MANUAL ON LOCAL PURCHASE OF MEDICAL SUPPLIES 2023

MINISTRY OF HEALTH AND NUTRITION

GOVERNMENT OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

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"SUWASIRIPAYA",
No 385, Rev. Baddegama Wimalawansa Thero Mawatha,
Colombo 10.
Sri Lanka

PREFACE

It is with great pleasure and a sense of accomplishment that we present the “MANUAL ON LOCAL PURCHASE OF MEDICAL SUPPLIES IN SRI LANKA." This comprehensive guide has been developed to provide essential information and guidelines to stakeholders involved in the procurement and supply chain management of pharmaceuticals and administrators within the Sri Lankan healthcare system.

The availability and accessibility of safe, quality, and affordable drugs are vital components in ensuring effective healthcare delivery. Recognizing this, the Ministry of Health, in collaboration with key stakeholders, embarked on the development of this manual to streamline the local purchase process and strengthen the overall pharmaceutical management system in Sri Lanka.

This manual serves as a valuable resource for treating consultants, procurement officers, pharmacists, healthcare administrators, and other professionals involved in the local purchase of drugs. It is designed to assist them in navigating the intricacies of drug procurement, from the identification of needs to the final receipt and storage of pharmaceutical products.

The content of this manual is the result of extensive research, consultations, and collaboration with experts in the field. It incorporates best practices and guidelines from the Ministry of Finance and takes into account the specific context and requirements of the Sri Lankan healthcare system. The manual outlines step-by-step procedures, provides practical tools and templates, and offers valuable insights to ensure transparency, efficiency, and accountability throughout the procurement process.

We would like to express our sincere gratitude to the dedicated individuals who contributed their time, knowledge, and expertise to the development of this manual. Their commitment to improving pharmaceutical procurement practices in Sri Lanka is evident in the comprehensive and user-friendly nature of this guide.

We sincerely hope that this manual will serve as a valuable resource to streamline the local purchase of drugs in Sri Lanka. By following the guidelines and recommendations outlined herein, we can collectively work towards ensuring a transparent, efficient, and sustainable procurement process that ultimately benefits the health and well-being of the people of Sri Lanka.

Dr Asela Gunawardhana
Chairman – The panel of Resource Personals
Director General of Health Service
Sri Lanka

ACKNOWLEDGMENT

The Ministry of Health considers its prime responsibility is to develop a healthier Sri Lankan nation that contributes to its economic, social, mental, and spiritual development. To fulfill this responsibility the Ministry of Health spends nearly 40% of its recurrent budget to purchase Medical Supplies. Local Purchases of Medical Supplies have been one of the most significant section of the Medical Supplies Management. Therefore, a new manual on the Local Purchase of Drugs was a dire need to regularize the process of Local Purchase of Medical Supplies in Sri Lanka.

I would like to express my sincere gratitude and appreciation to all those who have contributed to the development of the manual on "The Local Purchase of Medical Supplies in Sri Lanka." This comprehensive guide aims to provide essential information and guidelines to stakeholders involved in the procurement and supply chain management of medical supplies within the Sri Lankan healthcare system.

The creation of this manual would not have been possible without the unwavering support and collaboration of numerous individuals and organizations. We would like to extend our heartfelt thanks to the special committee of resource personnel chaired by the Director General of Health Services, for their guidance, vision, and commitment. Their dedication, commitment, expertise, a wealth of experience and hard work have been instrumental in the successful completion of this project.

I am deeply grateful to the experts and professionals including the procurement officers, pharmacists, healthcare administrators, auditors, and other professionals, who generously shared their knowledge, expertise, and experiences throughout the development process. Their valuable insights and inputs have significantly enriched the content of this manual, ensuring its relevance and practicality in the Sri Lankan context.

Furthermore, I would like to express our appreciation to the editors who meticulously worked on this manual. Their attention to detail, creativity, and dedication have ensured that the manual is user-friendly, visually appealing, and accessible to a wide range of users.

Lastly, we would like to thank all who contributed to their ongoing support and collaboration in implementing efficient and transparent procurement processes. By working together, we can ensure the availability of high-quality medical supplies and contribute to the overall improvement of healthcare services in Sri Lanka. I sincerely hope that this guide will serve as a valuable resource and catalyst for positive change, facilitating the local purchase of medical supplies and ultimately enhancing the cost-effectiveness and quality of healthcare delivery in Sri Lanka.

Dr. R.M.S.K Rathnayake
Additional Secretary – Production Supply and Regulation of Pharmaceuticals
Ministry of Health - Sri Lanka

Special Panel of Resource Personals

1.	Dr. Asela Gunawardhana	–	Director General of Health Services - (Chairman)
2.	Dr. H.M.K Herath	–	Deputy Director General – Medical Supplies Division, Ministry of Health
3.	Dr. Kapila Wickramanayake	–	Director- Medical Supplies Division, Ministry of Health
4.	Ms. L.C Wanniaarachchi	–	Assistant Director
		–	Medical Supplies Division, Ministry of Health
5.	Ms. Gayani Wijesooriya	–	Chief Accountant
		–	Division of Production, Supply and Regulation of Pharmaceuticals, Ministry of Health
6.	Mr. Shavindra Coorey	–	Chief Accountant
		–	Medical Supplies Division, Ministry of Health
7.	Ms. D.H.R.N Pemathunga	–	Chief Internal Audit – Ministry of Health
8.	Mr. W.K.L.S Weliwita	–	Pharmacist
		–	National Hospital of Sri Lanka
9.	Mr. R.M.G.M.B Rathnayake	–	Pharmacist
		–	National Hospital Kandy
10.	Mr. C.S Rajapaksha	–	Pharmacist
		–	District General Hospital Mathara
11.	Ms. Deepa Ranathunga	–	Chief Pharmacist
		–	Lady Ridgeway Hospital for Children
12.	Mr. Sumathipala Piyadigamage	–	Pharmacist
		–	Provincial General Hospital Badulla
13.	Mr. Anura Abeysinghe	–	Pharmacist
		–	Colombo South Teaching Hospital.

Editor

Dr. I.W.Y.K.C Rambukwelle	–	Division of Production, Supply and Regulation of Pharmaceuticals, Ministry of Health

Conveyer

Dr. R.M.S.K Rathnayake	–	Additional Secretary - Production, Supply and Regulation of Pharmaceuticals, Ministry of Health

List of Abbreviations

1.	LP	-	Local Purchase
2.	MSD	-	Medical Supplies Division
3.	NMRA	-	National Medicines Regulatory Authority
4.	DTC	-	Drug and Therapeutic Committee
5.	RMSD	-	Regional Medical Supplies Division
6.	PHN	-	Personal Health Number
7.	MQP	-	Maximum Quoted Price
8.	PE	-	Procurement Entity
9.	BEC	-	Bid Evaluation Committee
10.	TEC	-	Technical Evaluation Committee
11.	PC	-	Procurement Committee
12.	CAO	-	Chief Accounting Officer
13.	AO	-	Accounting Officer
14.	BOC	-	Bid Opening Committee
15.	RPC	-	Regional Procurement Committee
16.	PO	-	Purchase order
17.	GRN	-	Goods Receiving Note

Table of Contents

MANUAL ON LOCAL PURCHASE OF MEDICAL SUPPLIES

This guideline should be read in concurrence with the Procurement Guidelines for Goods and Works (Ministry of Finance) and the Guidelines for Procurement of Pharmaceuticals & medical devices of a consumable nature (2022) by the Ministry of Health and Ministry of Finance, Economics Stabilization, and National Policies. The broad principles of procurement stated in the latest Procurement will be to its fullest extent, for the Procurement of Pharmaceuticals and Medical Devices, unless they have been amended or modified in these Guidelines. The previously issued circulars and guidelines by the Ministry of Health regarding the "Local Purchase of Medical Supplies" will be replaced by this Manual.

1. Introduction

The Local Purchase (LP) is a facility given for institutions to purchase the most urgently required, life-saving medical supplies. LP process should always reduce the morbidity and mortality of the patient, reduce the out-of-pocket expenditure, or reduce the hospital stay thus benefiting the economy of the country.

Local Purchase is an emergency facility given to consultants to cater to the urgent need of patient care and should not be exercised as a regular function. Therefore, this facility needs to be utilized with utmost responsibility and accountability.

The Head of the Institution and the Medical Supplies Division (MSD) should take full responsibility to make this process transparent. The LP process exercised at an institution must strictly adhere to this manual and the latest other appropriate national procurement guidelines with amendments. Heads of Institutions should always make sure that patients receive the best quality medical supplies that outweigh the benefits compared to the cost.

The Local purchase should be done only from NMRA-registered suppliers and NMRA-registered pharmacies. Since LP is done to acquire urgent medical supplies the purchaser should consider the stock availability, delivery schedule, and lead time to receive the ordered medical supplies.

The Institutional Drug and Therapeutic Committee (DTC) must monitor the LP trends of the institution and the National Drug and Therapeutic Committee should monitor the National LP trends.

It is the duty of the institutional DTC to monitor the LP trends and report to the higher authorities. MSD is responsible to increase the availability of such supplies after careful analysis of the existing and expected trends.

2. When to Local Purchase

Purchasing should be done for the medical supplies which are either Unavailable at the MSD or unable to obtain from the existing stocks at MSD / RMSD to the institution. All LP requests should be requested by a consultant and must do to accompany an urgent requirement.

LP can be done for both Inward patients and outpatients. However, any inpatient for whom a LP request is made must be registered in the institution (preferably with a PHN) and all outpatients requiring local purchasing must be registered in the National Health System with a PHN.

LP can be done by the SPC at the National level (Ex – delaying of main tenders, supply chain issues, emerging and reemerging diseases, unforeseen changes in consumption patterns and etc) based on the request of MSD, RMSD at the Regional level, or Institutional level by each institution. LP process should be exclusively done only through the Medical Supplies Information Management System of the Ministry of Health (Swastha).

3. Registration of Suppliers for LP

Every Supplier (including Rajya Osusala) should be registered in a common National Register. This registration can be done at the MSD or at the local institution through the “Swastha system”. All registrations should be renewed yearly.

Suppliers must submit the following details with documents of proof at the registration.

A. Registered Name of the Supplier.
B. Business Registration (document of proof should be provided).
C. NMRA supplier / pharmacy registration no (document of proof should be provided).
D. Valid Email
E. Valid postal address
F. Valid Telephone no / fax
G. Items registered to supply with the maximum price for that item.

H. VAT registration number (document of proof should be provided).
I. Any supplier who has been backlisted by the NMRA, SPC, Ministry of Health or Ministry of Finance will not be registered. Every supplier should provide an affidavit stating that they have not been backlisted as mentioned above.

Suppliers should obtain registration for each item they expect to provide stating the maximum quoted price (MQP) in Sri Lankan rupees. MQP quoted must universally be available for the whole country. The provided MQP will be shared with all the institutions of the country.

Suppliers can request price increments/deductions twice a year. Each request must be approved by the institutional-level price revision committee. The institutional-level price revision committee must be appointed by the Head of the Institute yearly and must have a minimum of 5 members; The Head of the Institute, the Chief Accountant / Accountant, the Chief Pharmacist, and two consultants representing clinical fields (Ex – Consultant Physician and Consultant Surgeon). When required Head of the Institute must summon the clinical experts of the relevant field and obtain their opinion. (Ex – For oncology drugs, Special drugs, Special surgical items, machine-specific items and etc).
Each approved request should be informed to the Director of MSD through the Swastha system.

Any supplier who fails to provide the medical supplies with the requested quality will be removed from the registration for that specific item by the Head of the Institute. The Head of the Institute should inform the supplier in writing (by email and by post) regarding “the removal of the registration”. If any supplier expects to appeal against “the removal of the registration”, should officially make an appeal to the Secretary, Additional Secretary (Production Supply and Regulation of Pharmaceuticals), Director General of Health Services with relevant details, within 14 days from the original date of the “official removal of the registration”. The Secretary, Additional Secretary (Production Supply and Regulation of Pharmaceuticals), and Director General of Health Services should forward the recommendations to the Head of the Institution within 6 weeks of receiving the request. The authority to revoke the ‘removal of registration remains solely with the Secretary, Additional Secretary (Production Supply and Regulation of Pharmaceuticals), and Director General of Health Services.

4. Initiation of LP Process

All LP requests must be initiated by a consultant. Instances where this rule is inapplicable (Some consumables may not have a responsible consultant, Ex – ECG rolls, Blood glucose strips, surgical consumables etc). Such request can be initiated by the Deputy Head of the Institution (OR Any designated medical officer who discharges the duties in that capacity) followed by a request to local purchase medical supplies by the Chief Pharmacist of the Institution (Any designated pharmacist in that capacity).

Every LP should be requested through the 'Swastha system' and should have the following details duly filled by the requesting consultant or the relevant authority to request.

1. Name of the institution
2. Date of request
3. If Name patient basis,
    A. PHN
    B. BHT no / Clinic no
    C. Name of the Patient
    D. WD/ICU/Unit
    E. Generic Name of the item
    F. Requested quantity
    G. Justification
    H. Name of the requesting consultant

All LP requests once reached the designated pharmacist / relevant officer for that item, must be submitted to the authorizing officer with the following details,

A. Formulated at MSD
B. SR number (If available)
C. Category of the item (regular/complementary and relevant details)
D. Estimated / Not estimated / If estimated – Original / Supplementary
E. If estimated – Annual Estimate
F. If not estimate – reason
G. Monthly requirement
H. Amount received for that day
I. Available alternatives / substitutes (yes/no/specify) – The alternative / **substitute should be approved by the relevant consultant.**

J. Quantity already purchased locally (of the same item) during the year (–up to that date)

The Pharmacist / MLT / Radiographer in charge of the item should ensure that the item(s) concerned is either unavailable at the MSD or the inability to obtain the available stocks to the institution before finalizing the request.

When locally purchasing at the national level, the Director of MSD must initiate the LP process following the requests forwarded by the healthcare institutions or based on the recommendations of the National Therapeutic Committee. The National level LP process should follow the Guidelines for procurement of pharmaceuticals & medical devices of a consumable nature (2022) by the Ministry of Health and Ministry of Finance, Economics Stabilization and National Policies and when required the Procurement Guidelines for Goods and Works (Ministry of Finance).

5. Authorization Process

All LP requests must be recommended by the Head of the Institution (or by the designated medical officer working in that capacity). If no such officer is available in the institution, it should be authorized by the Deputy Director of MSD. The Authorization process should be done through the Swastha system.

It is the duty of the authorizing officer to verify the unavailability of the medical supply or the inability to obtain it from the MSD/ RMSD and to ensure the completeness of the forwarded request form as mentioned in section 2.

The Director General of Health Services will act as the authorizing officer for local purchases initiated at the national level.

6. Process of Approval

All LP requests should be approved by the Director MSD (the Director MSD can decide the internal approval process of the MSD). All such approvals should be officially communicated to the DDG – MSD through the Swastha system.

MSD should always confirm the availability of funds/allocations for LP.

Director MSD should provide the approval with the approved quantity to local purchase. The quantity should be decided base on availability, balance due on order, balance estimate of the institution, availability of alternatives / substitutes, and possibility of redistribution. Director MSD should always make sure that each LP request fulfills the conditions mentioned in section 2.

For National level LP initiated by the MSD, Secretary of Health / Additional Secretary of Production Supply and Regulation of Pharmaceuticals should provide the authorization.

