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Challenges and barriers for effective supply of medicines to the state sector and recommendations to the Ministry of Health Sri Lanka

A report by the
Sri Lanka Association of Clinical Pharmacology and Therapeutics (SLACPT)
for the
Ministry of Health, Sri Lanka

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LIST OF ABBREVIATIONS

DGHS	-	Director General of Health Services
DTC	-	Drugs and Therapeutics Committee
EML	-	Essential Medicines List
GDP	-	Gross Domestic Product
GOSL	-	Government of Sri Lanka
HTA	-	Health Technology Assessment
LKR	-	Lankan Rupees
LMIC	-	Low and Middle Income Countries
LP	-	Local Purchase
MEC	-	Medicines Evaluation Committee
MoH	-	Ministry of Health
MRP	-	Maximum Retail Price
MSD	-	Medical Supplies Division of the Ministry of Health
NMQAL	-	National Medicines Quality Assurance Laboratory
NMRA	-	National Medicines Regulatory Authority
SLACPT	-	Sri Lanka Association of Clinical Pharmacology and Therapeutics
SPC	-	State Pharmaceuticals Corporation
SPMC	-	State Pharmaceutical Manufacturing Corporation
TEC	-	Technical Evaluation Committee
USD	-	United States Dollar
VEN analysis	-	analysis as Vital, Essential and Non-Essential items
WHO	-	World Health Organization
WOR	-	Waiver of Registration

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EXECUTIVE SUMMARY

Background

The recent economic crisis in Sri Lanka has produced a crisis in the state health care system, exemplified by shortage of numerous pharmaceutical items. Over 100 essential medicines have not been available in the hospitals, in addition to shortage of various non-essential medicines and medical devices. This situation has been going on for several months despite the attempts of the government to provide funds through various loans and solicited donations. The situation has adversely affected the private sector also. The global Covid -19 pandemic which preceded the economic crisis was a major contributory factor to this situation. Until recent times Sri Lanka has maintained a reasonably good health service in comparison with the regional countries as shown by a multitude of health care indicators. These indicators have been achieved by spending approximately 4.00 to 4.25% of Gross Domestic Product (GDP) on health.

In this background, the Secretary to the Ministry of Health (MoH) requested the Sri Lanka Association of Clinical Pharmacology and Therapeutics (SLACPT) to assist the MoH in finding solutions to this crisis. While acknowledging that the main reason for this crisis being the "bankrupt" state of the country, the SLACPT was requested to look at other factors (*ie*. other than the acute shortage of funds) which could be addressed to improve the crisis situation and future medical supplies in an efficient manner.

This executive summary contains a list of summary challenges and barriers to the efficient supply of pharmaceuticals and a list of summary recommendations towards improvement of the pharmaceutical supply process. Further details about the challenges and barriers and the recommendations pertaining to the separate institutions of the MoH and the other stakeholder groups are given in sections 3 - 8 of this document.

The number of overall challenges and barriers identified with the recommendations, and challenges, barriers and recommendations for each of the stakeholders are given in Table 1.

Some key observations and recommendations given by Treasury officials and observations and recommendation given in government audit reports are also included.

The challenges, barriers and recommendations apply in a general way to all the medicines, medical and surgical devices, laboratory reagents and test kits supplied by the MSD to the state health care institutions, unless specifically mentioned as applicable to a particular category.

The number of challenges, barriers and recommendations in summary, applicable to stakeholders and observations and recommendations given by the Government Treasury and Auditor General's reports

	Number of challenges and barriers	**Number of Recommendations**
Executive summary	22	30
NMRA	17	15
NMQAL	6	6
MSD	7	12
SPC	13	6
Importers	6	5
Manufactures	5	6
Hospital pharmacist (forecasting)	13	8
Specialist colleges and associations	8	12
Donations	5	3
	Number of observations	**Number of recommendations**
Government Treasury	5	8
Auditor General's report	14	

Summary of challenges and barriers

1. Absence of an efficient software system to obtain updated information in a transparent manner on medicines ordered, tenders awarded, medicines registered, those pending registration, those granted waiver of registration (WOR), quality failures, stocks available, dates of the expected consignments, purchasing costs, etc by all stakeholders
2. Breakdown of the web based online registration system at NMRA, initiated in 2018 with loss of all submitted data. Since then, only hard copies are accepted which has led to serious issues such as lost dossiers, lack of traceability, inability to prioritize essential medicines registration and delays in registrations.
3. Lack of coordination amongst stakeholder groups during the estimation and current procurement process and delays in Technical Evaluation Committee (TEC) and tender committees
4. Lack of transparency in the registration and procurement process
5. Delays in the steps in the supply chain at all levels, especially the NMRA, MSD and the SPC contributing to the shortages of medicines and other medical supplies
6. Inadequate staff and expertise at the NMRA, MSD NMQAL and SPC
7. Sudden removal of large number of experienced staff prior to recruitment of new staff to NMRA and NMQAL by the administration of NMRA, creating a crisis situation for medicines registration, quality testing of medicines and all aspects of pharmaceutical supply for both the public and private sector
8. Lack of an efficient system for forecasting of the annual requirements by the pharmacists at the MSD
9. Lack of a monitoring systems of pharmaceutical situation and non-consideration of availability and amount of funding required for the purchase of the requested supplies.
10. Not prioritising and not allocating a minimum of 70% of the available funds to purchase the essential medicines
11. Accepting requests for high-cost medicines based on individual requests and preferences without performing Health Technology Assessment (HTA) using evidence of efficacy, cost effectiveness and the total funds required to provide the supplies on a continued basis to all patients equitably

12. Poorly functioning hospital Drugs and Therapeutics Committees (DTC) at institutional and national level, leading to poor monitoring of the use of high-cost pharmaceuticals, antimicrobials and local purchase (LP) items.
13. Lack of a regularly updated database of registered medicines with the Maximum Retail Price (MRP) at the NMRA.
14. Limited number of registered medicines and suppliers for vital and essential medicines whilst having large number of registered products for some medicines, which are not essential medicines. Evaluating such dossiers contributes to the heavy workload of the NMRA.
15. An increasingly large number of medicines supplied through WOR pathway with minimum evaluation to supply for government tender purposes.
16. Registered suppliers not quoting for government tenders floated by the SPC due to a multitude of reasons, mainly non-payment of over dues due to the economic crisis.
17. Absence of technical experts on pharmaceuticals in the initial tender approval process for unregistered medicines.
18. Inadequate facilities for quality testing of pharmaceuticals at the National Medicines Quality Assurance Laboratory (NMQAL) and lack of testing of post marketing samples mainly due to inadequate staff and other resources.
19. Lack of adherence to criteria for blacklisting manufacturers with past histories of quality failures by the SPC.
20. Non-adherence to recommended procedures and guidelines during the procurement process by the SPC.
21. Political and other interference to the existing systems with serious implications for the supply system.
22. Not taking steps to address the numerous recommendations given in the Auditor General's recent reports towards improvement in the processes, especially those covering monetary aspects.

Summary recommendations for improving the medical supplies

1. Establishing an electronic system where all stakeholders, (MSD, SPC, NMRA, Colleges, and end users in hospitals) would be able to obtain relevant data such as medicines requested, medicines registered, those pending registration, those granted WOR,

quality failures, orders, stocks available, dates of the expected consignments, prices, purchasing costs, etc. and to coordinate through an online system among stakeholders for necessary action.

2. Restart the electronic submissions in the E–CTD format at NMRA as soon as possible to make the process transparent, enable traceability and monitoring.
3. Improving coordination between NMRA, MSD and SPC during the existing procurement processes in the interim, until online systems are established.
4. Ministry of Health to establish a Unit with a Technical Advisory Committee with representation from colleges to review on a regular basis, the shortages, analysis of annual pharmaceutical supplies, rational usage, annual budgetary allocation, purchases and cost analysis of supplies in order to make recommendations on rational spending on pharmaceuticals, advice on decisions required during processing of tenders and the procurement process to prevent shortages and problems in supply.
5. Obtaining accurate forecasting of quantities required for hospitals based on previous actual consumption figures by better coordination between MSD and the hospitals.
6. Distribution of medicines to regional stores and hospitals to be based on actual consumption and stocks remaining to minimise shortages and wastage.
7. Consider the government budgetary allocation for pharmaceuticals when the list of items for procurement are prioritized. As there are budgetary constraints the priority should be for essential medicines before considering others.
8. The SPC to liaise with MSD to decide on priority pharmaceuticals before opening letters of credit for procurement, especially for high-cost items .
9. Prevent Local purchase (LP) at hospital level for high-cost items, named patient basis items and products outside the Formulary. The processes should be streamlined. New requests for any urgent such items should be approved by the hospital Drug and Therapeutics Committee (DTC) before supply. Such medicines should be subsequently forwarded to the national DTC with justification for consideration for inclusion at the time of formulary revision. Such items would need a Health Technology Assessment (HTA) prior to consideration in the Formulary Committee.
10. Hospital level DTCs to be held monthly on the Terms of Reference (TOR) given for DTCs, and National DTC chaired by the DGHS to be held quarterly on a regular basis

and any costly new additions to the Formulary to be done only after considering HTA on the efficacy and cost effectiveness data of such medicines.

