõ will act as local agent of the supplier for all matters arising out of supplies here of.

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 % De 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} $\tilde{o$

The Common Seal of M/s (supplier) $\tilde{0}$ $\tilde{$

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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.

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ANNEX-1

BID NO. : DHS/L/WW/64/22 DATE OF ISSUE : 20TH JULY 2021

CLOSING DATE & TIME : 30TH AUGUST 2021 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 product/s offered in compliance with the tender specification.

Shelf life & Warrantees

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

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

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

- **8.** Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th (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/Supplier'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).

15. Pack size, Labeling & Packaging

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 <u>or</u> when an exemption is notified in the special order conditions of the relevant MSD order list (**This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items**)

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

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

- **18.** Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and "STATE LOGO" of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
 - Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- **19.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- **20.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

Storage Conditions & Temperature

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

- 23. Maintenance of Cold Chain;
 - a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
 - C) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
 - d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
 - e) The suppliers shall dispatch consignments of the items, which require 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 mentioned in the item list. Bid Bond should be submitted with valid up to 28.03.2022 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/64/22 CLOSING ON: 30.08.2021 at 9.00 a.m.

ORDER LIST NUMBER: 2022/SPC/N/C/D/00075

Item No.	SR No.	Item Specification	Quantity	Delivery	Bid Bond Value
			Nos.		(LKR)
1	50800101	Disposable microtome blades, High profile 22 Cutting angle Packing: 100 Nos.	10,000	10,000-Jan/2022	66,804.00
2	55410602	Micro pipette, manual, fixed volume, conformity certified, should be able to use all standard tips, with tip ejector, 2 ul Packing: 1 Nos.	2	2-Jan/2022	N/A

The offer should be valid till 180 days from closing of bid. (26.02.2022)

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 19

19.1

(b) A Certified copy of NMRA Registration Certificate certified by Attorney-at-Law, Commissioner of Oaths of Justice of Peace should be submitted along with the bid

(5) 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 www.spc.lk Web Site)

(6) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(7) Annex – 1 to be amend as follows.

	SPECIMEN OF A	NNEX – 1		
			ANNEX	<u>– 1</u>
BID NO/ BI (TENDER N	D REFERENCE : IO)			
DATE OF IS	SSUE :			
CLOSING I	DATE & TIME : AN TIME)			
ORDER LIS	ST NO :			
SR No	Item Description/ Specifications	Quantity	Delivery Schedule	
	Bid Bond : LKR or USD I valid till (date)	to	be submitted along w	ith
Bid validity	period : Bid should be valid till	(date)		
	ent Fee : Paid in cash to SPC for each set of Bid D	ocuments)		
MSD CONI	DITIONS OF SUPPLY			
1. 2.				

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

28.1

v) The Corporation shall list out the bids which are conformed to the technical specifications as most responsive substantially responsive bids irrespective of prices they have offered as the lowest, second lowest, third lowest etc. to use in case of the lowest evaluated responsive bidder refuses to supply during the specified time frame. Please note that price quoted should be 10% range of the lowest bid. Instead of awarding 100% of quantities of respective items to be procured, the supply of quantities can be distributed among responsive bidders on a predetermined schedule Such as..

Name of the Bidder/	Rank as per the Price	Percentage of Supply of
Supplier	quoted	quantities
The lowest	1	60%
2 nd Lowest	2	30%
3 rd Lowest	3	10%

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957)

NO. 75, Sir Baron Jayatillake Mawatha, Colombo 01.Sri Lanka.

Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204

E-mail: dgmcomm@spc.lk or managerimp2spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA AGREEMENT

SPC Ref. No	Date :

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 75, Sir Baron Jayatillaka Mawatha, Colombo 01, 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

Bid Ref.

 $M/s\ \tilde{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}\

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

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 % De 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} $\tilde{o$

The Common Seal of M/s (supplier) $\tilde{0}$ $\tilde{$

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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.

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