7. The Procurement Process

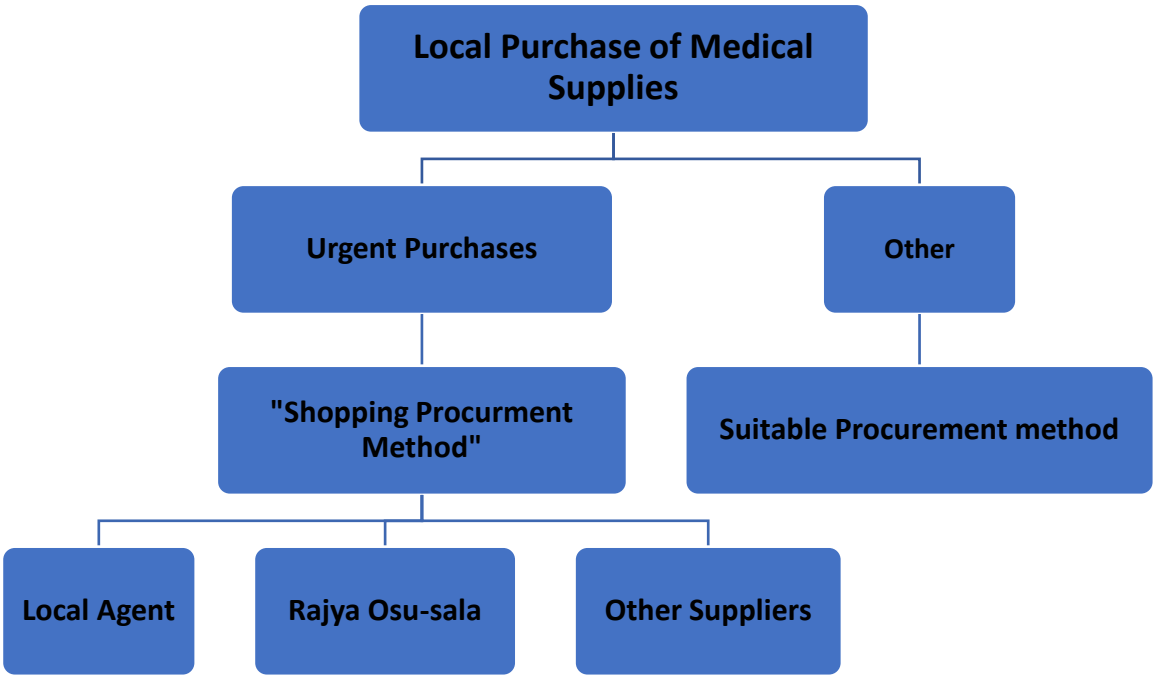
The procurement process should begin only after receiving the approval from MSD through 'swastha' system. The procurement committee should be selected appropriately based on the procurement limits of that year according to the latest circular issued by the Ministry of Health.

Urgent purchases should follow the limits mentioned in " Delegation of Financial Authority to government institution / මූල්‍ය පාලනය පිළිබඳ බලතල පැවරීම" circular issued by the Secretary of the Ministry of Health for that particular year.

Annual Allocation should be reserved by the Head of the Institution at the beginning of the year from the Ministry of Health. (For Institutions under the Regional Health Departments, PDHS should reserve the allocation for the entire province and must divide fairly for each institution in the RDHS. In RDHS Level division of allocation should go in accordance with the purpose of the hospital.)

The Procurement Entity (PE) shall appoint a suitable Procurement Committee based on institutional financial authority limits. Procurement activities from calling for the invitation of bids/proposals to the selection of the substantially responsive lowest evaluated bidder must be handled by the Procurement Committee.

Procurement Committees will be assisted by the Bid Evaluation Committee (BECs) / Technical Evaluation Committee (TEC) where necessary.



7.1 Urgent Purchases of Medical Supplies

An urgent purchase of a medical supply must be carried out according to section 7.8 of the Guidelines for Procurement of Pharmaceuticals & medical devices of a consumable nature (2022) by the Ministry of Health and Ministry of Finance, Economics Stabilization and National Policies.

Urgent purchases of Medical supplies within the institutional/provincial financial limit allocated by the Secretary of the Ministry of Health, or included in a list of special items mentioned by the Secretary of Health can be procured as an urgent procurement using the shopping method. . The medical supplies can be procured from the local agent, Rajya Osusala or another supplier/pharmacy (All local agents, rajya osusala and supplier/pharmacy must be registered as mentioned in section of 3 this manual). But it must be the best available quality product with the lowest price quoted.

For The details of the shopping method, section 7.6 of the Guidelines for Procurement of pharmaceuticals & medical devices of a consumable nature (2022) by the Ministry of Health and Ministry of Finance, Economics Stabilization and National Policies must be reffered. In addition to section 7.6, for the shopping method, the supplies registered in the Swastha system and the prices mentioned in the swastha system should be used. As mentioned in section 7.6.2 to ensure competitive prices, a minimum of 03 quotes must be obtained through swastha system (One bid request should be forwarded to the “Rajya Osusala”) .

The Secretary of the Ministry of Health holds the authority to amend the limits and the list of medical supplies which can be purchased by the shopping method and will be circulated among all Heads of Institutions. The limits and list of items will be circulated through a special circular issued by the Secretary of Health in each year.

LP process which does not belong to "Shopping procurement method" as stated in section 7.1 of this manual, should follow the suitable procurement method according to the Guidelines for procurement of pharmaceuticals & medical devices of a consumable nature (2022) by the Ministry of Health and Ministry of Finance, Economics Stabilization and National Policies and Procurement Guidelines for Goods and Works (Ministry of Finance) and instructions of section 7.1 to 7.5 of this manual. In such instances, the procurement should be handled by the Finance Department of the Institution with the assistance of the pharmacist responsible for the LP.

7.2 Calling for bids

The relevant procurement unit, with the assistance of the pharmacist responsible for the LP of the institution, should select registered suppliers and call for the invitation of bids as directed by the Procurement Committee (PC). This pharmacist should not be the same pharmacist who has obtained the approval for the LP from MSD.

A bid request must be sent to the "Rajya Osusala" and to all the possible supplies of that item. Transparency should be always maintained. Requests must be sent through the "Swastha"(BY email) and by post/fax as well.

The Technical Evaluation Committee (TEC) / Bid Evaluation Committee (BEC) must prepare the bids.

7.3 Bid Evaluation Committee (BEC) / Technical Evaluation Committee (TEC)

The Technical Evaluation Committee is appointed by the Head of the Institute / OR The Head of the Procurement Entity (PE).

TEC/BEC is responsible for preparing Bids/specifications, evaluation of The submitted bids, and determination of the substantially responsive lowest evaluated bidder.

No member should be appointed to serve in both the Procurement Committee (PC) and TEC/ BEC for ANY particular procurement.

TEC/BECs should consist of subject specialist/s and at least one member who is sufficiently knowledgeable on procurement procedures.

The relevant Head of the Institute / PE shall nominate suitable officers who could devote time to participate in the Bid/Proposal Evaluation Process and obtain approval from the relevant authority. A single officer should not be appointed to serve in more than three (03) BECs at a given time.

The BEC members should inform the completion of committee works to the respective Head of the Institute / PE, enabling the authority to make appointments to committees within the prescribed limit of 03 committees per member at a time.

However, in the event of appointing an officer for more than three (03) committees due to unavoidable circumstances, the approval of the Chief Accounting Officer /AO depending on the threshold should be priorly obtained stating valid reasons for such appointments.

All members of the BEC jointly and severally holds the responsibility and accountability for the following activities:

i. To review and approve the specifications while ensuring that the specifications are fit for the purpose and appropriate and generic in nature so as to promote competitiveness;

ii. To revisit specifications if objections are received from any bidder,10 days prior to closing of bids/proposals, enabling the PE to convey its decision to all the bidders who have purchased the Procurement Documents (not applied to the shopping method);

iii. To review and approve the pre-qualification documents/procurement documents prepared by the pe ensuring the requirements of these guidelines are met and accepted principles of procurement are complied with;

iv. To participate in negotiations, **only if directed by the PC;**

v. To carry out bid/proposal evaluations and make recommendations to PC;

Vi. To maintain proper Minutes/Records on the deliberations of the BEC s.

vii. Preparation of Bid Evaluation Reports and Bid Evaluation Summery

(Procurement Guideline Reference: 2.4.8 for the PROCUREMENT MANUAL – 2018 Goods, Works, Services and Information Systems)

7.4 Bid Opening

Bid Opening Committee (BOC) must be appointed by the Procurement Committee (PC).

Opening of bids/proposals shall be done by a BOC. The BOC is responsible to ensure that bid/proposals opening is commenced at the correct time, as specified in the Procurement Document and that all bids/proposals are received by post, courier, hand-delivered, or deposited in the tender box within the stipulated time period of the biding document

Bid opening should follow the standard protocols for bid opening as directed by the latest National Procurement Guidelines.

7.5 Technical Evaluation / Bid Evaluation

Bid Evaluation is the responsibility of the BEC.

The members of the BECs are jointly and individually responsible for the following activities of the BEC.

Since LP of medical supplies is an urgent requirement, the bid evaluation must be completed at earliest.

Each BEC Member is responsible to carry out the special tasks assigned to THEM by the BEC Chairman. These tasks may be related to the main subject matter of procurement or to an ancillary matter such as procurement procedures, finance, etc. The BEC Chairman IS responsible to complete at least one such task. The responsibility for the subject matter of the procurement can be assigned to more than one member for a given procurement. Each member must sign and accept the individual responsibility to the task assigned in addition to signing the joint responsibility of the BEC.

Any BEC member may submit a dissenting report on any issue.

The chairperson of BEC or his appointee from the members of the BEC must participate to any pre-bid meetings held.

7.6 Tender Board

A suitable Procurement Committee must be appointed by the Procurement Entity (PE) based on different financial authority limits. In order to complete the LP process without any undue delay , whenever possible Suitable REGIONAL PROCUREMENT COMMITTEE (RPC), should be used. RPC should be appointed according to the Guidelines for procurement of pharmaceuticals & medical devices of a consumable nature (2022) and / or according to the latest National Procurement Guideline. (Procurement Guideline Reference: 2.4.6 for the procurement manual – 2018 Goods, Works, Services And Information Systems)

The Procurement Committee should adhere to the Guidelines for the procurement of pharmaceuticals & medical devices of a consumable nature (2022) and refer when necessary to the latest national procurement guidelines. (Procurement Guideline Reference: 2.4.8 for the procurement manual – 2018 Goods, Works, Services And Information Systems)

PC has no authority to grant Covering approval for any contract award except in the case of emergency procurement.

7.7 Purchasing

Issuing of the Purchase order (PO) and purchasing should be done through the Finance department adhering to the Guidelines for procurement of pharmaceuticals & medical devices of a consumable nature (2022) by the Ministry of Health and Ministry of Finance, Economics Stabilization and National Policies and Procurement Guidelines for Goods and Works (Ministry of Finance).

When the PO is issued, the Head of the Institute–must obtain the certification from the Chief Pharmacist that the stocks are not either available at the institution or MSD ,or the inability to acquire any available stock at MSD/RMSD. Goods Receiving

Goods received at drug stores must be verified by the responsible pharmacists in concurrence with the specifications mentioned in the procurement and a “Goods Receiving Note” (GRN) must be issued to the Finance Department.

In any disparities, the responsible pharmacist or the CP must immediately inform the Head of the Institution and take necessary actions through the Head of the Institution.

7.8 Payment Process

The payment process must occur through the Finance department adhering to the Guidelines for procurement of pharmaceuticals & medical devices of a consumable nature (2022) by Ministry of Health and Ministry of Finance, Economics Stabilization and National Policies and Procurement Guidelines for Goods and Works (Ministry of Finance) after receiving the GRN.

8. Distribution of LP items

Distribution of the LP items must be done thoroughly based on the requirement and urgency. The In charge pharmacist–holds the responsibility of ensuring the timely arrival of the LP item to the requested patient without delay.

9. LP of Non Formulary items

Local purchasing process for a non formulated item must strictly adhere to the instructions given at the section 7.11 of the Guidelines for procurement of pharmaceuticals & medical devices of a consumable nature (2022) by Ministry of Health and Ministry of Finance, Economics Stabilization and National Policies.

Further to section 7.11, Nonformulary items can be locally purchased based on the requirement following the normal LP process. The Institutional Drug and Therapeutics Committee and National Drug and Therapeutics Committee should monitor the use of Non Formulary items and critically evaluate the usage to avoid misuse. MSD should take immediate action to initiate the required formulary revision and include most required Non Formulary items to the formulary based on the recommendations of the National Drug and Therapeutics Committee.

10. LP of special items

Local purchasing of special items must strictly done in concurrence with the section 7.11 of the Guidelines for procurement of pharmaceuticals & medical devices of a consumable nature (2022) by the Ministry of Health and Ministry of Finance, Economics Stabilization and National Policies.

Further to section 7.11, Special items can be locally purchased based on requirement. Such LP requests must be initiated by the treating Consultant with justification and must be approved by a Special Institutional Committee.

Special Institutional Committee should consist of a 3 member panel consisting the following officers: The Director (Head of the institution), a Consultant of the relevant field (not the same consultant who initiated the LP), and an Independent consultant/EXPERT who does not belong to the specialty the patient is treated but is related to the treatment method. (Ex – If the special item is an Antibiotic for a pediatric patient and requested by Pediatrician 'A ', the committee should have the pediatrician-'B' and a microbiologist). Such committees should be appointed by the Head of the Institution at the beginning of the year. Committee approval should be sent to the MSD through the Swastha system.
LP requests for Special items must follow the regular procedure hereafter and should get the approval of MSD.

The Institutional Drug and Therapeutics Committee and National Drug and Therapeutics Committee should monitor the use of special items and critically evaluate the usage.

11. Emergency Procurement of Medical Supplies

This should adhere to section 7.7 of the Guidelines for procurement of pharmaceuticals & medical devices of a consumable nature (2022) by Ministry of Health and Ministry of Finance, Economics Stabilization and National Policies.

12. Monitoring of LP Process

LP process must be monitored and critically evaluated at the Institution level by the Institutional / Regional Drug and Therapeutics Committee. At national level it should be monitored and critically evaluated by the National Drug and Therapeutic Committee.

The overall LP process in the country should be monitored by the MSD.

ANNEXES

GUIDELINES FOR

PROCUREMENT OF PHARMACEUTICALS

&

MEDICAL DEVICES OF A CONSUMABLE NATURE

TABLE OF CONTENTS

ACRONYMS

MRI - MEDICAL RESEARCH INSTITUTE

NMRA - NATIONAL MEDICINES REGULATORY AUTHORITY

MOH - MINISTRY OF HEALTH

MSD - MEDICAL SUPPLIES DIVISION/MINISTRY OF HEALTH

PE - PROCURING ENTITY

SPC - STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

SPMC - STATE PHARMACEUTICALS MANUFACTURING CORPORATION

SLR - SRI LANKA RUPEE

SLPMA - SRI LANKA PHARMACEUTICAL MANUFACTURERS' ASSOCIATION

NMQAL - NATIONAL MEDICINES QUALITY ASSURANCE LABORATORY

NFR - NATIONAL FORECASTED REQUIRMENT

DEFINITIONS

Unless the context otherwise requires, capitalized terms used in these Guideline for the Procurement of Pharmaceuticals & Medical Devices and its schedules, shall have the meanings ascribed to each of them herein below.