11. Capacity building and reactivating non-functioning hospital DTCs by hospital Directors to monitor and control medicines use at institutional level. Train the hospital pharmacists on DTC meetings, according to WHO recommendations.
12. Review the Vital, Essential, and Non-essential lists and the priority lists for purchasing pharmaceuticals with the inputs of the specialist colleges.
13. All submissions for registration of essential medicines for which there are limited suppliers to be evaluated by the NMRA on an expedited basis and decisions taken on registration promptly.
14. Limit the Waiver of Registrations (WOR) to what is specified in the NMRA ACT and adherence to guidelines and strict criteria when granting WOR. Request all companies submitting bids for government tenders with unregistered products to submit all documents stated in the WOR guidelines without delay.
15. Companies whose products were awarded government tenders on WOR must submit a full dossier for registration of the product subsequently. A product that was awarded a tender previously on WOR to be considered for subsequent tenders only if it is registered.
16. To consider granting exemption of registration fees charged by the NMRA for orphan medicines which are not economically viable to the supplier.
17. Avoid interference to the proper functioning of organisations, such as the recent transfer of several experienced staff at NMRA, and to take steps to increase the staff at NMRA and NMQAL urgently if necessary, by obtaining special permission for recruitment.
18. Increasing the quality testing capacity of NMQAL by increasing the analytical staff and other resources required and obtain testing from other independent laboratories such as universities or private laboratories capable of performing quality testing in the interim.
19. SPC to identify modifiable reasons for the long lead time of 9-12 months for supply of pharmaceuticals and take steps to reduce this lead time by efficient coordination.
20. The government treasury to inform the Director General of Health Services (DGHS), SPC and Director MSD the annual budgetary allocation available for medical supplies

and take steps to pay any outstanding payments due to the suppliers. The amount of funds available for the rest of the fiscal year also to be informed on a quarterly basis to enable realistic requests for purchase of medical supplies.

21. MSD and SPC to provide details of annual purchasing costs and quantities of all items purchased for review by the specialist colleges. This information could be used by the colleges when making decisions and recommendations later.
22. NMRA, MSD and SPC to address all issues raised in the recent government audit reports and rectify the deficiencies noted.
23. Publish a list of shortage items on a regular basis (eg. monthly) which can be accessed publicly by the donors. Communicate with the donors to ensure that the donations follow the WHO and/or local guidelines. Include donations when forecasting the requirements for the next year and during award of tenders.
24. The specialist colleges to consider HTA of all high-priced medicines used in their specialty and only request items for inclusion into the Formulary, after considering the cost effectiveness, national budgetary allocations and ability to purchase it for all such needly patients equitably in the country on a continuous basis.
25. The specialist colleges to prioritise the most essential items that need to be made available at all times, and the next levels of priority items, giving due consideration to annual consumption costs and cost effectiveness of the items.
26. All requests by specialists for inclusion of new high-cost items to the Formulary or to be supplied on a named patient basis to be reviewed by the respective speciality college and submitted to the MSD through the Colleges with due justifications. The MSD to draft a form with a list of information required for approval.
27. Increasing the local pharmaceutical manufacturing for identified most commonly used essential medicines, giving buy back guarantees for products to be purchased by the MSD. Provide equal opportunity to both the State Pharmaceutical Manufacturing Corporation (SPMC) and the other local manufacturers during this process. Consider the cost of local production and the cost of imported products when deciding on the products.
28. Utilize the expertise of the doctors who have obtained Masters in Clinical Pharmacology and Therapeutics (MSc in CPT) at the Postgraduate Institute of Medicine for the many activities listed by posting them to the NMRA on secondment

or the MSD or major hospitals. Services of those with special training in pharmacology, therapeutics or pharmacy who are already in the hospitals can be obtained to support the hospital DTCs.

29. Establish posts for consultant clinical pharmacologists at the NMRA and the MSD who will be able to support the pharmaceutical supply system.
30. A monitoring mechanism to be established to ensure that the recommendations given in this Committee Report are implemented by all stakeholders.

1. INTRODUCTION

One of the main sectors that was adversely affected by the economic crisis in Sri Lanka was the pharmaceutical sector. Severe shortages were noted in many medicines and medical devices throughout the country in an unprecedented manner. The World Health Organization (WHO) reported that Sri Lanka's economic crisis rapidly turned into a health crisis amidst growing shortages of essential medicines and devices (1). By January 2023, 164 of the 383 essential medicines were reported to be out of stock in the MSD, although some limited stocks were available in hospitals. Another 90 medicines were available in sufficient stocks only for one month, 38 medicines only for 2-3 months and 18 medicines only for 3 months (2).

Although the economic crisis precipitated the shortages, it was noted that a number of pre-existing shortcomings in the pharmaceutical supply process has contributed to this crisis. In this background the Secretary, MoH, requested the SLACPT to conduct a fact-finding exercise involving all stakeholders to identify challenges and barriers for the effective supply of pharmaceuticals and medical devices and to submit a report providing recommendations towards improvement. The MoH facilitated all the meetings with the stakeholder groups. This report is prepared based on the findings during this exercise and analysis of relevant data made available to the SLACPT by the MoH.

1.1 Terms of Reference

To identify challenges and barriers to the institutions involved in the supply of medicines, medical devices and laboratory items to the state institutions and state health care units make recommendations towards improvement. Achieving the following general and specific objectives using the methods described are the terms of reference for this assignment.

1.2 Objectives

1.2.1 General objective

Identify the pharmaceutical supply process in Sri Lanka, the pharmaceutical market, expenditure on pharmaceuticals and medical devices, financial capability of supplying the

current list of pharmaceuticals, challenges and barriers to the supply process and to provide recommendations for effective supply of pharmaceuticals and medical devices to the country.

1.2.2 Specific objectives

1. Describe the pharmaceutical market, financial allocations over the past years, compare with other countries and the performance of Sri Lanka on key health indicators prior to the economic crisis.
2. Situation analysis on the pharmaceuticals supplied using ABC-VEN analysis, on the MSD data about pharmaceutical supplies during the past 5 years,
3. Identify the total funds required to purchase the different categories of items (essential medicines, the formulary items and items supplied on named patient basis) for the country requirements as per the current list of items.
4. Analyze the registration data, Quality failures, pharmaceuticals supplied on WOR and the reasons for granting WOR during the past 5 years
5. Describe the situation pertaining to pharmaceutical donations
6. Identify the challenges, barriers, concerns, processes used, and solutions proposed as expressed by the key stakeholders and provide recommendations to the relevant the parties.
7. Identify overall challenges and barriers and provide recommendations based on the findings for effective supply of pharmaceuticals in the future.

1.3 Methods

This report was prepared using many methods, with literature review of relevant publications, desk review of relevant reports, data analysis of pharmaceutical supplies, cost analysis of MSD data, analysis of data provided by the NMRA and qualitative analysis of concerns and opinions expressed by stakeholders. In addition, observations of the members of the SLACPT who have served or are currently serving in many committees of the NMRA, MSD and MoH were also considered.

A. Desk review of documents, reports and literature review
    I. Guidelines for procurement of pharmaceuticals and medical devices of 2022 by Ministry of Finance, Economic Stabilization and National Policies (Public Finance Circular No 01/2023)

II. Auditor General's reports on MSD, SPC, SPMC and special report on procedures taken to avoid shortages of pharmaceuticals in government hospitals, 2022
III. Data on financial allocations provided by the Government Treasury
IV. World Bank financial data and WHO publications on pharmaceutical situation in Sri Lanka
V. Information from other relevant publications

B. Analysis of the following data
   I. ABC and VEN analysis (analysis as Vital, Essential and Non-Essential items) of pharmaceutical supplies using the MSD data during the past 5 years
   II. Cost analysis of purchasing all pharmaceutical supplies, the formulary and non-formulary items and the recently revised list of pharmaceuticals
   III. Analysis of registered medicines and those granted WOR

C. Stakeholder meetings held with members from following organizations and groups
   I. MSD, NMRA, SPC
   II. Local pharmaceutical manufacturers including the SPMC
   III. Sri Lanka Chamber of the Pharmaceutical Industry (SLCPI) and the Sri Lanka Chamber of Medical Devices Industry (SLCMDI)
   IV. Government Treasury officials in the Treasury Operations Department and Department of National Planning
   V. Regional Directors of Health Services, hospital directors and hospital pharmacists
   VI. Representatives of the Colleges and Associations of medical specialists

2. PHARMACEUTICAL SITUATION AND EXPENDITURE

In 2019, medical and pharmaceutical product imports to Sri Lanka reached a value of USD 553 million and this accounted for 2.8% of total imports to the country. In 2020 the pharmaceutical imports were recorded as USD 599.5 million (3). By 2022, the market was expected to reach a value of USD750 million, posting a five-year annual growth rate of 4.1%. Currently, 84.6% of pharmaceutical needs are imported and about 15 local manufacturing plants including the SPMC provide the balance 15.4% of the requirement with an estimated value of LKR 18 billion annually.

Sri Lanka's total health expenditure as a share of Gross Domestic Product (GDP) has been higher compared to other low- and middle-income countries (LMIC) and South Asian countries (4) (Table 1).

Table 1: Health expenditure as a share of Gross Domestic Product (GDP)

Health expenditure as a share of GDP	2000	2019
Total health expenditure (both public and private) - Sri Lanka	4.25%	4.08 %
Low and Middle-income countries (LMIC) - total expenditure	3.84%	3.76%
South Asian countries - total expenditure	3.72%	3.1%
All countries in the world - total expenditure	8.63%	9.83%,
Public health expenditure - Sri Lanka	2.3%	1.5 %
Public health expenditure of LMIC	-	1.5%
Public health expenditure in South Asia	-	1%

Source: World Bank, Current health expenditure as a percentage of GDP

2.1 Public sector health expenditure

Sri Lanka's public health expenditure amounts to 1.5% of GDP (Table 1), which is similar to the average public health expenditure of LMIC (5). In 2019, the Sri Lankan Government spent 23% of its healthcare budget, *ie*, LKR 54 billion of the total LKR 235 billion, on medical supplies. In 2022, Sri Lanka's total pharmaceutical expenditure covering both state and private sectors was estimated to be LKR 163 billion per annum (6).