For the purposes herein capitalized terms not defined herein shall have the same meaning ascribed to them in the Procument Guidelines-2006 to the extent required.

ABC Value Analysis	means methods by which pharmaceuticals are divided according to their annual usage (unit cost times annual consumption),into Class A items (the ten (10) to twenty (20) percent of items that account for seventy five (75) to eighty (80) percent of the funds spent).Class B items (with intermediate usage rates), and Class C items (the vast majority of items with low individual usage ,the total of which accounts for five (5) to ten (10) percent of the funds spent).
Accessory	means an article which is intended specifically by its manufacturer to be used with the "parent" Medical Device to enable the Medical Device to achieve its intended purpose.
Adverse Medicine Reaction	means any unexpected dangerous reaction to therapeutic products. An unwanted effect caused by the administration of a therapeutic product. The onset of the adverse reaction may be sudden or develop over time.
Association	means associations related to health care including but not limited to: *Diabetes Association of Sri Lanka* *Health Information Society of Sri Lanka* *Independent Medical Practitioners Association* *Sri Lankan Association of oral and Maxillo - Facial surgeons* *Sri Lanka Association of pediatric Surgeons* *Sri Lanka Association of Urological Surgeons*

Sri Lanka Dental Association
Sri Lanka Heart Association
Sri Lanka Medical Association
Sri Lanka Medical Educations
Sri Lanka Society of Gastroenterology

Base Line Year: means Year 2016

Borderline products means the products having combined characteristics of medicines and foods, medicines and medical devices or medicines and cosmetics and in deciding whether a product is a borderline product the following shall be taken into consideration:-

a) the intended use of the product (or its primary function) and its mode of action;
b) the therapeutic claims that the manufacturer makes about the product(claims to treat or prevent disease or to interfere with the normal operation of a physiological function of the human body);
c) the pharmacological active substance(s), if any, used in the produ
d) the concentration of the active substances;
e) the level of efficacy of the active substance of the product; and
f) the ingredients used and the concentrations at which they are used.

Change in Law means any change to existing legislation including the introduction of new laws and the repeal of, or modification of existing laws of, and which relates to taxation or imposes rationing or relates to duties and other import/export levies, which in each case is beyond the control of the supplier/manufacturer's responsibilities under the contract.
means Professional colleges related to health care including but not limited to:

College *College of Anaesthesiologists and Intensivist of Sri Lanka*
College of General Practitioners of Sri Lanka
and Head and Neck Surgeons

College of Opthalmologists of Sri Lanka
College of Otorhinolaryngologists
College of Medical Administrators of Sri Lanka
College of Microbiologists
College of Pathologists of Sri Lanka
Sri Lanka College of Microbiologists
Sri Lanka College of Psychiatrists
Sri Lanka College of Pulmonologists
The College of Surgeons of Sri Lanka

Consultant	means medical/dental specialists who have been certified as consultants by the Medical Council of Sri Lanka.
Contraceptives	means the intentional prevention of conception by artificial or natural means Artificial methods in common use include preventing the sperm from reaching the ovum (using condoms, diaphragms, etc.) , inhibiting ovulation (using oral contraceptivepills),preventing,implantation(using intrauterine devices), killing the sperm (using spermicides), and preventing the sperm from entering the seminal fluid (by vasectomy).
Critical Products	means the same as described with reference to vital products herein below.
Drugs	means Medicines as defined herein below.
Effectiveness	means clinical effectiveness when it produces the effect intended by the manufacturer relative to the medical condition.
Efficacy	means generally Effectiveness under an ideal controlled setting.
Essential Medicines List (SL –EML)	means the publication entitled “National List of Essential Medicines”(SL –EML)Report of the Expert Committee on Essential Medicines, 2009, Fourth Revision published by the MOH or any subsequent revisions thereto.
Essential Products	means products which are intended to be available in the health system at all times in adequate amounts, appropriate dosage forms and assured quality at reasonable price and includes the

	Medicines listed in Essential Medicines List.
Force Majeure	means an event or circumstance or situation which is beyond the reasonable control of a party and is not foreseeable, is unavoidable and which makes a party's performance of its obligations under the contract impossible or so impractical as to be considered impossible under the circumstances and shall include: • Acts of God, such as exceptionally adverse climatic conditions, lightning, earthquake, cyclone, flood, volcanic eruption;or • Rcontamination, epidemics, quarantine restriction or ionizing radiation, or • An act of war(whether declared or undeclared, invasion, armed conflict, blockade, embargo, riot ,insurrection, terrorist or military action, civil commotion, revolution, sabotage; or • Expropriation or compulsory acquisition by any governmental agency or any other government intervention in its sovereign capacity. Force Majeure shall not include the inability of the PE to make payments that are due to the supplier/manufacturer under the agreed terms of contract.
Generic	means a multisource pharmaceutical product which is intended to be interchangeable with the comparator product. It is usually manufactured without a license from the innovator company and marketed after the expiry of patent or other exclusivity rights with established pharmacopoial specifications and reference standards and are often marketed under international non-proprietary name(INN);
Generic Medicine	means medicine that : a) Has the same quantitative composition of therapeutically substances, being substances of similar quality to those usec

registered medicine;

b) Has the same pharmaceutical form;
c) Is bioequivalent; an
d) Has the same safety and Efficacy properties;

Good Manufacturing Guidelines	means good manufacturing guidelines issued by WHO.
Good Manufacturing practices (GMP)	means that parts of Quality Assurance which ensures that products are practices (GMP)consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization or product specification.
Government	means the government of the Democratic Socialist Republic of Sri Lanka.
Hospital Formulary List (HFL-Sri Lanka)	means (the list of medicines compiled by the MOH including Essential (HFL-Sri Lanka) Medicines and medicines requested by the different professional colleges)
Identity	means presence of the correct active ingredient in a pharmaceutical product.
Label	means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencil, marked, or impressed on, or attached to a container of pharmaceutical product or Medical Device.
Labelling	means all the printed information included with prescription medicine, over-the -counter medicine or any dietary supplement. They're strictly regulated by the National Requlatory Authority and provide plenty of useful information savvy healthcare investors use to evaluate a company's products.

	Lead Time: means the time that is taken from the receipt of the procurement request ending with a confirmed order being placed for a particular Product.
Limited Source Products	means a) Pharmaceutical products which are pharmaceutically Equivale are available from a limited number of manufacturers; b) Medical Devices which share a common generic description referred to in the Global Medical Device Nomenclature (GMDN) and/or Universal Medicine Device Nomenclature system and are available from a limited number of manufacturers.
Manual on the Management of Drugs	means a publication entitled "Manual on the Management of Drugs"Second edition, 2008 published by the MOH and Any subsequent revision thereto.
Medical Devices	Means any instrument, apparatus, appliance, implant, machine,reagent for in vitro use,software,material or other similar or related article,intended by the manufacturer to be used,alone or in combination,for human beings,for one or more of the specific medical purpose(s) of: a) monitoring, prediction, prognosis, treatment or alleviation of disease; b) treatment, alleviation of or compensation for an injury; or disability; c) Investigation, replacement, or modification or support of the anatomy or of a physiological or pathological process or state, d) supporting or sustaining life; e) providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations; and which does not achieve its principle intended action by pharmacological, immunological or metabolic means,in or on the

human body but which may be assisted in its intended function by such means.

The following products shall also be deemed to be medical devices:

a) Device for the control or support of conception
b) The care of human beings during pregnancy and at and after birth of the off-spring,including care of the off off-spring and includes a contraceptive device but does not include a medicines.

c) Products specifically intended for the cleaning,disinfection,sterilization of device,aids for persons with disabilities,and devices for in vitro fertilization or assisted reproduction technologies.

Medicines (Drugs) means:

a) Any substance or mixture of substances, manufactured, sold offered for sale or represented for use in–

I. the diagnosis, treatment, mitigation or prevention of disease, abnormal physical states or the symptoms thereof in man or animal;

II. restoring, correcting or modifying functions of organs in man or animal;

b) A medicine or combination of medicine ready for use and placed on the market under a special name or in a characteristic form, both patent and non-proprietary preparations;

c) a product made out of medicinal herbal extract;

d) nutraceutical with therapeutic claims; and

e) vaccines and sera,but does not include an Ayurvedic medicine or Homeopathic medicine.

Medical Equipment means any machine, appliance, software or related article including any component, part or Accessory thereof, which by nature is not a consumable product and is intended by the manufacturer to be used, alone or in combination.

Multi –Source Product means pharmaceutical products or Genric products which are pharmaceutically Equivalent and are available from a wide range of

	worldwide manufacturers with established pharmacopoial specifications and reference standards and are often marketed under international non-proprietary name (INN); and Medical Devices which share a common generic description referred to in the Global Medical Device Nomenclature (GMDN) and/or Universal Medical Device Nomenclature System and are manufactured by world-wide manufacturers.
Non-Essential products	means products which are neither Critical nor Essential and refers to pharmaceuticals classified as “non-essential drugs” in the SL-EML
National Health Policy	means the publication entitled “National Health Policy 2016-2025” by the MOH.
National Health Strategic Framework For Health Development 2016-2025	means the publication entitled “National Health Strategic Framework for Health Development 2016-2025” published by the MOH.
National Medicine Regulatory Authority (NMRA)	means the authority established pursuant to the National Medicine Regulatory Authority Act No 5 of 2015 as amended and which is responsible for the regulation and control of registration, licensing, manufacture, importation and all other aspects pertaining to medicines, medical devices borderline products and for the conducting of clinical trials in a manner compatible with the National Medicines Policy.
The National Procurement Commission	means the Commission which was established under Chapter XIX Constitution Commission of the Democratic Republic of Sri Lanka pursuant to the enactment of the 19th amendment to the Constitution.
National Medicines Quality Assurance Laboratory (NMQAL)	means the laboratory established pursuant to Section 38 of the NIMRA.
Orphan Medicines (Drugs)	means a medical product intended for the treatment of a rare disease.The designation of a medicine as an “Orphan” shall be carried out by the NMRA.

National Control Laboratory	means the Department of Vaccine Control of the MRI which is National Control Laboratory for Sri Lanka
Orphan Medical Devices	means a pharmaceutical agent developed to treat medical conditions which,because they are so rare,would not be profitable to produce without government assistance.The conditions are referred to as orphan diseases.
Nutraceuticals	means a product isolated or purified from food which is generally sold in medicinal form not usually associated with food and provide physiological benefit or protection against chronic disease.
Performance	Means Effectiveness and other factors such as technical functions and others closely related to safety.
Pharmaceuticals	means collectively Medicines, Borderline products and Nutraceuticals.
Pharmaceutically Equivalent	means pharmaceutical products that have identical amounts of the same active chemical ingredients in the same dosage form and that meet the identical compendial or other applicable standards of strength, quality and purity.
Pharmacovigilence	means the science and activities relating to the detection, assessment,understanding and prevention of adverse effects or any other medicine -related problem/medicine safety issues.
Price Revision Formula escalation	means a formula which shall provide for price escalation well as de-escalation as may be deemed appropriate, taking into account the following factors: *price of Raw materials;* *change in Law;* *change in freight charges; and* *Exchange Risk*
Procuring Entity	means the Ministry of Health.
Procurement Guidelines	means the Procurement Guidelines for Goods and Works -2006

	and any subsequent revisions made thereto.
Products	means collectively,pharmaceuticals ,Nutraceuticals, Borderline products and Medical Devices of a consumable nature.
Quality	means a) for pharmaceuticals an assessment of product compliance with pharmacopeial specifications concerning its identity, purity, potency and other characteristics, such as uniformity of the dosage unit, bio-availability and stability b) for Medical Devices compliance with international, regional or national, quality system Standards. Which reaches the patient is safe, effective and acceptable to the patient.
Radiopharmaceuticals	means medicinal product which, when ready for to use, contain one more radionuclides included for medicinal purposes.
Safety	Refer pharmacoviligence.
Single Source Product	means a product which Is generally under patent and is available only from one manufacturer.
Stability	means the ability of a pharmaceutical product to retain its properties relatingto chemical, physical microbiological and bio-pharmaceutical aspects within specified limits throughout its shell-life.
Standards Consistently Medical	means technical specifications or other precise criteria to be used consistently as rules, guidelines or definitions of characteristics, to ensure that the Medical Device to be procured is fit for that purpose and which are adopted as the requisite standards for Sri Lanka as determined by the NMRA.
Uniformity of Dosage Form	means consistency of dosage units with regard to appearance, size, shape, weight/volume and amount of active substance in each unit.

Vaccines	means highly regulated, complex biologic products designed to induce a protective immune re-action both effectively and safely.
VEN Analysis	means a system of setting priorities for purchasing drugs and keeping stock, in which drugs are divided according to their health impact into vital, essential,and nonessential categories.
Veterinary Surgeon	means a person registered as Veterinary surgeon or Veterinary practitioner under the Veterinary Surgeons' and practitioner Act No: 46 of 1956.
Vital products	means generally lifesaving pharmaceutical products which are considered as indispensable in treating urgent or emergency medical conditions which generally occur in readily recognizable clinical situations and refers to product categorized as "critical or lifesaving drugs" in the SL –EML.

INTERPRETATION

a) These Guidelines **shall be read in conjunction** with Procurement Guidelines for Goods and Works. The broad principles of procurement outlined in the Procurement Guidelines will continue to be applicable to the extent possible, for the Procurement of Pharmaceuticals and Medical Devices, unless they have been amended or modified in these Guidelines.The singular includes the plural and vice versa.

b) In the event of a conflict or inconsistency between the Procurement Guidelines and these Guidelines for the Procurement of Pharmaceuticals and Medical Devices of a consumable nature the latter shall prevail.

c) These Guidelines shall not be applicable for the Procurement of Medical Equipment and Medical Devices which are not of a consumable nature.

1. SCOPE OF THESE GUIDELINES

To ensure the attainment of the strategic objectives of the procurement of Pharmaceuticals and Medical Devices of a consumable nature, with the aim of improving the delivery of efficacious, safe and goods quality Products to the public at affordable prices.

2 GENERAL PRINCIPLES

All Pharmaceuticals and Medical Devices of a consumable nature to be procured must fulfill Quality, Safety and Efficacy criteria.All Medical Devices procured should satisfy Quality, safety, performance, Effectiveness and Efficacy criteria relevant to the healthcare needs of the public.

2.1 Strategic Objectives

(a) subject to satisfying the criteria stipulated in Guideline number 2 above, procure the most cost –effective Products in sufficient quantities;
(b) ensure supplier reliability with respect to service and adherence to agreed terms and cnditions;
(c) ensure timely delivery to avoid shortages and stock outs;

(d) ensure a level playing field to create competition;and

(e) achieve the aforestated objectives within the shortest possible Lead Times.

For this purpose the baseline benchmark for the lead time revealed in the study repo has been stated as 313 Days (baseline year 2016). The shortest possible lead ti described in the above strategic objective (e) should be equal or less than the abo established benchmark.

2.2 Ethics

All parties involved in the procurement process shall promote good governance practices and ethical conduct for the procurement of Pharmaceuticals and Medical Devices of a consumable nature, to enhance transparency in the process and eliminate corruption, with the aim of delivery of equitable healthcare benefits to the public compatible with the National Health Policy.

2.3 Procurement Plan

2.3.1 The annual procurement plan for the procurement of Pharmaceuticals and Medical Devices of a Consumable nature shall be integrated with the budgetary processes and the National Forecasted Requirements to ensure stock availability.

2.3.2 The Procurement plan should incorporate a schedule of completion dates/ anticipated deliveries.

2.3.3 The Procurement Plan should provide whether a particular Product is required within a single year or multi – year arrangement and as to whether it is to be procured from a domestic manufacturer.

2.4 Role and Responsibility of the Medical Supplies Division of the Ministry of Health (MSD)

2.4.1 MSD is primarily responsible for the selection, estimation, procurement, storage and distribution of Products for the government health sector entities coming under its purview and ensure that adequate measures are in place for handling and storage to prevent contamination, damage and wastage.

2.4.2 Prepare the National Forecasted Requirement (NFR) well in advance for the ensuing year/s based on the estimate/ forecasts provided through the Medical Supply Management Information System(MSMIS). NFR shall consider the Lead Times, re – order levels, safety/buffer stock levels, minimum and maximum stock levels as well as economic order quantities.

2.4.3 Establish shorter procurement Lead Times as performance benchmarks and measure improvements in meeting those benchmarks.

2.4.4 Measure improvements in reducing the number of urgent and local purchases annually with reference to the Baseline Year.

2.4.5 Consolidate the annual estimate and forecasts and place the order with the SPC/SPMC/SLPMA other local manufacturers registered NMRA for the next succeeding years/s to initiate Procurement actions and specify the minimum number of batches/lots required for each order to reduce wastage.

2.4.6 Compute the most economic order quantities taking into account factors including price discounts, Lead Times,stock out costs, storage costs,re-order levels and obsolescence costs as well as funding streams.In furtherance thereof establish a Review Committee nominated by the Secretary MoH.

2.4.7 Implement a robust oversight mechanism to monitor usage and capture reliable consumption data for the Products which shall facilitate the preparation of the NFR and the Procurement Plan efficiently.

2.4.8 Implement outsourced Procurement of select products to the United Nations Office of Project Services (UNOPS) to facilities procurement at reasonable costs, timely deliveries, reduce wastage and for use in Emergency and Urgent situations and pooled procurement schemes with neigbouring countries for select Products in consultation with SPC.

2.4.9 Implement framework contracting arrangements particularly for Vital Products and Products with recurring needs. Implement buy back arrangements for products sourced from domestic manufacturers/suppliers.

2.4.10 Facilitate e-tendering and utilize electronic communication methods to improve functional efficiencies.

2.4.11 Prepare technical specification for the products in conformity with the NMRA reference

standardsand specifications or jointly with NMRA and other relevant agencies/associations and consultants nominated by the relevant college, as may be applicable.

2.4.12 Implement a robust product recall procedure in consultation with NMRA/SPMC/SLPMA and SPC.

2.4.13 Establish a pool of independent reputed laboratories locally and overseas (country of manufacture/exporting country) jointly with the NMRA to carry out mandatory pre and post shipment random sample testing.
(please refer Schedule 3 for a list of such laboratories which shall be updated from time to time)

2.4.14 Implement a robust mechanism to obtain accurate statistics on vaccine wastage rates which will assist the PE to carry out more precise forecasting, and facilities multi – year procurement planning to reduce the potential for over stocking and understocking, resulting in significant cost reduction to the Government.

2.4.15 Take proactive measures to publish at least bi-annually the MoH Hospital Formulary List to facilitate expeditious procurement of products.

2.4.16 Establish a supplier/manufacturer default list under its purview regularly updated with feed back received from the SPC and disseminate such information to the relevantstakeholders.

2.4.17 Impement framework contracting arrangements to the maximum extent possible particularly for Essential Products instead of annual tenders in order to ensure sustainable avalilability

2.4.18 Establish a system to maintain quality assuarance records which shall include product quality complaints, quality assuarance tests performed, results and follow up.

2.4.19 Determine the prices for locally manufactured Products as per decisions of the pricing committee appointed in accordance with the composition approved by the Cabinet of Ministers .

2.4.20 Enter into buy back arrangements with SPMC/SLMPA as contemplated under Section 7.10

2.5 Role and Responsibility of the State Pharmaceutical Corporation (SPC)

2.5.1 Function as the procuring entity on behalf of the Ministry of Health.

2.5.2 Ensure timely procurement of Products which satisfy the criteria stated in Guideline 2 above, at the most reasonable costs.

2.5.3 Formulate and implement framework contracting arrangements to run for longer durations of one to three years to prevent stock outs , reduce Lead Times and minimize the need to resort to Urgent procurements to ensure sustainable availability of Prodcuts.

2.5.4 Liaise with the Medical Supplies Division to compute the most economic order quantities taking into account factors including price discounts lead time, stock out costs, storage costs, re-order levels and obsolescence costs in consultation with the MSD.

For this purpose:

(a) adopt and implement procedural improvements at SPC to shorten procurement Lead Times (11 months) as performance benchmarks, and measure improvements in meeting those benchmarks.
(b) Reduce the number of urgent, and local purchases annually with reference to the Baseline Year in accordance with guidelines issued by the MoH.
(c) Actively track suppliers' leadtimes which shall include information such as the number and value of contracts awarded to a Supplier and purchases made in chronological order.

2.5.5 Implement a harmonized electronic Product inventory control system jointly with the MoH/ MSD to facilitate better inventory control and timely procurements.

2.5.6 Implement a two-envelope system bidding process to the maximum extent possible as a means of avoiding quality failures and minimize wastage especially for Essential and Vital Products.

2.5.7 Facilitate e-tendering and utilize electronic communication methods to improve functional efficiencies.

2.5.8 Maintain and regularly update the data base of defaulted suppliers/manufacturers for bid violations, quality failures, unethical conduct etc and disseminate such information to the MoH/MSD.

2.5.9 Encourage suppliers registered under NMRA to participate in the biding process and promote local sourcing.

2.5.10 Establish a reliable and transparent supplier rating system in consultation with the MoH and regulary monitor supplier performance.

2.5.11 Implements outsourced procurements of selected Products to the United Nations Office of Project services (UNOPS) to facilitate procurement at reasonable costs,timely deliveries,reduce wastage and for use in Emergency and Urgent situations and pooled procurement schemes with neigbouring countries for Select products in consultation with MoH.

2.5.12 Take proactive measures to develop the technical capacity of staff engaged in procurement actions in contarct management.

2.6 Role and Responsibility of the State Pharmaceuticals Manufacturing Corporation (SPMC)

2.6.1 Manufacture select Pharmaceutical Products that fulfil the criteria stipulated in Guideline 2 above.

2.6.2 Take proactive measures to:

(a) Ensure an adequate supply of select Pharmaceutical Products to avoid stock outs;
(b) Improve administrative efficiencies and increased Value for money for the public procurement of select Pharmaceuticals.

2.7 Limits of Authority

PE shall abide by the authority limits in the Procurement Guidelines -2006 (Goods and Works) and any subsequent revisions made thereto.

3 REGISTRATION

3.1 All Products to be procured by the PE shall be registered with the National Medicines Regulatory Authority (NMRA) of Sri Lanka. Pharmaceuticals to be procured shall conform to international standards such as the British Pharmacopoeia, United States Pharmacopeia, Indian Pharmacopoeia and International Pharmacopoeia or when such standards are not available,applicable in-house standards/specifications as may be

determined by the NMRA from time to time.

3.2 The PE shall request the prospective bidders to attach a **certified** copy of the original registration certificate and any subsequent renewal certificates where applicable to the bid documents.–For purposes herein certification shall mean a copy duly certified by the Attorney-at- Law, Notary Public, Commissioner of Peace or Justice of Peace or the Authorized representative of the bidder as the case may be as a "true copy of the original seen by him/her".

3.3

(a) For Products which are imported to Sri Lanka, the registration should also be valid until at least six (6) months after the last consignment of the Products to be procured are due to be received in Sri Lanka.
(b) For Products which are manufactured in Sri Lanka, the registration should be valid for at least six (06) months after the last consignment of the Products to be procured are received by the PE.
(c) The PE shall ensure that the registration so issued has not been automatically cancelled pursuant to section 65 (4) of the NMRA Act.

3.4 If the bidder submits evidence that the Bidder's authorized local agent has applied for renewal of the registration at least six months before the date of expiry of the current registration, to the NMRA in terms of section 64 of the Act as per the relevant gazette notification, this shall be deemed sufficient to satisfy the requirements of registration.

3.5 No contract shall be awarded to any bidder unless the bidder is in possession of a valid certificate of registration demonstrating that the product registration is valid during the period of supply or a valid Waiver of Registration (WOR) issued by the NMRA (Subject to Guildeline 3.6 below) at the time of the closing of the tender Bidder is required to submit certified copies of a valid registration or a valid Waiver of Registartion to MSD when deliveries are made.

3.6 The requirement of registration stipulated above may be waived off in exceptional circumstances which is referred to as Emergency and Urgent Procurements or where there are no registered suppliers/manufacturers for a particular product, upon the issuance of a "waiver of registration" letter by the NMRA, Provided that the NMRA ascertains whether the particular consignment of a Product meets the requisite Quality, Safety and Efficacy criteria and in the case of Medical Devices, satisfies Quality, Safety, Performance, Effectiveness criteria by:

(a) perusing the available documents accompanying the said consignment of Products; and/or
(b) on the submission by the manufacturer/supplier of any additional

documentation as required by the NMRA for the said consignment; and/or on the submission by the manufacturer/supplies of a finished product analysis test report Final product inspection report issued by a recognized independent laboratory which is acceptable to the NMRA.

4. PRE -QUALIFICATION

This process is carried out for the purpose of establishing an initial list of pre-qualified suppliers to expedite the tender process.

4.1 Multi-source Products

41.1

(a) Pre –qualification shall be carried out of Multi-Source products which are registered with the NMRA(Minimum of five Products sources) for the purposes of evaluating manufacturer/authorized distributor capacity and reputation before bids are solicited and must be product specific and linked to specific manufacturing units. At least three suppliers/manufactures to be validated for each product.

4.1.2 Pre-qualified Suppliers/Manufacturers

(b) The list of pre – qualified suppliers/manufacturers for each Product should be revised at least once in every three years. Continuous efforts should be made by the PE to seek out potential suppliers/manufactures in order to maintain competitive pressure on established suppliers/manufactures that had been pre-qualified previously.

(c) If the PE determines that there are new market entrants or new applicants for any specific product for which there is already an established list of suppliers/manufacturers who have been selected after a pre –qualification process, the PE may at its own discretion, at any time, pre-qualify such potential new suppliers/manufacturers on the most recently used and identical criteria by which other suppliers/manufacturers have been pre-qualified, for that specific product, in order to maintain competition.

(d) The PE shall ensure that the Pre-qualification criteria for any specific product are consistently applied to all such potential suppliers/manufactures and the process is carried out fairly and transparently.

(e) The Pre-qualification process referred to above shall be based on

documentation.The PE shall, particularly in the case of new suppliers/manufacturers, for whom there is no past track record,verify the authenticity of documentation submitted by any such supplier/manufacturer pertaining to licensing aspects, by independently obtaining confirmation from the regulatory or licensing authorities which purportedly have issued such certification.

(f) The PE, shall also obtain independent confirmation from the relevant regulatory or licensing authority to ensure that the suppliers/manufacturers who are to pre-qualified have not been blacklisted/suspended by such regulatory/licensing authorities nor have had their products recalled for quality failure during the preceding three (03) years.

4.1.3

(a) Once pre-qualified, the supplier/manufacturer for any specific product shall be deemed to remain pre-qualified until the next revision, except those suppliers/manufacures who have been disqualified by the PE for non-compliance with contractual obligations or product recalls or failures, or in circumstances resulting in a change in the status-quo of suppliers/manufacturers stated at the pre-qualification stage, which warrants a review of the established list.

(b) Suppliers/manufacturers who did not pre-qualify previously are eligible to re-apply at the next revision.

(c) The PE shall thereafter solicit bids for each product from the list of such pre-qualified suppliers/manufacturers.

4.2 Criteria for Selection of Products for Pre-qualification

4.2.1 ABC and VEN Analysis

The criteria for the selection of products to be pre-qualified shall be determined by the MOH/MSD/SPC using the VEN and/or ABC Value Analysis on the following basis:

(a) All multi-Source Pharmaceuticals products irrespective of whether they are Non-Essential, Essential and Vital products which are categorized as high usage products by the MOH/MSD/SPC shall be pre-qualified no later than twenty four (24) months from the date these Guidelines come into effect;

(b) All Multi-Source Pharmaceuticals products irrespective of whether they

are Non-Essential, Essential and Vital products which are categorized as medium usage products by the MOH/MSD/SPC shall be pre-qualified no later than thirty six (36) moths from the date these Guidelines come into effect.For the purposes herein there shall be at least be five suppliers/ manufacturers**.**

(c) Every effort shall be made to ensure that Medical Devices which are categorized as high and medium usage products by the MOH/MSD/SPC shall be pre-qualified no later than thirty six (36) months from the date these Guidelines come into effect.

4.2.2 The PE may at its own discretion pre-qualify any other Multi-Source Pharmaceutical and Medical Devices as it considers necessary.

4.2.3 PE shall to the maximum extent possible carry out procurement of vaccines through WHO pre-qualified manufacturers/suppliers to ensure Safety and Efficacy of the vaccines.

4.2.4 Uninterrupted Supply during pre-qualification

The PE shall ensure that the carrying out the pre-qualification process shall not result in any disruption of the supply of pharmaceuticals and Medical Devices of a Consumable nature and cause stock outs.

4.3 Criteria for Pre-qualification

4.3.1 Criteria for pre-qualification must be clearly stipulated in the pre-qualification document and should include but not limited to the following:

a) **Required Annual Average Turnover** of the supplier/manufacturer/ should be at least three (03) times the estimated value of the contract. Annual turnover statements and copies of balance sheets and profit and loss account for the three immediately preceding years duly certified by the company's auditors must submitted with the bid.

b) **Required annual production capacity** of the supplier/manufacture should be at least three times the quantity specified under the contract.

c) **Required number of similar contracts completed** depending on the size and

complexity of the proposed contract a range between three to five within the last five (05) years is acceptable.

d) **Required Quality Assurance**

(a) The PE shall ascertain if the NMRA certification provides sufficient assurance with regard to the quality the product to be procured.

(b) The manufacturer's Letter of authorization must be submitted by the bidders as a mandatory requirement.

The following provisions are for the purpose of general reference:

I. In the case of manufacturers they must provide the following

(x) In the case of pharmaceuticals a valid certificate of registration (Certificate of pharmaceutical Product **(CPP)** issued by the regulatory/competent authority in the country of manufacture that the Pharmaceutical item to be procured has been authorized to be placed in the market for sale and use in the country of manufacture. This certificate should indicate the number of permit and date of issue. If the product is not permitted to be marketed and used in the country of manufacture, reason for such action should also be stated-(a model CPP is given in schedule 2), and in the case of Medical Devices a valid **free sale certificate** issued by the regulatory /competent authority in the country of manufacture that the Medical Devices item to be procured has been authorized to be placed in the market for sale and used in the country of manufacture should be submitted. This certificate should indicate the number of permit and date of issue. If the Product is not permitted to be marketed and used in the country of manufacture, reason for such action should also be stated; and

(y) For Pharmaceuticals, the CPP should also certify that the manufacturing plant in which the particular Pharmaceutical to be procured is produced, has received a satisfactory GMP inspection certificate in line with the WHO certification scheme on pharmaceuticals moving in International commerce from the regulatory/competent authority from the country of manufacture of goods or has been certified by the competent authority of a member country of the Pharmaceutical Inspection Convention and has demonstrated compliance with the quality standards during the past two years, and in the case of Medical Devices certification that the manufacturing plant in which the particular

Medical Device to be procured is produced has received a satisfactory GMP inspection certificate in line with WHO has to be submitted.