Table 2: Estimates on expenditure on medical supplies and the actual expenditure by the Government Treasury in the past 5 years (LKR millions)

	2018	2019	2020	2021	2022	2023
Estimate	45,025	45,000	85,205	60,000	74,300	110,000
Revised Estimate*	46,025	54,068	85,205	76,504	76,300	110,000
Actual expenditure	43,331	54,068	83,545	73,638	73,050	18,618**

**Actual Expenditure as at 31.03.2023 *after additional allocations

Source : Government Treasury, Sri Lanka

The Treasury allocations for medical supplies ranged approximately from LKR 45 billion in 2018 to LKR 74 billion in 2022 (Table 2). When compared to 2019, the allocations for both 2020 and 2021 showed increase due to the Covid-19 pandemic. Expenditure for 2020, 2021 and 2022 also include Covid-related purchases like Covid vaccines, oxygen, and PCR kits other than regular purchases. Table 3 compares the consumption costs for pharmaceuticals, surgical supplies and laboratory reagents, with the actual expenditure by the Government Treasury.

Analysing the consumption cost data of pharmaceuticals and medical devices of the past 5 years (2018-2022) provided by the MSD revealed that the total consumption cost has been consistently exceeding the allocation provide by the Treasury, even when the expenditure for Covid supplies are excluded (Table 3). When the above annual allocations are considered the excess of expenditure over the allocation has steadily increased from LKR 5.7 billion in 2018 to LKR 29 billion in 2022. There has been an unprecedented excess expenditure of LKR 69 billion in 2021. Although the Covid related expenditure was calculated to be about LKR 142 billion in 2021, some amount of expenditure estimated as regular supplies could also be Covid related expenditure giving a partial explanation for this unprecedented excess. The total expenditure on laboratory supplies including Covid-19 related expenditure has been a staggering LKR 250 billion (which includes the cost of PCR testing) while the usual expenditure on laboratory items in 2019 was about LKR 1.5 billion according to the data provided by MSD

(Table 3). However, this data and analysis needs to be further verified from primary sources to confirm their accuracy.

Table3: Consumption cost for pharmaceuticals, surgical devices and laboratory reagents and test kits in the Ministry of Health from 2018 to 2022 (LKR millions)

Consumption cost	2018	2019	2020	2021	2022
Pharmaceuticals	36,961	41,959	43,610	46,517 (97,367)*	41,777 (47,020)*
Surgical devices	11,226	13,224	13,948	16,508 (23,329)*	13,716 (17,663)*
Laboratory supplies	857	1,637	9,326 (47,278)*	79,523**(249,140)*	47,320** (96,100)*
Total	49,044	56,821	66,884 (104,836)*	142,548** (369,836)*	102,813** (160,783)*
Allocation provided	43,331	54,068	83,545	73,638	73,050
Amount spent in excess of Treasury allocation for regular supplies	5,713	2,753	-16,661*** (21,291)*	68,910 (296,198)*	29,763 (87,733)*

*consumption cost including estimated expenditure for Covid supplies

** Probably includes some Covid related supplies

***Additional contribution probably for Covid related expenditure

Source – Calculations based on MSD data, Ministry of Health

WHO reported that as of January 2023, Sri Lanka was facing a funding gap of 220 million US dollars to import essential medicines and medical supplies (1). Already the Sri Lankan government owed LKR 25.7 billion in arrears to foreign pharmaceutical suppliers. These figures indicate how the economic crisis affected the pharmaceutical supplies in the country as non-payment of bills resulted in delayed or non-supply of pharmaceuticals (7).

2.2 Performance of the health sector of Sri Lanka prior to the economic crisis

Sri Lanka significantly outperformed its peers on major health indicators, such as the low child and maternal mortality rates and increasing life expectancy at birth (8). Sri Lanka's child and maternal mortality indicators are already lower than the relevant targets set under the Sustainable Development Goals and are on par with those of developed countries. The national immunization program of Sri Lanka has an excellent record, with more than 95% coverage for all Expanded Program of Immunization (EPI) vaccines and there is low incidence of EPI covered diseases in the country. There has also been considerable progress in eliminating several communicable diseases, including malaria, polio and filariasis.

Considering the availability of medicines, several studies conducted over the years report the availability of selected essential medicines as high (>80%) or fairly high (50-80%) in both the public and private sectors in Sri Lanka (9-13) according to the WHO categorisation of availability of medicines (14). Most medicines were also affordable to the lowest income groups in the community (9, 11). The WHO emphasises that as a country that has performed consistently well on key health indicators with significant achievements well above the fellow countries, it is imperative to ensure that the progress is not rolled back (1).

2.3 Pharmaceutical supply in the state sector

The pharmaceuticals and medical devices supply to the state sector involves several stakeholders and an optimal interplay among them is crucial for an efficient supply system. The key stakeholders include the NMRA, MSD and the SPC, local pharmaceutical manufacturers, including the SPMC and the pharmaceutical importers.

Representatives of the professional medical colleges, associations and university departments serving in many technical committees of the NMRA, MSD and SPC provides technical support to the supply chain at various points. The hospital administration and hospital pharmacists, both under the line ministry and provincial ministries and the MSD play a crucial role at government level in forecasting the annual requirements. The government treasury under the finance ministry providing finances for purchase is also a key stakeholder. During this crisis period, various donor agencies and other donors, both local and international, have become important sources of pharmaceuticals and their contributions

need consideration. All pharmaceuticals and medical devices imported for the state sector are procured through the SPC while the MSD and hospitals also procure some emergency supplies directly as local purchase (LP).

2.4 The procurement process

The pharmaceutical items purchased by the state is decided at the MSD by a Formulary Committee, which is revamped every 2-3 years. The publicly available current Essential Medicines List (EML) is the 4th revision of 2009 (15). It was revised in 2021 and this revised list is used now. The medicines in the EML and those not in EML but are required for patient care as decided by the Formulary Committee of the MSD are submitted for purchase by the SPC. The medicines are categorized as Vital, Essential and Non-essential (VEN)(16). The basis for this categorisation is given below as defined by the Formulary revision committee of the MSD. The medicines included under each category needs review and revisions.

V- Vital medicines are potentially lifesaving and crucial for providing basic health services. They should be available at all times. There are 14 vital items identified.

E- Essential medicines are medicines that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford.

N- Non-essential medicines are used for minor illnesses, may be of questionable efficacy or have a comparatively high cost for a marginal therapeutic advantage.

The medicines used in the state sector are also categorised as regular, complementary or to be supplied on a named patient basis. Regular items are approved to be included in the formulary for regular use by the 4 levels of healthcare facilities of the MoH. These items will be regularly supplied by the MSD. Complimentary items are essential medicines for priority diseases for which specialized diagnostic or monitoring facilities and/or specialist medical care and /or specialist training are needed. Named patient items are issued for a particular patient for a specific indication.

The purchasing process begins with forecasting the annual requirements for the country. The quantity needed is decided by the pharmacists in the hospitals based on the consumption of

each medicine during the previous year and by adding about 10% to the previous years supply. Whether the stocks were adequate and/or there was a surplus is also taken into account.

The MSD collates all annual estimates of pharmaceuticals, surgical supplies and devices as well as laboratory reagents and test kits from all hospitals and other healthcare institutions and makes annual estimates of requirements for the entire country. Next it places procurement orders with the SPC. The SPC calls for tenders for which the suppliers quote. The tenders are evaluated by committees appointed at different levels based on the total tender value and the tenders are finalized by the SPC. The products (medicines, medical devices and test kits etc) of successful bidders for tenders must be registered with the NMRA. This regulatory requirement is a safeguard to ensure efficacy, safety and quality of medicines. In addition, the affordability is also looked at through price regulation. Under exceptional circumstances a WOR is granted as per guidelines of the NMRA.

The SPC procures the medical supplies with funds received from the government treasury, and the supplies are received by the MSD. The MSD distributes the stocks to the hospitals and other healthcare institutions based on the estimates and quantities requested by each institution. This process of supply of pharmaceuticals is illustrated in Figure 1 indicating the main stakeholder groups.

In the following pages the challenges and barriers faced by the institutions involved in the supply of pharmaceuticals, and the recommendations towards improvement are discussed. Information in relation to the other stakeholder groups are also given in the same format.