PE shall ensure that there is stringent quality assurance certification from the National Control Authority of the manufacturing country for Vaccines which are procured from non WHO pre-qualified manufacturers, to ensure they meet the required criteria.

II. In the case of bidders who are not manufactures, the bidder should provide evidence of being duly authorized by the manufacturer, meeting the criteria stipulated in Guideline 4.3 (d) (x) &(y) above;

III. If the product certificate is submitted through the manufacturer or the importing agent rather than receiving directly from the issuing regulatory/competent authority, then the PE should seek supplementary references, for example from purchase with previous experience with that bidder.

IV. The bidder should submit duly certified copies of the Market Standing Certificate for each product quoted issued by the relevant regulatory authority.

V. An award shall be denied to any bidder who fails to meet the criteria for quality assurance stipulate above.

(e) Required number of years of manufacturing experience

The bidder should have manufactured and marketed the specific Pharmaceuticals and the Medical Devices to be procured for at least a period of three years and for similar goods for at least five years.Bidders wishing to pre-qualify for products that they do not manufacture must Submit documentary evidence corresponding to the primary manufacture of goods who shall comply with these manufacturing requirements.

(f) Required experience on packaging and distribution

The bidder should provide proof of experience with knowledge of modesof distribution and transportation of Pharmaceuticals under logistical and climatic similar to Sri Lanka. It should provide names of countries to which the firm ha including (package, distributed and transported) Pharmaceuticals products wor three times the value of Contract within the past three years.

4.3.2 Monitoring Pre-qualified Suppliers'/Manufactures' of the manufacturer's

Performance

Selected pre-qualified manufactures/authorized distributor of the manufacturers should be monitored by the PE through a process which considers lead time, compliance with contract terms, product quality, remaining shelf-life,compliance with specifications/standards, packaging and labeling instructions etc, service reliability delivery time and financial viability.

Any supplier/manufacturer of Multi-Source products whose performance is deemed unsatisfactory by the PE, particularly in product quality and delivery time shall not be eligible to participate in any future bidding process for that particular product for a at least two (02) years.

4.3.3 Invitation to pre-qualify/pre-qualifying documents

(a) The invitation to pre-qualify for bidding on specific contracts or groups of similar contracts shall be given wide local and international publicity. The PE shall publish such advertisement:

(i) in at least one widely circulated in national newspaper;
(ii) transmit such invitations to embassies and trade representatives of countries where suppliers and manufactures are likely to participate;
(iii) post them in relevant websites such as the SPC and MOH websites.

(b) The pre-qualification document setting out the scope of the contract (i.e. the magnitude of the contract) and a clear statement of the requirements for qualification shall be issued to the suppliers/manufactures who responded to the invitation to pre-qualify.

(c) The results of the pre-qualification shall be informed to all the applicants who have applied to be pre-qualified for a particular product, in response to such advertisement.

(d) After the pre-qualification is completed, applicants who meet the specified criteria for a particular product (qualified prospective bidders) will issued the bidding documents at the time the PE at its discretion wishes to invite bids for Such product.

(e) Verification of the information provided in the submission for requalification shall be confirmed at the time of award of contract. No award shall be made a bidder who is determined to no longer have the capability or resources to

successfully perform the contractual obligations.

(f) The PE may at its own direction and where it deems necessary, carry out physical inspection of the manufacturing facilities of any supplier / manufacturer which it intends to pre-qualify for a particular product/s for purposes of verifying the information provided by such supplier/manufacturer. *The composition of the inspection team shall be as stated in Section 10.2.*

5 Post Qualification

5.1

a) Post-qualification of supplier/manufacturer shall be carried out for each particular product, when the supplier/manufacturer of such product has not been pre-qualified in accordance with the provisions of these Guidelines.

b) Post qualification of supplier/manufacturers shall be carried out to:

(i) ensure that the lowest evaluated, responsive, eligible supplier/manufacture is qualified to perform the contract in accordance with the qualification requirements;

(ii) eliminate substandard suppliers/manufacturers; and validate supplier's/manufacturer's capacity to supply good quality products at the optimum price for the Government.

5.2.1 The criteria to be met shall be set out in the bidding documents which shall include the criteria stipulated in Guideline 4.3.1(a), (b), (c), (d), (e) and (f) above.

5.2.2 For the avoidance of doubt, any supplier/manufacturer who fails to meet the quality assurance criteria stipulated in 4.3.1 (d), shall be rejected during bid-evaluation.

5.3 If the supplier/manufacturer whose bid is determined to be the lowest evaluated cost is unable to satisfy the criteria for post qualification stipulated above, such bid shall be rejected. In such event, the PE shall make a similar determination for the next lowest evaluated bidder

5.4 Suppliers/manufacturers who have been pre-qualified, verification of the information provided in the submission for pre-qualification shall be confirmed at the time of award of contract and award shall be denied to a bidder that is judged to no longer have the capability/resources to carry out the contract successfully.

5.5 The PE may its sole discretion and where it deems necessary, carry out physical inspections of the manufacturing facilities of any supplier/manufacturer who has been determined to offer the lowest evaluated cost for a particular product/s, for purposes of verifying the information provided by such supplier/manufacturer, prior to contract award. *The composition of the inspection team shall be as stated in Section 10.2.*

6 STANDARD BIDDING DOCUMENTS, BID EVALUATION AND CONTRACT AWARD

6.1 Bidding Documents

The standard bidding documents shall contain provisions to ensure that the following mandatory requirements are met:

(a) Ensure uniformity in the bidding process;
(b) Increase competition with the aim to reduce costs; and
(c) Reduce review time.

6.2 Bid Evaluation

6.2.1 Except to the extent modified hereto the PE shall strictly comply with the general principals relating to Bid Evaluation set forth in the Procurement Guidelines.

6.3 Evaluation Criteria

a) PE shall adopt a pass/fail evaluation criteria for the purpose evaluating the bids. A bidder who fails to satisfy all the stipulated criteria for evaluation shall be rejected.

b) Bids which are submitted with cross conditions such as *"subject to availability"* "*supplies will be made as and when supplies are received* "*at current market rates*" shall not be allowed.

c) A bid for a product that is deemed to be the lowest evaluated substantially responsive, shall not be rejected by the TEC, during bid evaluation, merely for the reason that another product is of a higher quality/standard, provided that such product meets the quality assurance criteria stipulated in 4.3.1(d). The specification of the product offered with the bid shall match with the tender specification and any form of alternative offers shall be rejected.

d) If the product offered deviates from NMRA accepted product details and unless the bidder in such instance submits a declaration along with the bid certifying NMRA accepted product details, such bid shall be rejected.

e) A bid submitted by a bidder who has engaged in corrupt, collusive, coercive or obstructive practices either directly or indirectly when competing, shall be rejected and black listed.

6.4 The Composition of the Technical Evaluation Committee (TEC)

6.4.1 Except in Emergency and Urgent Procurements made hereunder, the TEC for purposes herein shall be comprised as follows:

- Representative of the Ministry of Health – *rank not below Director*
- Representative of the SPC - *rank not below Deputy General Manager*
- A minimum of two consultants in the relative specialty nominated by the relevant College
- Representative of the Treasury
- Representatives of the MRI and Epidemiology Unit for vaccines – rank not below Consultant in the relevant specialty.

7 METHODS OF PROCUREMENT

Pharmaceuticals and Medical Devices of a consumable nature may be procured by International Competitive Bidding (ICB), National Competitive Bidding (NCB), Limited /restricted International Competitive Bidding (LIB), in accordance with the applicable provisions stipulated in the Procurement Guidelines, subject to any modifications contained herein.

7.1 International Competitive Bidding (ICB)

ICB shall be used, when the capacity of the domestic contractors, suppliers and service providers are limited and the advantage of ICB is evident.

a) For Pharmaceuticals, ICB is appropriate for Multi-Source Products which generally have well-established long history of use, pharmacopoial specifications and reference standards and are often marketed under international non-proprietary name.

b) For Medical Devices of a consumables nature, ICB is appropriate for Multi-Source Products which generally have well established Standards.

c) ICB shall be used when the PE determines that the domestic capcatiy to

manufacture a particular Product is limited and the advantage for ICB is evident.

7.2 ICB with pre-qualification of suppliers/manufacturers

a) An invitation to bid is issued to group of pre-qualified manufacturers or suppliers who have been selected after carrying out a pre-qualification process in accordance with the Guideline 4 above.

b) **ICB without pre-qualification**
An invitation to bid is issued to worldwide suppliers/manufacturers. This method is appropriate for large volume purchases.

7.3 National Competitive Bidding (NCB)

Bidders supplying Products manufactured locally should demonstrate that the locally manufactured products meets comparable international standard,/ NMRA approved in-house standards in instances when there are no declared pharmacopeia standards and that their prices are competitive with international pricing.

7.4 Limited/restricted international Competitive Bidding (LIB)

a) This method is appropriate for Limited Source Products.

b) For Pharmaceuticals if pharmacopoeial quality standards and publicly available reference standards for testing are not available, the PE may validate the quality of such pharmaceutical product by reference to international or intra-governmental organizations.

Reference to the following sources are encouraged:

(i) United Nation Procurement Quality and Sourcing Project, list of pre-qualified suppliers who are deemed suitable for procurement by UN Agencies; and/or

(ii) The product authorized for use by the appropriate regulatory/competent authority of a member of the pharmaceutical Inspection Convention or an entity participating in the Pharmaceutical Inspection Corporation Scheme; and/or the product authorized for use by the regulatory/competent of a member of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for human use.

c) For Medical Devices, if publicly available reference standards for testing are not available, the quality of the product must be ascertained by reference to standards as determined by the NMRA/ NMRA approval laboratory.

7.5 Limited/Restircted National Competitive Bidding (LNCB)

This method is appropriate for limited Products which have been registered with the NMRA.

7.6 Shopping

7.6.1 This method is only appropriate for procuring small amounts of readily available "off the shelf" Pharmaceuticals registered with the NMRA/established pharmacopoeial reference standards/NMRA approved in-house Standards and Medical Devices with established Standards from several local or foreign suppliers/manufacturers, and when a bidding process will be unnecessarily expensive and resource intensive.

7.6.2 (a) To ensure competitive prices, at least three quotes must be obtained.

If there are suppliers/manufacturers who have been pre-qualified by the P.E.for the specific product/s to be procured, questions should in the first instance be obtained from such suppliers/manufacturers. Subject to above,quotations may be obtained from suppliers/manufacturers who are registered by the MSD/SPC/NMRA as may be applicable.

7.7 Emergency Procurements

7.7.1 For the purposes herein, Emergency shall be deemed to be a situation which has arisen due to either of the following courses:

(a) Man-made or natural disasters which is declared as an Emergency by the Government of Sri Lanka; or

(b) The sudden outbreak of disease as declared by the Government/ MoH.

7.7.2

a) The PE shall in such exceptional circumstances be authorized to procure the required quantities of Pharmaceuticals and Medical Devices, without resorting to any of the procurement methods stipulated in Guideline 7 from:

State Organizations or UN Agencies where appropriate;

- *established list of suppliers/manufacturers/authorized distributors pre qualified as per the criteria stipulated in these Guidelines;*
- *Suppliers/manufacturers registered by the MSD/SPC/NMRA where appropriate*

b) If the product to be procured is not available from the above source the PE shall procure such items from:

- local authorized agents for such particular product;
- any world wild manufacturer/s, supplier/s, distributor/s.

7.7.3

a) Except in the case of Single Source or Limited Source products, PE shall ensure that the suppliers/manufacturers/authorized distributors have not over priced the products to be sourced. For this purpose the PE shall refer to historical prices.

b) For Pharmaceutical products the PE may also refer to the Annual International Drug Price Indicator Guide published by the Management Sciences for Health.

Website:www.msh.org/
Address:
Development Offices, MSH, 165 Allandale Road,Boston, MA
Telephone: (617)5247799
Fax: (617)5240783
Email: development@msh.org

c) PE may also consult with neighboring countries to check on prices offered to them by such Suppliers and manufacturers

Limits of Authority

7.7.4

- Secretary to the Ministry of Health -upto a maximum limit of LKR 50 (fifty)million or equivalent thereof in any other foreign currency per event;
- Director General Health Services -upto a maximum limit of LKR 25 (twenty) million or equivalent thereof in any other foreign currency per event;
- Deputy Director General MSD-upto a maximum limit of LKR 10 (ten) million or equivalent thereof in any other foreign currency per event;
- Chairman, SPC upto a maximum limit of LKR 10 (Ten) million or equivalent thereof in any other foreign currency per event or such other limits that may be determined by the Government from time to time.

7.8 Urgent Procurements

7.8.1 Pharmaceutical and Medical Devices of a consumable nature may be procured from the domestic and/or international market in very limited quantities as an urgent procurement and until the resumption of normal supply, in a situation which has arisen due to one or more of the following courses:

a) withdrawal of a product/s due to quality failure; or
b) Shortage of product/s due to suppliers default; or
c) Shortage of a product/s due an event/circumstance of Force Majeure as defined herein; or

On a written request made by a Consultant in order to treat a grave/life threating situation of a patient, on a case by case basis.

d) In the aforesaid circumstances every effort shall be made to procure such products initially from the list of pre-qualified suppliers/manufacturers or with the approval of the relevant procurement Committee.

7.8.2

a) Except in the case of Single Source of Limited Source products, PE shall also ensure that the suppliers/manufacturers have not over priced the Pharmaceuticals to be sourced by reference to historical prices.

b) For Pharmaceutical products the PE may also refer to the Annual International Drug Price Indicator Guide published by the Management Sciences for Health.

7.8.3 In Circumstance where an Urgency have arisen due to withdrawal of products as a result of quality failure then the PE shall ensure that suppliers/manufacturers are disqualified from participating in any future bidding process for that particular product

at least for a minimum period of Two (02) years.

7.8.4 a) In circumstances where an urgency has arisen due to suppliers/manufacturers default in complying with contractual obligations, the PE shall issue a "show-cause notice" to such suppliers/manufacturers.

b) If the PE is not satisfied with the explanation offered by such suppliers/manufacturers,PEshall ensure that such suppliers/manufacturers are disqualified from participating in future bidding process for that particular product at least for a minimum of two (02) years.

7.8.5 The names of suppliers/manufacturers who are disqualified under these provisions shall be promptly added to the defaulted suppliers/manufacturers data base maintained under the purview of the MoH.

7.8.6 Any additional costs that are or may be incurred by the PE due to such default on the part of manufacturer/supplier should borne by such manufacturer/supplier and a provision to this effect should be included in the Bidding documents.

7.8.7 Limits of Authority

- Secretary to the Ministry of Health -upto a maximum limit of LKR 4 (Four) million or equivalent thereof in any other foreign currency per event
- Director General Health Services -upto a maximum limit of LKR 2 (Two) million or equivalent thereof in any other foreign currency per event or such other limits as may be determined by the Government from time time.

7.9 Purchases from Non-Manufacturers

7.9.1 The PE is authorized to purchase products from non-manufacturers of such products only in circumstance when manufacturers or their authorized agents for a specific product have not responded to an invitation to bid/failed to quote for such a product, which has been given due publicity in accordance with the provision of these Guidelines and Procurement Guidelines. In such instance, the non manufacturer must be duly authorized by the manufacturer of the Products to supply such products to Sri Lanka.