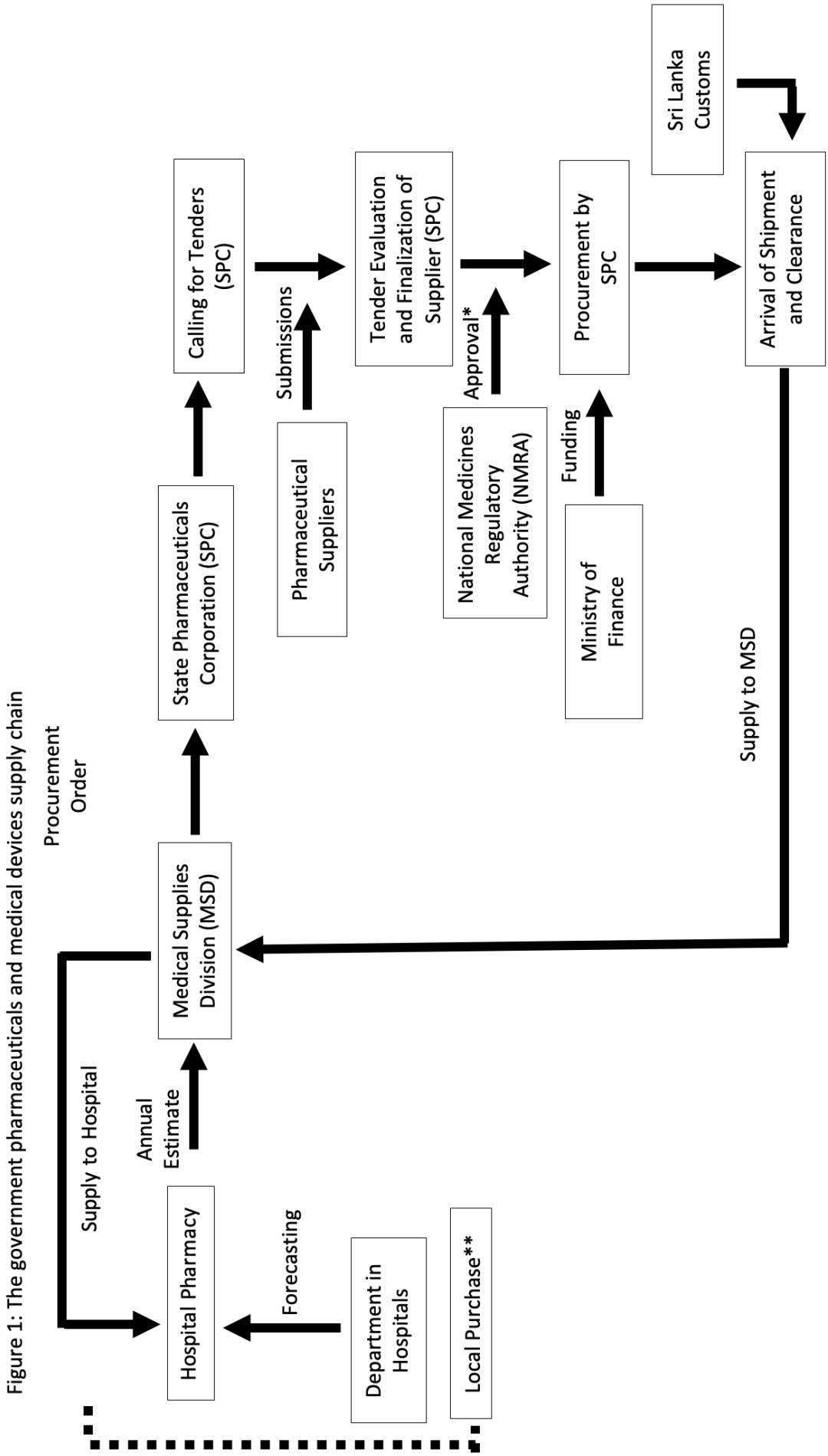

Figure 1: The government pharmaceuticals and medical devices supply chain

3. THE INSTITUTIONS AND KEY STAKEHOLDERS

3.1. The National Medicines Regulatory Authority (NMRA)

The regulatory body for pharmaceuticals in Sri Lanka is the NMRA (17). The NMRA Act of 2015 provides the legislative framework to regulate and control the manufacture, importation, sale, storage and distribution of pharmaceuticals, borderline products, and medical devices. The main objective of the NMRA is to ensure that all pharmaceuticals available in Sri Lanka are safe, efficacious, and of acceptable quality. NMRA also has the responsibility of regulation of medicines prices, monitoring of suspected adverse drug reactions, conducting quality checks on samples, recalling pharmaceuticals from the market on safety grounds and control of advertisements on medicinal drugs.

There were 8,095 registered products at the NMRA, including medicine, vaccines, and devices in 2015 (18). A product is registered after careful evaluation of information submitted in a dossier compiled according to guidelines. Evaluation of medicines is the responsibility of the Medicines Evaluation Committee (MEC) of the NMRA. The MEC comprises of representatives from the major medical speciality colleges, pharmacologists and pharmacists. The NMRA Act provides to co-opt members on a need basis.

3.1.1. Challenges and barriers relevant to the NMRA

i. Increasing number of medicines brought into the country under WOR pathway (Clause 109 of the NMRA Act)

All medicines that are made available to the public requires registration except when a WOR is granted under exceptional circumstances as stated in the NMRA Act. The special circumstances include a medicine used to save a life, to control an outbreak of an infection or an epidemic or any other national emergency or for national security. In the recent past the NMRA has published guidelines to be followed when WOR is requested (19).

Although attempts have been made over the recent years to reduce the number of products for which WOR is granted as shown in the Information about the WOR during the past 5 years

(Table 4), still the number granted WOR remains high. Furthermore, the number of WOR granted in 2023 is not available and there were many complaints recently about a large number of WOR being granted by NMRA administration, without the approval of relevant NMRA committees which were highlighted in media and by professional associations.

Table 4: Waiver of Registrations during the last 5 years

	2018	2019	2020	2021	2022
Granted	136	270	185	93	98
Not granted	0	98	183	208	130
Decision unclear or not mentioned	64	44	10	19	12
Decision pending	2	7	33	18	28
Order cancelled (WOR not needed any more)	2	0	3	0	0
Total submitted for WOR	204	419	414	338	268

Considering the reasons why WOR is granted, often WOR is granted when there are no registered suppliers for items required for government tenders. Sometimes although there are valid registrations the companies are not interested in quoting for the SPC tenders due to many reasons, including non-payment of dues for previous supplies due to the economic crisis. Also, pharmaceutical importing companies are not interested in obtaining registration for medicines which are required in small quantities or where the sale is not profitable.

The list of products submitted for WOR at each Medicines Evaluation Committee (MEC) meeting is available in the NMRA website, gives information whether the request was granted or the reasons for not granting approval. However, the data are not updated and most recent lists granted WOR are not available. The reasons for not granting WOR (Annex 1) includes availability of registered suppliers, price quoted being too high, requesting party not giving justification for the request, MSD having sufficient stocks etc. Over the recent years it is noted that purchase of medicines through WOR has become a regular phenomenon rather than an

exception, and this could jeopardise the quality of pharmaceuticals entering the country. A critical review of reasons for WOR is urgently needed to minimize such purchases.

There were reports of political interference in the registration process by granting WOR to several pharmaceuticals without adherence to guidelines. This situation led to several professional organisations complaining to the relevant authorities, informing the public and even seeking legal action. Implementing the available guidelines for WOR strictly, insisting on applicants to submit all the required documents and taking steps to further revise the guidelines appropriately, and steps to limit the applications for WOR is urgently needed to minimise products which have not been properly evaluated being used in Sri Lanka.

There are certain common medicines (eg. atorvastatin, metformin, and losartan) which have several registered suppliers in Sri Lanka. It is surprising that WOR have sometimes been requested for such products also. The MEC has recommended restriction of registrations to 15 for each pharmaceutical product in order to encourage and enable priority registration of products which has only a few registered products. The NMRA board has also given the permission to permit free registration of products which are not economically viable for the supplier in 2021. Unfortunately, this has not been implemented due to the delay in gazetting the board recommendation, in spite of several reminders.

Although Clause 109 of the NMRA Act provides for the import of medicines without going through the registration process this provision was meant for import of medicines in emergency or special circumstances only. An example would be in unforeseen circumstances, such as the recent Covid pandemic. Recently WOR is used to clear large numbers of medicines that have not been properly evaluated, and also to clear the donations. Although shortage of a medicine to treat a patient could be considered as an emergency, it is the view of this Committee that Clause 109 of the NMRA Act was not meant to be used as it is being done presently.

ii. Need for expedited evaluation of products submitted for tender purposes

There is a notable staff shortage in the NMRA, limiting its capacity for timely evaluation of dossiers for items for which only a limited number of registered products are available.

Expedited evaluation of dossiers is also needed for award of tenders for procurement of emergency stocks. Delays are also noted in clearing of donations.

In addition to staff shortages and inability to recruit competent skilled staff, lack of proper up-to-date databases, poor maintenance of documents, shortage of space and poor working conditions has also contributed to the delays.

iii. Sudden transfer of large number of experienced staff at both NMRA and NMQAL

At a time when the NMRA is already severely short staffed, transferring many experienced staff has created a huge problem for evaluation of medicines aggravating the delays. This issue needs to be urgently rectified and more new staff needs to be recruited enabling them to be trained under experienced staff. Unless this issue is rectified soon, the evaluation of medicines for registration will be done by inexperienced staff and there would be many delays in evaluation of dossiers further aggravating the shortages and quality of the registered medicines.

iv. Pricing of medicines and medical devices

When the NMRA was established in 2015, the NMRA Act gave powers to regulate prices of pharmaceuticals. However, this area is new to the NMRA and the institutional experience is limited. The NMRA had an established Pricing Committee and resorted to regulation of prices by fixing a MRP for selected medicines and a few medical devices (eg. cardiac stents and lenses for use in the eye). The Pricing Committee at the NMRA has been contributing in a major way negotiating the tender prices and MRP in the recent past without allowing companies to dictate the prices despite sometimes having pressure to increase the prices of medicines. The NMRA has not extended the term of office of the existing Pricing Committee which was well functioning and appointed a new committee and the reason for this is not clear. This type of actions can have a major impact on price control measures for the future.

Issues pertaining to price regulation are listed below

1. Insufficient expertise about price regulation at NMRA worsened by lack of access to international databases etc.
2. Difficulty in arriving at a pricing mechanism and a pricing formula. Although the pharma Industry has accepted price regulation they have consistently pressed for a

pricing mechanism and formula. In fairness to them the depreciation of LKR and the shortage of US dollars that Sri Lanka faced has made their operations difficult

3. Price regulation requires a multi-pronged approach with inputs of expertise from fields such as health economics, accounting etc. The Pricing Committee needs this input.
4. During the last 4 years the Covid situation followed by the economic crisis has made price regulation difficult. The LKR has shown wide fluctuations against the US dollars (sometimes over short period of time) and this has caused difficulty to all stakeholders (both the regulator and the regulated)
5. Lack of a monitoring mechanism to ensure that the benefits of price regulation percolate to the patients.
6. The term of the pricing committee should be extended with new members appointed if needed, instead of appointing a totally new committee as the pricing committee has been functioning well and pricing formula is still in the process of being improved and stabilised.

v. Breakdown of processes and organisational structure at NMRA

In the recent months, there have been several concerning developments which have taken place within the NMRA that has led to the collapse of previously established processes and structures for administration of its functions. The vacancy of a pharmacologist in the NMRA Board has not been filled. Further the NMRA board has recently reversed certain technical decisions of the MEC without consultation with experts in the field. The Pricing Committee has been dissolved, and a new committee appointed. Similar situation with the functioning of Quality Failures Evaluation Committee. (also identified as the Recall Committee). As indicated earlier, competent, qualified senior level staff, mostly in pharmacists cadre, have been reverted to the MoH compounding matters in the already short-staffed Authority. These developments are alarming as these actions prevent the development of a work ethos in the NMRA. All these are retrograde steps weakening the NMRA, when in fact it should be strengthened.

vi. Other challenges and barriers relevant to the NMRA

i. Not having data on registered products in a publicly available database, that is updated regularly. Although a list of registered products is available in the NMRA website the information is not updated regularly.

ii. The web based online registration which was initiated in 2018 was lost. Since then, only hard copies are accepted which has led to serious issues such as lost dossiers, lack of traceability, inability to prioritize essential medicines registration and delay registrations with a few registered products etc.

iii. Not having comprehensive databases on updated information on local agents and overseas manufactures and principals.

iv. Difficulties in evaluation of dossiers especially due to change in manufacturing sites during the Covid pandemic

v. The present method of registration of products at the NMRA is predominantly based on evaluation of document submitted by the importers and/or local manufacturers. Such a method has its own limitations.

vi. Having a large number of products registered for certain medicines, while there are no registered products for others.

vii. Although the NMRA has a mandate to regulate all aspects related to pharmaceuticals, when the local agents do not bring products for registration or do not import the products they have registered the NMRA has become helpless. It has been unable to provide the background to have a continuous supply of pharmaceuticals.

3.1.2. Recommendations for the NMRA

1. Adhere to the structure and functions stipulated in the NMRA Act and take measures to fill the vacancies in the NMRA Board and the Committees as soon as possible. In addition to serving in the Authority Board, the NMRA should consider appointing a fulltime pharmacologist to its staff. Some of the PGIM trained doctors with a post graduate qualification in Clinical Pharmacology can be appointed for this purpose.
2. It is highly recommended to restart electronic submissions in the E–CTD format as soon as possible to make the process transparent, enable traceability and monitoring. There should be back-ups of all files submitted and safeguards put in place to prevent

the loss of data if any problem occurs with the electronic system as that happened earlier.

3. Restore the Pricing Committee and re-start the Quality Failure Evaluation Committee of the NMRA to enable blacklisting of manufacturers etc.
4. Increasing the NMRA staff by obtaining special permission for recruitment of new staff if required and to absorb the experienced staff who were transferred out as they are willing to join NMRA as there is ample justification for requesting that even in the presence of the current embargo on recruitment.
5. To avoid delays in dossier evaluation, external expertise from departments of pharmacology in universities can be commissioned through memorandums of understanding.
6. Capacity building of staff by retaining experienced senior staff members who are competent in their roles and at training and upskilling new staff.
7. Commission WHO expertise for price regulation whilst training local staff. Needs political commitment for full implementation of price regulation provisions.
8. Update and maintain databases including those of registered products, registered suppliers, registered manufacturers and importers and make these databases accessible to the public.
9. Prioritise and expedite the registration process of essential medicines which have only a few registrations.
10. Request suppliers whose products are not registered with the NMRA if applying for SPC tenders, to submit all the required documents given in the WOR guidelines. This will require all applicants whose products are not registered to apply for WOR, instead of only the one selected after award of the tender. This process will allow time for the NMRA to review the applications while the tender process is progressing.
11. Include a clause in the WOR guidelines stating that any supplier who applies for a government tender should submit the product for the normal registration process after obtaining WOR once. Those who fail to do so should not be granted WOR for awarding subsequent government tenders. This step should prevent suppliers from applying for WOR repeatedly without registering their products.
12. Take steps to blacklist manufacturers having major quality failures and not to consider their products during the period of blacklisting. Also ensure that the deficiencies

detected are corrected prior to reconsideration of products from such manufacturers for registration.

13. Conduct market surveillance and monitoring on pricing and availability of registered medicines periodically. Take measures to see that benefits of price regulation get passed on to the public.
14. The number of Food and Drug Inspectors is grossly inadequate. Steps need to be taken to increase cadre and recruit them as early as possible.
15. Establish a formal mechanism to obtain feedback from patients, patient groups and prescribers

3.2 The National Medicines Quality Assurance Laboratory (NMQAL)

The quality of medicines is checked by the NMQAL, which comes under the authority of the NMRA. The capacity of the NMQAL is inadequate to monitor the quality of medicines effectively due to the large number of imports and inability to have a post market testing scheme effectively. The number of analytical staff is currently only about 11 while there were nearly 30 earlier and some senior staff are also due to retire soon. The current number of staff is grossly inadequate to perform the quality testing of post marketing samples that was conducted to some extent previously before 2015, when the NMRA was established. Many medicines are already in use or indeed the entire stock has been used up by the time quality failure is detected. Other than the danger to the public caused by consumption of quality failed medicines, replacing them is a tedious procedure (7). Furthermore, NMQAL lacks the ability to analyse a significant number of compounds and the reports are often delayed.

3.2.1 Challenges and barriers relevant to the NMQAL

1. Acute shortage of qualified staff which needs to be rectified on an urgent basis
2. The NMQAL has not been proactive in identifying quality failures, reporting or preventing quality failures of medicines in the country. Aspect of communicating information has also been deficient.
3. Failing to establish and maintain a basic drug quality surveillance program in the country.

4. There is a failure to utilize available resources effectively both internally and through collaborations with other organisations.
5. The NMQAL has not evolved with time using new technologies which would enable more efficient functioning.
6. Lack of coordination with other stakeholders leading to delays and suboptimal delivery of expected services.

3.2.2 Recommendations for the NMQAL

1. Recruitment of new staff and absorbing the experienced staff who were transferred out who are willing to join the NMQAL.
2. The quality testing capacity of the NMQAL needs to be enhanced urgently. Capacity building of existing staff through training and appraisal is needed.
3. Testing of random post-marketing samples to be initiated to identify quality failures early.
4. Collaborate with additional independent laboratories such as university laboratories and other government laboratories that can perform quality testing of medicines to support the NMQAL (7).
5. Establish storage space under standard conditions to store samples to enable testing of post-marketing samples that are stored under recommended conditions. Such a step will avoid the companies blaming poor storage as the reason when their products fail in quality.
6. Take steps to establish a new state of the art accredited quality testing laboratory with sufficient capacity to fulfil the quality testing requirements of the country.

3.3 The Medical Supplies Division (MSD)

The MSD has to supply medicines to various state health care units which includes 622 hospitals and 475 central dispensaries and primary care units (18). Each unit of the MoH getting medicines from the MSD (which is between 1000 to 1100 in number) has to send its annual requirements to the MSD about 1 year in advance. Arriving at the annual requirement has a component of estimation and forecasting. The more important task of arriving at the

entire country requirements is done by the MSD. In this exercise the MSD collates the estimates sent by the various units. In addition it has to do forecasting based on the stocks at hand, orders expected, donations, requirements of any new units coming up and other factors. The MSD has to do this estimation for the different medicines, devices, reagents and test kits totalling about 14,100 items. This is a herculean task.

The formulary revision in 2019 included a total of 1346 medicines for purchase for the state sector, which were categorised as vital (14 items), essential (675 items) and non-essential (657 items) in their different dosage forms. The EML itself has 383 medicines which includes 675 items in different dosage forms (15). The most recent revision of the list of medicines for the hospitals, chaired by the DGHS with representatives of the speciality colleges and associations held from February to April 2023 has identified a list of 850 items. This list has 753 stock items and 97 items to be supplied on a named patient basis.

Tenders are scheduled according to ascending prices and evaluated technically at 3 levels for purchasing based on the total value of the tender (20). For tenders of up to LKR 200 million, the Department Procurement Committee (DPC) of the SPC, up to LKR 500 million, the Ministry Procurement Committee (MPC) of the MoH, and for tenders over Rs 500 million, the Cabinet Appointed Procurement Committee (CAPC) is responsible for selecting and awarding the tenders. Some selected hospitals have the privilege of LP where they are given funds approximating 10% of their allocated budget for direct procurement needs. Other than the LP all other budgeting and procurements of the state are dealt centrally by the MSD and the SPC.