7.9.2 If such procurement is made by the SPC on behalf of the MSD, the SPC must obtain the prior approval of Deputy Director General MSD prior to effecting such procurements.

7.10 Purchases from the State Pharmaceuticals Manufacturing Corporation (SPMC)/ Sri Lanka Pharmaceuticals Manufacturers' Association (SLPMA)

The MSD is authorized to negotiate with the SPMC/SLMPA and directly purchase

Pharmaceutical products from SPMC/SLMA, on buy back arrangements provided that the SPMC/SLMPA is able to supply such Pharmaceutical products at a unit price lower than the unit price at which the MoH/MSD purchased such a particular Pharmaceutical products through the SPC at the previous tender or as determined by the Cabinet appointed pricing committee.

7.11 Purchase on demand/specialized purchases

This method shall only be used:

(a) In special circumstances when the particular Pharmaceutical/ Medical Device item is not included in the Sri Lanka Hospital Formulary, but is registered with the NMRA or instances personal user License is pending with NMRA approval as the case may be, on the written request of specialist consultant and shall only be made in generic/brand names stated in the prescription.

(b) Registered local suppliers with pre-agreed prices/rates with MSD, for low value and small quantities.;
(c) Purchases from *Rajya Osu Sala* outlets within applicable authority limits pursuant tp guidelines

Bidding time for purchases made hereunder shall be made at least within three working days and offers shall be invited pursuant to standard criterion approved by the relevant Procurement Committee with the consent of the Chief Accounting Officer.

7.12 Products which have not been registered with the NMRA/Waiver of registration not issued.

8 DIRECT CONTRACTING

8.1 This method is appropriate only in the following circumstances:

(a) For single Source Products; or
(b) Emergency Procurements; or
(c) Urgent Procurement; or
(d) Purchase from SPMC**/** SLPMA in accordance with Guideline 7.9 above;
(e) Procurements from UN Agencies, the WHO, Global Drug Facility Inter-Agency Procurement Services Office or the Green Light Committee; or Equipment/Machine specific Medical Devices and Accessories/consumabal to enable the “parent” Equipment/Medical Devices to achieve its intended use and reduce wastage.

8.2

a) To ensure that the PE obtain competitive prices the PE should have reference to historical prices and Annual International Drug Price Indicator Guide published by the Management Sciences for Health.

b) PE may also consult with neighboring countries on prices offered to them and inquire into the possibility of pooled procurement scheme.

9 TYPES OF CONTRACT

9.1 Contract Options

PE may use any one of the following contract options to enter into contracts with

(a) Fixed quantity – scheduled delivery; or
(b) Estimated quantity – periodic order; or
(c) Framework Agreements.

9.2 Fixed Quantity/Schedule Delivery Contracts

The fixed quantity contract specifies guaranteed quantities and delivery in either one large shipment or partial shipments over the life of the contract.

9.3 Estimate Quantity/Periodic Order Contract

(a) This method may be resorted to only in circumstances when the PE is unable to determine the exact quantities to be purchased due to unknown demand for such products. Hence, the quantity is just an estimate.
(b) The supplier/manufacturer agrees deliver the required quantities on a draw-down system, at an agreed unit rate which is guaranteed for the entire period of the contract.
(c) If the period of the contract exceeds twelve (12) months, a Price Revision formula may be included.

9.4 Framework Agreements

General Principles

9.4.1 (a) A framework agreement shall stipulate terms and conditions under which the PE is able to award individual contracts/purchase orders ("call offs") from potential supplier/manufacturers when the requirements arises, without resorting to a full procurement process.

(b) Framework agreements which are time bond (up to three years) can be entered into with single or multiple suppliers/manufacturers.

(c) Multi supplier framework agreements (minimum of three suppliers/manufacturers) will not bind the PE to a particular supplier and can assist the PE to ensure supply security of products. In the event of a shortfall of one supplier/manufacturer can be replaced by supplier/manufacturer who has singed the Framework Agreement.

(d) Framework Agreement shall not impose any obligation on the PE to purchase the estimated quantity or any quantity from the suppliers/manufacturers who sign the Framework Agreement. No Agreement/Contract shall come into effect until the PE issues a call off order once the Framework Agreement is established. The essential characteristics of the Framework Agreement cannot be modified at the call off stage.

(e) Framework Agreements shall not be carried out in a manner that hinders competition.

(f) Pricing shall generally remain fixed during the validity of the Framework Agreement unless otherwise specified based on economic/market conditions for a particular product justifies the inclusion of a Price Revision Formula in the Framework Agreement. In such instances, a Price Revision Formula shall be incorporated into the agreement to avoid on bidding on speculative prices.

9.4.2 Criteria for the establishment of Framework Agreements

(a) This method shall be used:

I. To procure Vital Products, Essential Products and Products with recurring needs to ensure supplier security;
II. Standardized Products (Pharmaceuticals with established

pharmacopoeial reference standards Medical Devices with established Standards);

III. If the PE determines that it will lead to significant reduction in lead times associated with international tenders and stock outs between tenders;

IV. Reduce costs and resources required to carry out a resource intensive full procurement process resulting in overall efficiency gains;

V. Reduce circumstances which compels the PE to resort to Urgent procurements and facilitate prompt acquisition of supplies when the necessity arises for a particular product;

VI. Minimal contractual quantity can be determined;

VII. Supplier/ manufacturer agrees to deliver the Products within the delivery schedules prescribed by the MSD/PE during call offs;

VIII. Products with price volatility;

IX. Reduce stock holding expenses and wastage;

X. Maximizes value for money for the Government.

(b) If the PE determines that there are new market entrants for a particular product subsequent to establishing a framework arrangement and pricing under the said framework arrangement is no longer competitive/ does not represent the best value for money, the PE may consider resorting to a competitive procurement process for such product, whilst ensuring supply security.

(c) PE shall ensure it possesses adequate financial and technical capacity to administer the implementation and management of framework agreements to achieve the aforesaid objectives.

(d) Framework agreements shall incorporate provisions that facilitate entrance of new manufacturers during the course of an existing multi year agreement.

9.4.3 Types of Framework Agreements

(a) Framework Agreement *with a single supplier/manufacturer on fixed terms* where the call off order is made by the PE as per the terms and conditions laid down in the arrangement;

(b) Framework Agreement *with multi suppliers/manufacturers with fixed terms*.

Call of orders shall be made on the basis of the terms and conditions laid down in the agreement. If one supplier/manufacturer is unable to deliver, a call of shall be made with the next available supplier/s.

9.4.4 Procedure

a) Stage 1

i. A competitive procedure as determined by the PE (ICB, LIB, NCB) shall be carried out for selected Product/Products.
ii. Bids submitted pursuant thereto shall be evaluated in accordance with the provisions set forth these Guidelines.
iii. A framework agreement shall be executed with a single or multi suppliers/manufacturers, as the case may be.

b) Stage 2 (Call offs)

i. On the basis of requisitions made by the MSD, specific contracts (Call offs) shall be awarded within the limits of the terms (including price) laid down in the Framework Agreement, from suppliers/manufacturers who have entered into a Framework Agreement for a particular product/products with PE.

ii. When a contract is awarded pursuant to a call off order as aforesaid, the PE nor the supplier/s or manufacturer/s as the case may be shall include terms and conditions that deviate from or substantially alter those terms stipulated in the Framework Agreement for a particular product.

iii. Call off orders shall be communicated in writing and may be made in the usual form of the PE's purchase orders.

iv. Call off orders must be awarded prior to the expiry of the Framework Agreement.

9.4.5 Invitation to Bids for Framework Agreements

Invitation to bids for Framework Agreements shall stipulate the following:

(a) Intention of the PE to establish a framework arrangement;
(b) Whether it is for single or multi supplier/manufacturer framework agreement;
(c) Duration of the proposed Framework Agreement;
(d) Broadly define/Estimate of the quantities and value of call offs anticipated under the framework arrangement;
(e) Procurement method – (LCB, LIB, NCB)
(f) Evaluation and Award criteria; and
(g) Price Revision Formula as deemed required.

9.4.6 Bidding Documents

The following specific terms and conditions shall be incorporated into the bidding documents under framework agreements;

(a) A provision which states that performance or delivery shall be made as per the call off orders;

(b) That the delivery schedule is indicative;

(c) Minimum and Maximum quantity/value during the validity period of the framework agreement;

(d) Specify the minimum lot size for the particular product;

(e) Price Revision Formula if required;

(f) Storage Conditions if not specified by the NMRA in the certificate of Registration;and

(g) Criteria for rejection/elimination of the bidder as may be applicable.

9.4.7 Supplier / Manufacturer Performance under Framework Agreements

PE shall assess Suplier /Manufacturer performance under framework arrangements and compile a list of reliable manufacturers / suppliers who have performed creditably and disseminate such information to the stakeholders.

9.5 Long Term Contracts-Multi-source Products

a) For Multi-Source Products only, PE may award long term contracts for any specific product, for a period exceeding twelve (12) calendar months subject to a maximum of thirty six (36) calendar months.

b) PE shall not enter into any contract exceeding a period of twelve (12) calendar months, unless it has carried out a pre-qulification process in accordance with the provisions contained in these Guideline.

c) The criteria for determining the types of Pharmaceuticals and Medical Devices which may be procured on long term contracts are as follows:
   (i) High and Medium usage products;
   (ii) Products which have been in usage for more than ten (10) years;
   (iii) Pharmaceuticals which have acceptable pharmacopoeial quality standards and publicly available reference standards of testing.
   (iv) Medical Deviceswhich have acceptable Standards.

d) In the above circumstances the value of contract should be sufficiently high to attract competitive bids which results in significant cost advantages to the Government.

e) For contracts exceeding a period of twelve (12) months, a Price Revision Formula which is effective after the lapse of a minimum of twelve (12) months shall be incorporated into the bidding documents.

9.6 Buy Back Agreements

This method shall be used to procure Products from domestic manufacturers/suppliers in accordance with criteria that may be approved by the Cabinet of Ministers from time to time.

10 QUALITY ASSURANCE

10.1 Inspections

a) As a measure of :

i. reinforcing quality assurance, i.e.verify adherence to contract specifications and order completeness; and
ii. inspecting samples of products to spot any gross abnormalities,

Visual pre-shipment inspections may be carried out by the PE , particulary for new suppliers/manufacturers who have no past track record.

b) Inspection in the exporting country prior to shipment may also be arranged for early detection of non-compliance with contract terms or defective products through independent agencies. For such purpose, the PE shall designate and independent agency in the exporting country to carry out inspections/ random quality check prior to export from any agency from the pool of independent overseas laboratories established pursuant to Guideline 2.5.10 above or a WHO recognized laboratory.

c) The Bidding documents must clearly state:

i. The type of inspection which the PE requires;
ii. Where they are to be conducted; and
iii. Identity (by institutions) of representatives of the PE, retained for such purposes.

10.2 Composition of the Inspection Team

Pre and post shipment inspections when required shall be carried out by not more

than five (05) technically competent officers who are appointed by the Secretary, MOH, in consultation with the Director General of Health Services. A representative of the NMRA shall always be present. The other members may represent any of the following institutions:

- *MSD*
- *MRI for vaccines*
- *SPC*
- *NMQAL*

At least one member from any of the above institutions shall be allowed

If the situation so warrants, the Secretary, MOH, may also appoint any member external to the above referred institutions as a member of the inspection team, subject only to the limitation of the number of members.

11 TESTING

11.1 The PE shall carry out pre-purchase testing of samples in order to detect defective products. However, the PE shall bear in mind that the samples may not be representative of the product that will be actually sold or delivered. Hence, the PE shall to the maximum extent possible carry out laboratory analysis of individual batches, either by itself or through international quality control organizations/ laboratories in order to ensure that the product to be sourced meet with the stipulated criteria.

11.2

a) PE shall carry out laboratory testing of random batch samples, mandatorily for new suppliers and manufacturers.

b) PE may carry out micro-biological tests and pharmacological tests for selected Pharmaceutical products.

c) PE shall request supplier/manufacturer post marketing random test reports for at least three batches from an accredited laboratory.

11.3 Pre-Shipment Testing

Pre-purchase/shipment testing,shall be carried out by an independent WHO

recognized laboratory/any agency from the Pool of independent local and overseas laboratories established pursuant to Guideline 2.4.10 above, as determined by the PE, certifying that the product procured meets with the required standards.

This requirement may be waived on a case by case basis for bio-similar products which have been registered with the NMRA.

11.4 Post-Shipment testing

PE shall cause/carry out laboratory testing of post shipment random batch samples and locally sourced products (as may be determined by the PE/MSD) from the NMQAL or any agency from the pool of independent local and overseas laboratories established pursuant to Guideline 2.4.10 above.

11.5 The type of tests which the PE requires, where they are to be conducted must be clearly stated in the bidding documents.

11.6 The costs to be incurred for pre and post shipment testing shall be borne by the supplier / manufacturer and shall be so expressly stated in the biding documents.

11.7 The templete in a generic format for Performance, Quality and Safety Testing (PQS) which is mandated for use by WHO as a means of reporting test results by WHO accredited laboratories can be used as a model format by the PE.

Template can be accessed on the WHO PQS website.

11.8 Testing for Vaccines

PE shall carry out batch/lot testing for Vaccines procured from non WHO prequalified manufacturers in order to verify quality as per the testing policy of the National Control Laboratory, MRI.

12 CONDITIONS OF CONTRACT

12.1 The Contract shall specify that:

(i) the Pharmaceuticals and Medical Devices of a consumable nature to be supplied under the contract shall comply with the

requirements stipulated under section 2 of these Guidelines,

(ii) if all Products are to be shipped to the same destination on the same delivery schedule,

(iii) that the supplier will indemnify the PE against all claims that may arise on account of patent rights, trademarks, proprietary designs or royalties,

(iv) when brand names etc., are given in the specifications it should be specifically stated that standards as well as references to brand names designated in the technical specifications are intended to be descriptive only and not restrictive and bidders may substitute[alternative standards,] brand names, and/or catalog numbers in its Bid, provided that it demonstrates to the PEs satisfaction that the substitutions are Pharmaceutically Equivalent to those designated in the technical specifications,

(v) that the supplier / manufacturer must be ar any additional costs that may be incurred by the PE due to default and on the part of the supplier /manufacture to comply with his contractual obligations particularly in the case of quality and delivery failures,

(vi) if a Force Majeure situation as defined herein arises, the supplier/manufacturer shall promptly notify the PE in writing of such condition and the cause thereof, and shall continue to perform its obligations under the contarct as far as is reasonably practical and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event, unless the supplier/ manufacturer has received written instructions from the PE to the contrary,

(vii) Pre and Post shipment inspections and testing required by the P.E.,

(viii) Stringent quality assurance conditions and penalties for non compliances,

(ix) the PE in its sole discretion has the discretion to spilt the tender among more than one bidder to ensure sustained supply, provided the rates and other conditions of the tender being equal.

13 MISCELLANEOUS PROVISIONS

13.1 General Technical Specifications/Standards

Technical specidications and Standards stipulated in the bidding documents shall be drafted in such a manner in order to promote the broadest competition.

13.2 (a) The general technical specifications shall provide information on:

- Good Manufacturing Practices (GMPs)
- Pharmaceutical standards, nomenclature and description required for each product;
- Shelf life and expiration date parameters;
- Labeling and packaging instruction;
- GMP and quality assurance certificates required; and
- Other evidence of product quality to be submitted with the Bid and with each shipment and shall be in conformity as stipulated by the NMRA for registered products.

(b) For products which are not registered:

- GMP certificate of the manufacturing facility
- Manufacturing license for the particular product
- Certificate of Pharmaceutical product
- Real time stability report for three commercial batches
- Sample of the commercial pack with label
- Certificate of analysis according to the product specification.

13.3 Pharmacopoeia Reference/Standards

(a) Specificpharmacopoeia reference standard/s, such as the international Pharmacopoeia published by the WHO and the US, European, Japanese and British Pharmacopoeias or other appropriate reference, should be listed for each product and shall be in conformity with the reference standards stipulated by the NMRA.

If the product is not registered with the NMRA and is not available in the official pharmacopeia in house specification submitted by the manufacturer may be accepted.

(b) Standards will as far as possible be internationally acceptable. Where such

internationally acceptable standards are unavailable or inappropriate ,national standards may be specified and shall be in conformity with the requirements stipulated by the NMRA.

(c) Medical Devices to be procured shall be described by reference to standards formulated by the of the NMRA.

13.4 Labelling for Pharmaceuticals and Medical Devices.

13.4.1 For Pharmaceuticals and Medicals Devices which have established Pharmacopoeial quality standards.

a) Generic / Approved name of the Product with or without specification
b) Brand name of the product (if any)
c) List of active ingredients showing:
   (i) The amount of each ingredient present in each dosage unit (e.g.per 5ml etc.)
   (ii) A statement of the net content (e.g.number of dosage unit, weight or volume)

d) Any special storage conditions that may be necessary(provided that NMRA has not indicated specific storage conditions together with the registration of Products).
e) Warning and precautions that may be necessary
f) The date of manufacture.
g) The date of expiry
h) The batch or lot number assigned by the manufacturer
i) Name and address of the manufacturer
j) Child attractive pictures should not be in labels
k) If alcohol is contained in a liquid oral preparation, the content of alcohol should be mentioned on the label.
l) Any special indelible identification marks required by the PE
m) Language as required by the PE
n) Name and address of the manufacturer
o) Child attractive pictures should not be in labels
p) If alcohol is contained in a liquid oral preparation, the content of alcohol should be mentioned on the label
q) Any special indelible identification marks required by the PE
r) Language as required by the PE.

13.4.2 a) For Pharmaceuticals and Medical Devices which are procured from sources other than the principal manufacturer (loan/contract manufacturers, etc) the lable should clearly identify the name and address of such manufacturer as follows:

"Manufactured by …….for……."

The country of origin should also be clearly stated in the label

b) If the particular Pharmaceutical and Medical Devices item is distributed by a source other than the principal manufacturer the label must clearly identify the name and address including the country of origin of the distributor as follows:

" Manufactured by…….Distributed by……."

13.4.3 Any other requirements for labeling that may be mandated from time to time by the NMRA shall be complied with in addition to the above.

13.4.4 It should be clearly stipulated in the technical specifications that failure to conform to specificationa to print a description of the contents, the date of manufacture and the date of expiry on the primary container and the outer package shall result in the rejection of the products upon inspection.

13.5 Packaging

13.5.1 Product Specifications for Pharmaceuticals

This should indicate:

(a) Dosage from (e.g., tablets, capsules, injection, dry syrup, liquid, ointment emulsion, suspension, etc.) and
(b) Content per tablet, capsul or milliliter or gram on the basis of weight by volume (W/V) or volume by volume (V/V)
(c) For Pharmaceuticals or vaccines not included in a compendium, the PE should clearly indicate acceptable limits.

13.6 Product Packaging for Pharmaceuticals

13.6.1 (a) All packaging components must meet compendial standards and be approved for Pharmaceutical packaging by the supplier's /manufacturer's regulatory competent authority.

(b) All the packaging materials primary containers, including immediate packing should be from Pharmaceutical grade materials.

13.6.2 primary containers should:

(i) Maintain quality, safety and stability of the Pharmaceuticals or vaccine contained;
(ii) Withstand mechanical hazards of handling and transport;
(iii) Prevent leakage and environmental degradation; and
(iv) Have no physical or chemical effect on the contents;
(v) Be export worthy and suitable to withstand rough handling in transit and during storage

(a) For liquids:

(i) Containers should be sufficiently transparent for visual inspection; and
(ii) Should be covered with outer packaging to protect the contents from incidental radiation;
(iii) All liguid oral preparations should be less than 750ml.

(b) For injectable Preparations
(i) All anti-cancer product should be in vials (not in ampoules)
(ii) All parenteral preparations should be in rubber bunk type (not in nipple type)

SPC shall also ensure that any specific product labelling and packaging required by the MSD is incorporated into the bidding documents.

13.7 Shelf life and Stability

(a) The required minimum shelf-life remaining for the Products must be clearly stated.
(b) Pharmaceuticals should have the minimum specified shelf life remaining on arrival at the port of entry. (Products should also have an 85% (eighty five percent) minimum shelf life at the time of delivery at MSD and a surcharge shall be levied for violations.

(c) Suppliers/ manufacturers should be required to specify the shelf-life for every product in their bids to enable the PE to consider shelf-life in bid evaluation.

Extreme environmental conditions existing in the area of final delivery and use, if any, must be specially stated.

13.8 Schedule of Requirements

The schedule of requirements of the MSD should provide:

(a) A concise description of each product and the quantity required along with any technical specifications unique to that item.
(b) Sufficient space to enable the suppliers to enter all relevant information including the name of the original manufacture
(c) Whether the listed package sizes are only ones acceptable, or whether the PE shall accept offers on all package sizes available.
(d) Special packging or labeling or shipping instructions required for a subset of products.

14 ORPHAN MEDICINES AND MEDICAL DEVICES

14.1 GENERAL

The Procurement of Orphan Medicines or Medical Devices shall be made on a patient by patient basis, considering the fact that patients with rare diseases do not have recourse to readily available treatment options.

14.2 Criteria

The following criteria may be factored in considering such procurements:

(a) the severity and the complexity of the disease;
(b) the availability of other alternative Medicines;
(c) the availability of therapeutic alternatives;
(d) the availability of alternative technologies to treat the disease;
(e) prognosis with current treatment;
(f) risk/benefit assessment; and such other factors

as may be recommended by the Specialist Consultant/Consultants.

14.3 Limits Authority

- Secretary to the Ministry of Health -upto a maximum limit of LKR 2 (two) million or equivalent thereof in any other foreign currency per event;

- Director General Health Services -upto a maximum limit of LKR 1 (one) million or equivalent thereof in any other foreign currency per event;

15 RADIO ACTIVE SUBSTANCES

Procurement of radio active substances will be made considering the following factors:

(a) Rate of natural radio active decay; and

(b) Time taken for such substances to reach the destination.

SCHEDULES

01. Guideline for Prequalification
02. Model Certificate of a Pharmaceutical Product
03. Pool of laboratories

SCHEDULE 1

Guideline for Prequalification

All information provided should be relevant to the specific procurement

Section 1: Company Details and General Information

1.Name of firm:			
2.Street Address:	Postal Code:	City:	Country:
3.P O Box and Mailing Address:			
4.Telephone Number:			
5.Fax Number:			
6.E-mail Address:			
7.Web Address:			
8a.Contact Name:			
8b.Contact Title:			
9.Parent Company, if any (full legal name)			
10.Subsidiaries, Associates, and/or Overseas Representative(s), if any:			
11.Nationality of the Firm:			
12.Type of Business:			
13.Nature of Business:			
14.Year Established:			
15.Key personel: (include name of candidate, position,professional qualifications and experience) Technical Production Management			
16.date, Numbers and Expiration Dates of Current Licenses and Permits:			
17.Current health authority registration information:			

18.Proof of product and facility registrations with purchaser's country regulatory authority and international agencies, (e.g.WHO Certification Scheme,GMP)

19.Name of government agency (ies)responsibility for inspecting and licensing of facilities in the country of origin of the raw material and or processing of the goods" Date of last inspection:	
20.Quality Assurance Certificate (Please include a copy of your latest certificate with the PQ application:	
21.Production capacity: [Insert peak and average production capacity over the last three years in units/day or units/month, etc]	
22.List of names and addresses of sources of raw material:	
23.Raw materials tested prior to use:	
24.Presence and characteristics of in-house quality control laboratory:	
25.Names and address of external quality control laboratories used:	
26.are all finished products tested and released by quality control prior to release for sale? ☐ Yes ☐ No.if not, why?	
28.Procedurers for dealing with rejected batches:	
29.List tests conducted after production and prior to release of product on market:	
30.List product recall linked to defects during the last 36 months. Include reason and date of recall.	
31.Are technical documents available in: [Purchaser should insert language] ☐ Yes ☐ No	
32.Working languages (Language of bid and contract) : [Purchaser should insert working language]	
Section 2: Financial Information	
33/34.Annual Sales Value for the last 3 years:	
Year	Total Slaes(USD)
35.VAT No./Tax I.D.	
36a.Bank Name:	

36b.Swift/BIC Address:	
36c.Bank Address:	
36a.Bank Account Number:	
36b.Account Name:	
37.Please mail a copy of the company's Annual or Audited Financial Report of the last three years.	

Section 3: Curent Contract Commitments/Contracts in Progress

38. Name of Contract(s)
39.Purhaser Contact Information [insert addresss, Telephone,fax,e.mail address]
40.Value of outstanding contracts[current US$ equivalent]
41.estimated delivery date
42.Average monthly invoice over the last six months(Us$/mon.)

Section 4.Experience

43.Contracts over [insert amount] during the last three years:				
Purchaser	Value	Year	Goods/Services Supplied	Country of Destination

Section 5 : Other

44. Please list any disputes your company has been involved in over the last 3 years.

Year	Award FOR or AGAINST application	Name of client, cause of litigation, and matter in dispute.	Dispute amount (current value, US$ equivalent)

Signed:…….
Date: …….
In the capacity of: [*Insert title or other appropriate design]*

SCHEDULE 2

Model certificate of a Pharmaceutical Product *		
CERTIFICATION OF A PHARMAEUTICAL PRODUCT		
This certificate confirms to the format recommended by the World Health Organization (General instructions and explanatory notes attached). No.of certificate. Exporting (certifying country): Importing (requesting country):		
01		Name and dosage from of the product.
	1.1	Active ingredient (s) 2 and amount (s) per unit dose. For complete composition including recipients, see attached.
	1.2	Is this product license to be placed on the market for use in the exportig country? (Key in as appropriate) Yes/no
	1.3	Is this product actually on the market in the exporting country? Yes/no/unknown
If the answer to 1.2 is **Yes**,continue with section 2A and omit section 2B.If the answer to 1.2 is **no**, omit section 2A and continue with section 2B.		
	2.A.1	Number of Product license and date of issue:
	2.A.2	Product license holder (name and address):
	2.A.3	Status of product license holder. (Key in an appropriate category as defined in note 8)
	2.A.3.	For categories b and c the name and address of the manufacturer producing

	1	the dosage form is:
	2.A.4	Is a summery basis for approval appended? (Key in as appropriate) Yes/no
	2.A.5	Is the attaced, officially approved product information complete and consonant with the license? Key in as appropriate. Yes/no/not approved.
	2.A.6	Application for certificate, if different from license holder (name and address)
	2.B.1	Applicant for certificate (name and address):
	2.B.2	Status of applicant : Key in appropriate categary as defined in footnote 8)
	2.B.2.1	For categories (b) and (c) and name and address of the manufacturer producing the dosage form is 9.
	2.B.3	Why is marketing authorization lacking?
	2.B.4	Remarks.
3.	Does the certifying authority arrenge for periodic inspection of the manufacturing plant in which the dosage from is produced. (Key in as appropriate) If not or not applicable, proceed to question 4. Yes/no/not applicable.	
	3.1	Periodicity of routine inspections (years)
	3.2	Has the manufacture of this type of dosage from been inspected? Key in as appropriate.

		Yes/No
	3.3	Do the facilitied and operations confirm to GMP as recommended by the world Health Organization. (Key in as appropriate) Yes/no/not applicable.
4	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product. (Key in as appropriate) If no, explain: Yes/no Address of certifying authority: Telephone Fax Name of authorized person: Signature Stamp and date	
General Instructions Please refer of the guidelines for full instructions on how to complete this form andinformation on the implementation of the scheme. The forms are suitable for generation by computer. They should always be submittes as hard copy, with responses pinted in type rather than handwritten. Additional sheets should be appended, as necessary, to accommodate remarks and explanations.		
Explanatory notes		
1	This certificate, which is in the format recommended by WHO establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrengements and approved information for different dosage forms and different strengths can vary.	

2.	Use, whenever possible, International Non proprietary Names (INNs) or national non proprietary names.
3.	The formula (complete composition) of the dosage form should be given on he certificate or be appended.
4.	Details of quantitative composition are preferred but their provision is submitted to the agreement of the product license holder.
5.	When applicable , append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product license.
6.	Sections 2A and 2B are mutually exclusive.
7.	Indicate, when applicable, if the license is provisional, or the product has not yet been approved.
8.	Specify whether the person responsible for placing the product on the market. a) Manufactures the dosage form; b) Packages and/or labels a dosage form manufactured by and independent company; or c) Is involved in none of the above.
9.	This information can only be provided with the consent of the product license holder or, in the case of non registered product, the applicant. Nin completion of this section indicate that the party concerned has not agreed to the inclusion of this information. It should be noted that information concerning the site of production is part of the product license. If the productions site is charged, the license has to be updated or it is no longer valid.
10.	This referes to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
11.	This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)
12.	In this circumstance, permission for issuing the certificate is required form the product license holder. This permission has to be proved to the authority by the applicant.
13.	Please indicate the reason that the applicant has provided for not requesting

	registration.
	a) The product has been developed exclusively for the treatment of conditions- particularly tropical diseases – not endemic in the country of export;
	b) The product has been reformulated with a view to improving its stability under tropical conditions;
	c) The product has been reformulated to exclude excipients not approved for use in pharma ceutical products in the country of import;
	d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient;
	e) Any other reasons, please specify.
14.	“Not applicable” means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture. The requirements for good practices in the manufacture and quality control of drugd referred to in the certificate are those included in the thirty-second report of the expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No.823,1992. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standasdization (WHO Technical report Series No.823,1992)
15	This section is to be complete when the product license holder or applicant conform to status (b) or (c) as described in note 8 above. It is odf particular important when foreign contractors are involved in the manufacture of the product.,In these circumstances parties responsible fore ach stage of manufacture of the finished dosage form, and the extent and nature of any controls exercise over each of these parties.

Model Statement of Licensing Status of Pharmaceutical Products

No.of statement .....Exporting (certifying) country:
Importing (requiring) country ;
Statement of Licensing Status of pharmaceutical Product(s)
This statement indicates only whether or not the following products are licensed to be put on the exporting country.

Applicant (name/address):

Name of product	Dosage Form	Active ingredient (2) 2 and	Product

		amount(s) per unit dose	

The certifying authority undertakes to provide, at the request of the applicant (or, if different,the holder) a separate and complete Certificate of a Pharmaceutical Product in the format recommended for each of the products listed above.