3.3.1 How are the funds utilized?

Review of MSD data shows that 70% of the drug budget is used to purchase just 115 items (8.2%) out of a total of 1403 items decided by the Formulary Committee for purchase for the entire country (Table 5 and Annex 2: Supplementary Table2). These 115 items contains only 7 vital and 59 essential items (totalling 66 items) and 31 non-essential items. It was noted that only 10% of the total expenditure is spent on purchasing 718 medicines which constitutes 51% of the total requirement of the country, including the non-essential items. Therefore, if

items are prioritized at time of purchase considering their cost it would be possible to avoid the shortages of the essential medicines in the country in the future.

Table 5 : ABC analysis of medicines purchased in 2021 and 2022 – number and percentage of medicines that are using 70%, 20% and 10% of the total consumption cost (MSD data)

	2021* **N = 1368 (%)** V=18, E=710, N=640			**2022*** **N = 1403 (%)** V=19, E=708, N=676		
70% of total cost (Category A)	120 (8.7)			115 (8.2)		
	V	E	N	V	E	N
	6 (5.0)	66 (55.0)	48 (40.0)	7 (7.2)	59 (60.8)	31 (32.0)
20% of total cost (Category B)	200 (14.6)			196 (14.0)		
	V	E	N	V	E	N
	4 (2.0)	138 (69.0)	58 (29.0)	3 (1.5)	132 (68.0)	58 (29.9)
10% of total cost (Category C)	774 (56.6)			718 (51.2)		
	V	E	N	V	E	N
	7 (0.9)	413 (53.4)	354 (45.7)	8 (1.1)	393 (54.7)	318 (44.3)
Not purchased/ consumed	274 (20.0)			293 (20.9)		
	V	E	N	V	E	N
	1 (0.4)	93 (33.9)	180 (65.7)	2 (0.7)	93 (31.7)	198 (67.6)
Donations	1 (0.1)			81 (5.8)		

V – Vital, E – Essential, N – Non-essential
*Covid-19 vaccines have been excluded from the analysis

The estimated cost for purchasing all the 1403 pharmaceutical items listed in the formulary would be about SLR 50 billion using the purchasing cost in 2022 and the total estimated consumption for the year (Table 6). As the total budget for medical supplies is about SLR 73 billion, which includes the cost of surgical supplies and laboratory items, the treasury allocation would not be sufficient to purchase the total list, which would lead to continuous shortages of medicines. The list prioritized in 2023 by the Specialist colleges containing about 850 items however would cost over LKR 35 billion (Table 7) and it may be possible to purchase that list with the current allocation. Similar analysis for the total cost for surgical and

laboratory supplies is needed to determine what can be purchased within the government allocation and revise the listed items.

Table 6: Estimated cost to purchase vital, essential and non-essential items based on standard costs and annual estimates in 2022

	Vital	Essential	Non-essential	Total
Number of items	19	708	677	1404
Estimated cost in LKR millions *	3,856.1	27,247.3	19,514.6	50,618
Percentage of total estimated cost for pharmaceuticals*	7.6%	53.8%	38.6%	100%

*Estimated cost may be lower than the actual cost because of nonavailability of data on standard cost and annual estimates of some items in each group

Table 7: Estimated cost to purchase the priority list of items based on based on standard costs and annual estimated in 2022

	Stock items	Named patient basis	Total
Number of items	753	97	850
Estimated cost in LKR millions	32,641.4**	2,738.4*	35,379.9
Percentage of the estimated total cost for pharmaceuticals	92.3%	7.7%	100%

* Estimated cost for 54 items only.

**Estimated cost for 679 items only

Detailed analysis of the individual items consuming most of the drug budget shows that nearly 2 billion LKR is spent to purchase tenecteplase (in 2 strengths), which is more than double the cost spent on supplying 0.9% sodium chloride solution (*ie*. normal saline) for the entire country (Annex 3: Supplementary table 3). Anti-rabies vaccine and rabies immunoglobulin, human albumin, intravenous immunoglobulin, dried Factor VII, meropenem are the other items costing most. Judicious use of these items and having evidence based guidelines for

their use would ensure that they are used optimally, reducing the cost incurred on purchasing these high -cost items.

Therefore, careful selection of necessary items within the available medical supplies budget needs to be done if the shortages of medical supplies are to be avoided in the future. If requests for very expensive pharmaceutical and other medical supplies items are added to the formulary without consideration of availability of funds the shortages of essential medicines cannot be prevented as the very expensive items may be purchased at the expense of the essential supplies.

Regular analysis of items purchased and expenditure for each of the items would help to identify those costing most and to pay special attention to them during procurement, distribution and use in hospitals.

3.3.2 Challenges and barriers relevant to the MSD

1. The MSD is tasked with supplying approximately 1403 pharmaceutical products, 9138 of surgical items including devices and 3603 of testing reagents and kits to all state sector health care institutions from teaching hospitals to peripheral units, and Medical Officers of Health areas as well as designated national campaigns. Estimation, procurement, and distribution of such a large assortment of items, as well as accurate record keeping in itself is challenging. It was noted that records maintained lack uniformity across the years, sometimes incomplete and not up to date in certain instances.
2. Accurate estimates based on forecasted estimates sent from individual healthcare institutions are vital for maintaining supply whilst optimally utilising the available limited resources. The MSD has noted over the years that the estimates they receive from hospitals are not based on proper forecasting, particularly for surgical items, often not considering existing stocks. However, there is no systematised mechanism in the MSD to request the hospitals to re-do their estimates or call for explanations when there are concerns.
3. Delays in the procurement process occurring due to difficulties in scheduling Technical Evaluation Committee (TEC) meetings at different levels (eg MoH and Cabinet) based

on the availability of its members. Poor coordination is noted between the main stakeholders including the NMRA, MSD and SPC and sometimes members not being prepared for the tasks at hand when attending meetings contributes to delays. Such avoidable and unavoidable delays in procurement contributes to the current shortage of medicines and devices in the country.

4. MSD does not consider the treasury allocation for medical supplies when deciding on the new items to be added to the formulary and the purchasing cost to supply the essential medicines. The tenders are called for when the items are requested by the users, rather than in a planned manner prioritizing essential medicines over non-essential items to optimally use the budgetary allocations. Therefore, shortages of life saving and essential medicines arise as the budgetary allocations become insufficient.
5. Absence of an annual review and monitoring mechanism of the pharmaceutical requirements, supplies, utilization, shortages, cost analysis, treasury allocation to identify problems before they escalate.
6. The national DTC has not met regularly in the recent past and therefore there is no national body which overseas and makes decisions on important technical matters related to procurement etc. The MSD presently reaches out to professional colleges or individual consultants in an ad hoc manner for these issues at present, which is neither sustainable nor sound practice.
7. Lack of an online system that can be viewed by all stakeholders on the current stocks available and pending tenders and purchases.

3.3.3 Recommendations for the MSD

1. Establish an online system urgently for coordination amongst the hospitals, MSD and SPC to enable each party to check on the currently available stocks of all medical supplies, the stage of processing of tenders and stage of procurement by SPC.
2. Coordination between different stakeholders should be improved with focal points of contact identified for different functions.
3. The TEC for tenders should be given deadlines for vetting and approval at each level and should be streamlined to avoid delays.
4. The purchasing of essential medicines to be prioritized and the non-essential items to be purchased after securing funding for the essential medicines.

5. Identifying priority items based on the available budgetary allocation, considering prices quoted and required specifications would help to maintain the supply of the most essential medicines, overcome shortages of essential medicines and some of the delays and to take decisions based on the needs of the country.
6. Establish a Unit for monitoring the use of pharmaceuticals and medicines shortage to monitor such shortages in the MSD and notify relevant stakeholders.
7. Appoint a central technical advisory committee to support such a unit at MSD/Ministry of Health comprising of representatives of specialty colleges and associations and other relevant persons and hold regular meetings at the MSD; such a committee will help to address some of the technical issues during the tender process and purchase orders such as prioritizing a new item over an old item, before problems of shortages arise.
8. Analysis of cost of medical supplies purchased for the country on an annual basis, comparing with the annual budgetary allocations for medical supplies and providing such information to colleges and associations along with the purchasing prices in a transparent manner can be done by the monitoring unit. This would help the colleges to decide the priority list of items considering the disease burden and their therapeutic use.
9. Regularise meetings of the national DTC chaired by the DGHS to be conducted quarterly to discuss technical issues pertaining to medicines reported by hospital DTCs.
10. The national DTC should decide on adding any costly new medicines to the Formulary only after HTA considering efficacy, safety and cost effectiveness.
11. Review the Vital, Essential, and Non-essential lists and the priority lists for purchasing pharmaceuticals with the inputs of the specialist Colleges
12. Include any new items into the formulary or named-patient basis items for purchase only after recommendation by the relevant college and decided at the national DTC after considering data on cost, disease burden and annual cost required, and not accepting requests made by individuals directly.

3.4. The State Pharmaceuticals Corporation (SPC)

The SPC is the agency responsible for public procurement when a procurement order is placed by the MSD. The commonly used procurement method is worldwide tender, but the SPC procures through both local and international tendering procedures also (21). The tenders are awarded considering the prices quoted, past performance, quality of the samples submitted and registration status (22). Tenders are generally for supply of one years stock. There are allegations about lack of transparency in the steps of the procurement process (22). Though the Sri Lankan health system is decentralized, the countrywide requirement of medical supplies is purchased centrally by the SPC and distributed by the MSD. The quarterly requirements based on the estimates are distributed to regional depots located in the 25 Districts.