Address of certifying authority: Name of authorized person.
Telephone/fax number:
Signature:
Stamp and Date:

This statement conform to the format recommended by the World Health Organization general explanatory notes below)

General Instructions
Please refer to the guidelines for full instructions on how to complete this form and information on the Scheme.
The forms are suitable for generation by computer. They should always be submitted as hard copy printed in type rather than handwritten.
Additional sheets should be appended, as necessary, to acconnodate remarks and explanations.

Explanatory notes

1	This statement is intended for use by importing agents who are required to screen made in response to an international tender and should be requested by the agent as condition of bidding.the statement indicates that the listed products are authorized to be placed on the market of use in the exporting country. A certificate of a Pharmaceutical Products in the format recommended by WHO will be provided, at the request of the applicant and, if different, the product license holder, for each of the listed products.
2	Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.

3	If no product license has been granted, enter " not required", "not requester" , "under consideration" or "refused" as appropriate.	
Model Batch Certificate of a Pharmaceutical Product* **Manufacturers / Official Batch Certificate of a Pharmaceutical Product**		
This Certificate conforms to the format recommended by the World Health Organization (general Instructions and explanatory notes attached)		
1. No.of Certificate: 2. Importing (requesting) authority: 3. Name of product		
	3.1	Dosage form
	32	Active ingredient(s) and amount(s) per unit dose.
	3.2.1	Is the composition of the product identical to that registered in the country of export? Yes/No/not applicable (key in as appropriate) If no, please attach formula (including excipients) of both products
4	Product license holder(name and address):	
	4.1	Product license number
	4.2	Date of issue
	4.3	Product license issued by
	4.4	Product Certificate number
5.1	Batch number……	
5.2	Date of manufacture:	
5.3	Shelf life (years):……..	
5.4	Contents of container	
5.5	Nature of primary container	
5.6	Nature of secondary container/wrapping	
5.7	Specific storage conditions	
5.8	Temperature range	

6.	Remarks	
7.	Quality analysis:	
	7.1	What specifications apply to this dosage form. Either specify the pharmacopoeia or append company specifications
	7.1.1	In the case of product registered in the exporting country, have these company specifications been accepted by the competent authority? Yes/No
	7.2	Does the batch comply with all parts of the above specifications?
	7.3	Append certificate of analysis.

It is hereby certificate that the above declarations are correct and that the results of the analyses and assays on which they are based will be provided on request to the competent authorities in both the importing and exporting countries.

Name and address of authorized person:

Telephone No.
Fax.No.
Signature of authorized person
Stamp and Date.

General Instruction

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

These forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

Certificate of individual batches of a Pharmaceutical product is only undertaken exceptionally by the competent authority of the exporting country. Even then, it is rarely applied other than to vaccines, sera and biological. For other products, the responsibility for any requirement to provide batch certificates rests with the product license holder in the

exporting country.

The responsibility to forward certificate to the competent authority in the importing country is most conveniently assigned to the importing agent.

Any inquires or complains regarding a batch certificate should always be addresses to the competent authority in the exporting country. A copy should be sent to the produce license holder.

1.	Strike out whichever does not apply
2	Use, whenever possible, International Non proprietary Names (INNs) or national non proprietary names.
3.	“Not applicable” means that the product is not registered in the country of export.
4.	All items under 4 refer to the product license or the Certificate of a Pharmaceutical Product issued in the exporting country.
5.	This refer to the Certificate of a Pharmaceutical Product as recommended by the World Health Organization.
6.	Indicate any special storage conditions recommended for the product as supplied.
7.	For each of the parameters to be measured, specifications give the values that have been accepted for batch release at the time of product registration.
8.	Identify and explain any discrepancies of specifications. Government batch release certificates issued by certain governmental authorities for specific biological products provide additional confirmation that a give batch has been released, without necessarily giving the results of testing. The letter are contained in the manufacturer’s certificate of analysis.

SHEDULE 3 – Pool of Laboratories

Laboratories in Sri Lanka

01. Industrial Technology Institute (ITI)
02. Medical Research Institute (MRI)
03. National Medicines Quality assurance Laboratory (NMQAL)
04. Sri Lanka Standards Institute (SLSI)

LIST OF PREQUALIFIED QUALITY CONTROL LABORATORIES BY WORLD HEALTH ORGANIZATION

NO	COUNTRY	NAME OF THE LABORATORIES	ADDRESS	E-MAIL ADDRESS
African Region				
01	Algerie	Laboratories National de Control des produits Pharmaceutiques, LNCPP (Algerie)	Lot Geraud, petit Staoueli, Dely Inbrahim (Site du NouvelInstitut Pasteur) Algiers Algeri	Incpp@sante.dz; incpp@hotmail.com
02.	Ghana	United States Pharmacopoeia -Ghana	No.3, Park Avenue,Motory way extention, North Dzowulu, Accra, Ghana	cepat@usp.org
03.	Kenya	Laboratory of the Mission for Essential Drugs and Supplies – (MEDS)	Po Box 78040, Viwandani Nairobi, 00507 Kenya	Lab@meds.or.ke
04.	Nairobi Kenya	National Quality Control laboratory (NQCL)	Hospital Road – KNH Complex, 00202 - KNH, Nairobi Kenya Postal add: P.O.Box 29726,00202-KNH, Nairobi Kenya	hchepkwony@nqcl.go.ke
05.	South Africa	M & L Laboratory	40 Modulus Road, Ormonde,	Milly.vandayar@za.bureatas.com

		Services (Pty) Lt	Johannesburg, South Africa, 2091	
06.	South Africa	Adcock Ingram Limited-Research and Development	Private Bag X69 Bryanstone, 2021 South-Africa	Palka.Parbhoo@adcock.com
07.	South Affrica	Research instituite for Industrial Pharmacy (RIIP) incorporating CENQAM	North – West University, Potchefstroom Campus, Hoffman Street, Potchefstroom 2531, South Africa Postal address: P/Boag X6001 Potchefdtroom 2520 South Africa	Erna.Swanepoel@nwu.ac...
08	Tanzania	Tanzania food and Drugs Authority (TFDA) Quality Control Laboratory	Mandela Road, Mabibo, External P.O.Box 77150 dar es Salaam, Tanzania	dls@tfda.or.tz info@tfda.com
09	Uganda	National Drug Authority – National Drug Quality Control Laboratory (NDA – NDQCL)	Mulago Hill, P.O.Box 23096, Kampala, Uganda	laboratory@nda.or.ug
10.	Zimbabwe	Medicines Control Authority of Zimbabwe (MCAZ)	106 Bainess Avenue, P.O.Box 10559, Harare, Zimbabwe	mcaz@mcaz.co.zw; gnmahlangu@mcaz...

		Quality Control Laboratory		
Region of the Americas				
01	Bolvia	Laboratoria de control de Calidad de Medicamento s y Toxicologia (Concamyt)	Calle Rafael Zubieta No.1889, Zona de Miiraflores, la Paz, Bolvia	Garnicalopez@yahoo.com
02.	Brazil	Ezequiel Dias Foundation (Funded) Instituite Octavio Magalhaes Medicines Service of Public Health Central laboratory	Conde Pereira Carneiro street 80, Gameleria neighbourhood, Belo Horizonte, Minas Gerais, 30510-010, Brazil	dpgp@funded.mg.gov.lk medicamentos@funed.br
03.	Brazil	Instituto Nacional de Control de Qualidadeem saude (INCQS)	Av.Brasil no 4362, manguinhos,CEP210 40-900, Rio de Janeiro, Brazil	incqs@incqs.flocruz.br;... Vdquali @incqs.flocruz.br Vere.machado@incqs.fi..
04.	Brazil	The drug Service of the Pubic Laboratory Dr Giovanni Cysneiros (LACEN-GO)	Av contorno No 3556, Jardim Bela Vista, Goiania, Goias, 74853-120,Brazil	rosa.machado@incqs.fi... Lacen.dirgeral@saude.g...
05.	Canada	K.A.B.S.labor atories Inc.2	4500 de Tonnancour, st-Hubert, Quebec J3Y 9G2, Canada	Kabsafric@kabs.com
06.	Mexico	Comision de Control	Calzada de Talalpan No. 4492, Colonia	faarguelles@cofepris.gob

		Analitico y Ampliacion de Cobertura(CCAYAC)	Toriello Guerra, DelegacionTlalpan, C.p.14050 mexico, D.F.Mexico	
07	Uruguay	Comision para el Control de Calidad de Medicamentos (CCCM)	Br.Artigas 3223, Montevideo 11800, Uruguay	blua@msp.gub.uy mhirschhorn@msp.gub.uy cccm@msp.gub.uy
South – Est Asia Region				
01.	India	SGS India Pvt.Ltd.(Life Science Services)	2nd Floor, TICEL Bio Park Ltd. Tharamani Road, Tharamani, Chennai-600113, Tamil Nadu India	In.lifeqc@sgs.com
02.	India	Stabicon Life Sciences Pvt Ltd	Plot No 28, Bommasandra Industrial Area (sub - layout), 4th Phase JiganiHobli, Anekal Taluk Bangalore, 560 100, India	Vijay.ranka@stabicon.com
03.	India	Vimta Labs Limited	Life Sciences Facility Plot, No.5, S.P.Biotech Park, Genome Valley,Hyderabad, 500078, India	quality@vimta.com
04.	India	Indian Pharmacopoiea Commission – Indian Pharmacopoeial Laboratory	Ministry of Health & Family Welfare, Sector 23, Raj Nagar, Ghaziabad, Uttar Pradesh, 201002, India	Ipclab@vsnl.net
05.	Thailand	Bureau of Drug and Narcotic	88/7 Tiwanond Road, Muang Nonthaburi 11000, Thailand	Suratchanee.s@dmsc.mail.... Boonatarika.b@dmsc.mail...

		(BDN) Department of Medical Sciences Ministry of Public Health		
06.	Thailand	Health Concepts International Ltd	113 thailand Science Park, Paholyothin Rd, Klong 1, Klongluang, Pathumthani, Thailand, 12120	Lester.chinery@conceptfoon.org
European Region				
01	Belarus	Republican Control and Analytical Laboratory	78 Pritytskiy St.220140 Mink, Belarus	rkal@rceth.by maisak@rceth.by
02.	Belgium	Medicines Control laboratory (SCMDGO)	Stevinstraat 137,1000, Brussels, Belgium	dgo_scm@apb.be
03.	Belgium	SGS Lab Simon S.A	Vieux Chemin du Poete 10 b 1301 Wavre, Belgium	Be.lifeqc@sgs.com Wim.vanimmerseel@sgs.com
04.	Belgium	University of Liege, faculty of Medicine, Department of Pharmacy	B36 Building, Tower Pharmacy, Level2, Hospital District, Hippocrate Avenue 15, 4000 liege,Belgium	rmarini@ulg.ac.be
05.	Croatia	Agency for Medicinal Products and Medical Devices (HALMED0	Official Medicines control, Laboratory (OMCL), Ksaverskacesta 4, 10000 Zagreb, Croatia	Rajka.truban@halmed.hr
06.	France	Centre	4, voiemilitaire des	contract@chmp.org,

		Humanitaire des Metiers de la Pharmaci (CHMP)	Gravabches, F 631000 Clermont – Ferrand, France	aba@chmp.org
07.	France	APTYS Pharmaceuticals	Biopole Clermont-Limagne, F- 63360 saint Beauzire, France	contact@aptyspharmaceu.com
08.	France	Gimopharm	1, Chemin de Saulxier, 91160 Longjumeau, France	Aurelie.bertheault@gimop.com contacts@gimopharm.com
09	Germany	InphA GmbH – Institute for Pharmaceutical and applied analytics4	E mail-Sommer-Strasse 7, D -28329 bremen, Germany	Konrad.horn@inpha.de
10.	Netherlands	PROXY Laboratories B.V	Archimedesweg 25, 2333 CM Leiden, The Netherlands	info@proxylab.nl
11	Netherlands	Synergy Health Utrecht B.V, Pharmaceutical Laboratories (SHPL)7	Reactorweg 47A, 3542 AD Utrecht, The Netherlands	utrecht@synergyhealthp...
12	Portugal	INFARMED I.P.3	Direccao da Comprovacao da, Qualidade (DCQ) , av. Brasil No. 53, Edificio Tome Pires, 1749-004 Lisboa, Portugal	Majoao.portela@innformec..
13.	Portugal	Lbaoratorios Basi-Industria farmaceutica, S.a, Quality Control Unit6	Parque Industrial de Mortagua, lote 15, 3450-232, Mortagua, Portugal	basi@basi.pt
14	Russian Fedaration	Laboratory of chemical	Schukinskaya stret, 6-1 Moscow 123182	gladkaja@expmed.ru

		pharmaceutical prepparations No 2 and laboratory of antibiotics of the Fedaral state Budgetary Institution	Russian federation	
15	Rusian federation	Rostov-on-Don Branch of Federal state Budgetary Instituition	Chentsova street 71/63B, Rostov-on-Don, Rostov region, 344037, Russian federation	annagranf@yandex.ru
16	Switzerland	Intertek (Schweiz) AG5	Mattenstrasse 22, Biopark Rosenthal, Building 1047 CH 4058 Basel, switzerland	Mara.guzzetti@intertek.com
17	Ukrain	Central Laboratory for Quality Control of Medicines and medical Products, SE State drug Administration of Ukrain	10G Kudryavskaya street, Kiev, 04053 Ukraine	CL@statelab.kiev.ua
18	Ukraine	Laboratory of Pharmaceutical analysis state Expert Centre Ministry of Health of Ukraine	14, EzhenaPottier st.03680, Kiev, Ukraine	sashavbfc@yandex.ru
19	Ukraine	State Scientific research	50 Popudrenkastr, Kiev,02660,Ukrain	3526309@ukr.net

		Laboratory on Quality control of Medicines (SSRL)		
Eastern Mediterranean Region				
01	Iran	Food and Drugs Control Reference Laboratories (FDCRL)	No 31 Imkam Khomeini Avenue, Tehran, 11136-15911, Islamic Republic of Iran	FDCRL@fda.gov.ir or h.rastegar@fda.gov
02.	Maroc	Laboratoire National de Controle des Medicaments - LNCM (Maroc)8	Rue LamfadelCharkaoui-Medinat al, Irfane, Rabat 10000,Maroc Postal address: BP 6202, Rabat-Instituts,Rabat, Maroc	d.Incm.dmp@sante.gov.n
Wetern Pacific Region				
01	CHINA	National Institutes for Food and Drug Control (NIFDC)	2 TiantanXili (Temple of Heaven), 100050 Beijing, P.R.CHINA	yandgx@nifdc.orh.cn zhanghz@nicpbp.org.cn
02.	china	Shenzhen Instituite for Drug Control (SZIDC)	No 28, Gaoxin Central 2nd avenue Nanshan District, Shenzhen, Guangdong, P.R China	szidc@szidc.org.cn wangxiaowei@szidc.org.cm
03	Singapore	TUV SUD PSB pte Ltd Chemical & Materials (Food and Pharmaceuti	1 Science Park Drive, Singapore 118221	Jianhua.lin@tuv-sud-psb.s

		cal Testing)		
04	Vietnam	National Institute of Drug Quality Control of Vietnam (NIDQC)	48 Hai Ba Trung Street, Hoankiem District, Hanoi, Vietnam	npthaodz@yahoo.com.vn nhilenvkn@gmail.com tranthuyhanh1974@yahoo.com
05	Viet Nam	Institute of Drug Quality control (IDQC)	200 Co Bac Street, District 1,Ho Chi Minh city, Viet Nam	info@idqc-hcm.gov.vn