3.4.1 Challenges and barriers relevant to the SPC

1. The existing Medical Supplies Management Information System (MSMIS) which is shared across the main stakeholders in the supply chain including the MSD and SPC is not being utilized optimally. Some basic data which should be updated by the SPC is not available to the other parties.
2. Although the MSD makes a request to purchase a specific item not infrequently the specifications, amounts needed and delivery schedules are changed by the MSD. This makes the SPC to revise documents several times causing delay.
3. The lead time to bring down the annual supplies of medicines from the time of submitting the requests to the SPC is about 9-12 months, as companies need to manufacture the quantities needed (which are often large), according to the specifications
4. There are delays in scheduling meetings of the TECs and different tender boards due to poor coordination among stakeholders and the limited availability of all its members at any given time.
5. Insisting on written confirmation of tenders by the SPC rather than accepting computer information from the MSD (18 day delay vide Auditor General's report)
6. The system of maintenance of records is suboptimal and the SPC does not have up to date information on even some of the salient indicators such as the number and value of tenders awarded each year.

7. Lack of registered suppliers for some of the procurements
8. Suppliers not meeting the tender requirements
9. Changing the specifications of the tenders after they have been called
10. Wide variations in the prices quoted by the registered suppliers and of the lowest quoted prices
11. When tender samples or pre-shipment samples fail in quality new suppliers must be identified. The whole process causes delay leading to shortages.
12. Punitive action needs to be taken for companies that fail to honour the tender requirements
13. There are staff shortages and inability to recruit skilled staff for the tasks required, which also hampers the functioning of the SPC. However, SPC staff feel that the situation should improve with the conversion to a new software system.

3.4.2 Recommendations for the SPC

1. Take steps to supply the essential medical supplies before the non-essential items as the funding is not available for all the supplies requested. Seek advice from the MSD in such prioritisation informing the available funding status.
2. Shortening the lead time by proper coordination between different units of SPC, MSD and NMRA.
3. Implementing an effective electronic system such as the planned programme (Swastha) replacing the MSMIS enabling all parties to monitor the state of the processing of tenders. This could overcome some of the current problems encountered. The existing MSMIS use should be optimised across all users.
4. Establish a Technical Advisory Committee comprising of representatives of specialty colleges and other resource persons to obtain the necessary technical advice needed for speedy action on pending tenders.
5. Analyse the details and reasons on items where long delays in purchasing has been experienced causing shortages and inform the reasons to the relevant parties to rectify problems.
6. We also include a statement from one of the Auditor General's reports *verbatim,* " It is concluded that there is a continuous shortage of medical supplies due to failure in following the procurement procedures by officers purposely, negligently or efficiently

and due to the non-maintenance of buffer stocks for many items of medical supplies. Therefore, the medical supplies had been purchased at high costs under emergency procurement to avoid such shortages. Thus, it is concluded that an additional cost of Rs.5166 million had to be borne by the Government during a period of 10 years from the year 2007 to 2016 while the relevant officers are responsible thereof" (23). The SPC should have addressed this concern and at least look into this matter now to rectify the concerns stated.

7. Appoint technical experts such as pharmacologists or members of the NMRA medicines evaluation committee to evaluate tenders. This was practiced in the 1990s and early 2000s.

3.5 The Pharmaceutical Importers

Over 180 private local firms are registered as importers with the NMRA. These include local conglomerates who distribute drugs from multi-national companies as well as agents for smaller regional manufacturers (7). The state sector accounts for about 33% of overall imports. Most medicines (96%) sold in the local pharmacies are imports and they come from India (50%) followed by China, Pakistan, Bangladesh, and Indonesia. Branded products from European countries, France, UK and USA are also marketed. Most vaccines found in the market are from reputed manufacturers or WHO approved sites.

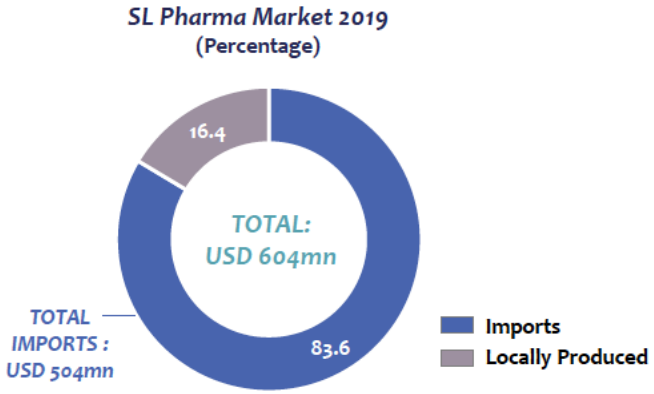

Figure 2 : Sri Lankan pharmaceutical market 2019 (from reference 7)

3.5.1 Challenges and barriers relevant to the pharmaceutical importers

1. Most importers had issues pertaining to the prices of medicines and devices. The depreciation of the LKR and wide fluctuations of the LKR against the US dollar has made it difficult for pharma business. This has affected more for items which are under price control by the NMRA. Some admitted of having incurred losses.
2. The medicines importers also had issues about use of currency *ie.* LKR vs US dollar when quoting for SPC tenders, the SPC batch/product withdrawal procedure, compliance with the 75% residual shelf-life requirement and certain stipulations in the tender documents. The importers of medical devices had issues with certain taxes such as the social security contribution, value added tax, certain HS codes, maintenance and service contracts, request for medical devices industry specific procurement guidelines, transparency in procurement procedures, need of a MoH appointed committee comprising of all stakeholders to discuss their problems, need for the MoH to use the eGP procurement information technology infrastructure. These issues should be addressed.
3. Suppliers are not inclined to obtain registration when the market share of a product they supply is comparatively low due to the high cost of registration.
4. Non-payment of dues in time for previous supplies has discouraged many previous registered importers from applying for government tenders.
5. Reduced profit margin due to penalty charges incurred for non-adherence to stipulated shelf-life requirement.
6. The SPC and relevant authorities should re-visit the regulations stipulating the method of determining the lead period from the time of LC opening instead from time of securing indent for tenders

3.5.2 Recommendations for the pharmaceutical importers

1. Minimise resorting to use of the WOR option. If this is used, need to follow guidelines completely. Submit registration dossiers of such products to the NMRA without delay.
2. Those agents with valid registrations should strive to quote for the government tenders as responsible pharma companies to meet the national requirements.
3. Strive to get down medicines from overseas manufacturers who have good track record

4. Ensure that the products imported are from GMP ensured manufacturers and meet the pharmacopoeial quality standards.
5. Submit complete dossiers containing all information required for registration.

3.6 The Local Manufacturers including the SPMC

In Sri Lanka 16.4% of the pharmaceutical market is captured by the local manufacturers including the SPMC (7). The SPMC is the largest drug manufacturer in Sri Lanka, providing 43 medicines to the MoH at low profit margins. Currently, 20 manufacturers approved by the NMRA are in operation and about 5 new facilities are being commissioned. There are about 150 locally manufactured medicines listed in the NMRA and they appear in multiple dosage forms. These dosage forms include capsules, tablets, syrups and the recently introduced parenteral products and intravenous infusions. These add up to about 300 dosage forms. Locally manufactured products are generally supplied to the state sector via the SPC through open tenders and buy-back guarantees and to the private sector through their distribution networks. Presently there were 17 locally manufactured products with buy-back agreements.

Local manufacturers currently produce about 8.5 million units of medicines per year (7) and most of these manufacturers are not operating to full capacity. They are able to expand their supply to the market.

3.6.1 Challenges and barriers relevant to the local manufacturers including the devise manufacturers

1. Pharmaceuticals and medical devices do not always share the same parameters or characteristics in the market. The medical device suppliers face difficulty when applying for tenders because there are no separate specific guidelines for medical device suppliers.
2. The SPMC supplies for tenders under the joint ventures with local manufacturers keeping a profit margin which is a disadvantage to the local manufacturers. As the SPMC is a government undertaking it gets preference over the other local manufacturers when supplying the local market. The local manufactures also should be able to supply the local market competing with the SPMC on equal terms.

3. Raw material which are required to manufacture certain medical devices are taxed when they are imported into the country, although raw material for medicines are exempt from tax. This may be due to sharing of a HS code with industry material. This leads to an increased production cost leading to high prices of the locally manufactured devices and reduces their profit margin.
4. Based on the current guidelines, the local manufacturers are required to bid in LKR for international competitive tenders and, therefore are compelled to absorb the losses due to inflation if tenders are awarded to them.
5. Because of the Covid situation and the exchange crisis, getting raw material has caused a lot of difficulty. Wide fluctuations of the LKR against the dollar has caused difficulty in getting material as well as in arriving at prices.

3.6.2 Recommendations for the local manufacturers

1. Identifying the top essential molecules sold in Sri Lanka, both by volume and value across both the state and private sectors, and encouraging more than one local manufacturer to supply the market can reduce the reliance on imports for widely used essential medicines such as atorvastatin, metformin and losartan.
2. Limiting the number of imported products for locally manufactured medicines enables the local industry to develop.
3. Allow the local manufacturers to supply to the MSD without the SPMC playing an intermediary role through joint ventures, which increases the price of items and is unfair by the local manufacturers.
4. Focus on manufacturing items considering the country needs and offering at competitive prices compared to importers
5. Explore options on how local manufacturers of medical devices can be relieved of undue tax burdens eg. by tax reimbursement
6. To introduce necessary amendments that allows local manufacturers to bid in USD, although they are to be paid in LKR based on a pre-defined conversion rate if the tender is awarded.

3.7. The Hospital Pharmacists Involved in estimating of pharmaceutical requirements

Officers of various grades and seniority function as custodians of medicines and do the dispensing function. They were of the view that despite shortages they were managing the medicines situation reasonably well prior to the Covid situation and the economic crisis. There has been considerable improvement in the major drug stores while the stores in the peripheral stations need upgrading. They admitted that large scale expiry of medicines is not happening now. Occasionally issues arise for donated items and also due to transfer of specialists who have requested supply of certain surgical items for their use.

3.7.1 Challenges and barriers to hospital pharmacists during estimation and forecasting

1. Accurate estimation of the annual requirements has been difficult due to a multitude of reasons and it is not uncommon to go with the previous year's estimate with a 10% increase.
2. Forecasting is done using consumption data over the previous years, consultant preferences and other factors. However, use of previous years data can sometime be inaccurate. For example, if the item was not available due to a shortage in that year the usage will be low and this low figure will not accurately reflect the needs of that hospital. Hence better data are needed for accurate forecasting.
3. Sometimes difficulty arises in surgery and related specialties. A particular surgeon may request a specific equipment and by the time the equipment arrives the surgeon may be not in that station. The replacement officer may not use that equipment.
4. The MSD admitted that the estimates from the hospitals are not an accurate representation of their actual requirement. Although the data is available for the hospitals/ institutions in the current MSMIS system, it is not optimally utilized in forecasting the requirements.
5. Some surgical items are estimated and included as a routine during the annual estimation. Information on their real use (occurring in operation theatres and intensive care units etc) does not come to the pharmacists. This practice leads to pile up of certain surgical items
6. The Covid situation caused cancellation of surgeries and procedures and this led to non use of certain equipment. Some of these items went past their expiry dates.
7. Short expiry medicines are a problem.

8. Some donated items are literally dumped in their stations and this causes difficulty. This issue is acute for donations having short expiry times.
9. Polypharmacy and repeat all prescriptions cause difficulty. These habits lead to increased consumption, shortages and wastage.
10. Prescribing patterns differ amongst specialists even in the same field. It can cause difficulty to service all of them.
11. Of late quality failure circulars have become frequent and "withhold" and "withdraw" instructions and their follow up has been difficult. It has added to the regular work load.
12. There are nationally about 14,100 items whose annual requirements need to be forecasted. However for certain fast moving items (e.g. paracetamol and insulin) the annual requirement can be forecasted centrally (*ie.* at the MSD) and decided, thereby minimising burden on hospitals.
13. It was felt that at least for certain selected items it is better if estimates are reviewed 6 monthly and orders made accordingly. This request was not accepted by the SPC stating procurement difficulties.

3.7.2 Recommendations for hospital pharmacists and administrators

1. It is crucial that institutional estimates are done on the actual consumption rather than on guesswork. Attempts must be made to get accurate estimates.
2. Use of up to date IT systems for identifying annual consumption and stocks available online.
3. Communicating information to all the relevant parties in a timely manner needs to improve
4. Upgrading their soft skills, information technology and other skills and training required for efficient functioning has to be provided.
5. Obtaining accurate consumption figures from theatres and catheter labs from the staff in charge of the inventories
6. Request only the required quantities without overestimating
7. Inform the MSD, other relevant parties and prescribers when the stocks are nearing low levels before they go out of stock

8. Inform about the excess stocks which are nearing expiry to the MSD and other hospitals for redistribution

3.8 The Specialist colleges and associations

The specialist colleges play a vital role in medical supplies chain as they are involved in formulary revision, and are the prescribers who influence the consumption of these items. At present there is no HTA done to evaluate the cost effectiveness of medicines, particularly high-cost medicines such as biologics when decisions are made during formulary revision. The committed members of the College of Oncology should be commended for doing cost effectiveness analysis of the oncology medicines recently and identifying the medicines that need to be supplied through the MoH to patients. Moreover, it is noteworthy that many colleges have taken initiatives to ease the burden of the economic crisis on the country's healthcare system by attempting to rationalise the use of medicines and medical devices as well as seeking donations to maintain supply of essential items. Some of the colleges such as the Sri Lanka College of Cardiology has taken steps to develop guidelines on cost effective use of tenecteplase. The Association of Sri Lankan Neurologists has taken steps to prioritise the medicines. Such attempts must be commended.

3.8.1 Challenges and barriers relevant to the colleges and associations

1. Shortage of medicines, surgical supplies and dental supplies are the main challenges faced by the medical and dental practitioners in the country. Furthermore, the prescribers, medical specialists and colleges are not fore-warned when the medicines are low in stocks and informed only when they go out of stock. There is also no formal system of information sharing in the MoH and the MSD with the specialist colleges which warns them of out of stock or low stock items.
2. All colleges have been involved in identifying the priority list of medicines which has been revised several times. However, equal priority is given to all items and there is no demarcation of essential lifesaving medicine and medicines that cannot be substituted. The medicines which should be made available at all times are not identified. There is a need to prioritise the medicines in this list as the funds are limited.

3. Lack of an online system where the specialist colleges could have access to the stocks of medicines and the purchasing costs.
4. There are often no national guidelines on the use of high-cost medicines which are utilizing a large proportion of the money spent on medicines in Sri Lanka (eg. tenecteplase, human albumin, human Immunoglobulin, Factor VIII, infliximab). Even when there are guidelines (eg. guidelines set by the Sri Lanka College of Cardiology on the use of tenecteplase in myocardial infarction), there is poor adherence to them due to the lack of monitoring of prescribing practices. This has led to a huge variation in prescribing amongst the specialists and other prescribers. As the resources are limited such practises contribute to non-availability of medicines for patients who need it most.
5. There is no systematized mechanism for the specialist colleges to know which medicines are required when they are approaching donors. Therefore, some donations contain items which are not required, or which do not meet the requirements of the country.
6. Wastage of devices and surgical appliances is a major issue in hospitals due to expiry of unutilized stocks. (eg. cardiac devices and stents, surgical meshes). The hospitals continuously receive stocks despite having adequate stocks to meet their needs. Sometimes the stocks received are hugely in excess of their requirement. This occurs because when the requirement is forecasted at institutional level, the available stocks are not taken into account due to lack of information sharing between the surgical theatres, catheterisation laboratories and other units which store surgical items and the pharmacist responsible for finalising institutional estimates. There is minimal involvement of the clinicians in forecasting as well.
7. Sometimes orders are placed at the request of individual consultants including orders for non-formulary items based on their personal preferences with no accountability on the utilization of the items purchased. Such requests can be due to the influence of pharmaceutical and devices industry, which in turn could lead to corruption and waste of limited resources in the MoH.
8. Participation of specialists in the hospital DTCs is limited due to their workload and timings of these meetings which clash with their clinical commitments. Sometimes the hospital pharmacists and other members of the DTCs lack the knowledge and skills on

how to carry out their duties as members of the DTC, which leads to poor outcomes of these committees.

3.8.2 Recommendations for colleges and associations

1. The MSD to inform the specialist colleges when a medicine is low in stock along with details of when the next consignments is expected. The MSD could also provide a viewer access to the MSMIS system to specialist colleges for ease of information sharing across different stakeholder groups.
2. To further rank the current priority list of items into Priority 1: Essential medicines which are lifesaving or disease modifying and cannot be substituted, Priority 2: Essential, but can be substituted by others, Priority 3: Lifesaving for a few patients, and Priority 4:Medicines which are needed, but may not be essential and to be supplied if funding is available. Such as exercise has been done by the Association of Sri Lankan Neurologists, to identify which medicines should be given the highest priority based on the population needs, therapeutic necessity, cost, disease burden of patients requiring this item, annual cost required and cost effectiveness. This list should be published by the MSD and revised and updated regularly. All colleges and associations should strive to assist the MSD by going through such exercise.
3. Guidelines should be developed by the specialist colleges, particularly focusing to high-cost medicines, in order to make their use rational and more cost-effective as done by the cardiologists. The guidelines should be circulated to all specialists through the MoH as circulars for adherence.
4. An institutional level committee consisting of content experts is proposed to evaluate and approve requests for high-cost medicines for non-emergency treatment. The institutional DTC should review their use and prescription, and if there is non-adherence to guidelines, those need to be raised and discussed.
5. The MSD should publish a list of items which are out of stock, which is updated regularly (at least monthly, if not more frequently) and make this information readily available to the specialist colleges to facilitate the process of obtaining donations when needed. All colleges should liaise with the MSD, rather than pharmacists in individual hospitals when seeking information on availability of medicines.

6. An online system be made available to the specialist colleges, through which they could have access to the stocks of medicines, annual utilisation and the purchasing costs, based on which colleges can take decisions on requirements.
7. Surgical supplies and devices should be stored in a central surgical store in the hospital, and units using these devices should not maintain large stocks. They should only stock needs for few weeks only. Such a strategy will facilitate monitoring of stocks at intuitional level. The pharmacists must liaise with these units when forecasting and take into account the available stocks and the requirement of each item.
8. Purchase of items on the requests of individual consultants should not be allowed. Such requests should be perused by the professional colleges before going to the MSD. The professional colleges should have a group that vets these requests and approves them to be sent to the MSD. Furthermore, local purchasing of non-formulary items should be prevented, and requests should be submitted through professional colleges to the MSD.
9. The previously imposed ceiling values for local purchases by hospitals should be reinstated.
10. Capacity building and reactivating hospital DTCs is needed to monitor and control medicines use at institutional level.
11. The representatives of the colleges who serve in many committees of the NMRA, MSD and SPC need to attend the meetings regularly and provide their expert advice without delay to expedite the registration and/or selection of suppliers for tenders.
12. Each specialist is an important role model as their prescribing habits are often copied by their trainees and the medical students. They have a responsibility to set a good example. In addition, they have a role in perusing prescriptions of their trainees to minimise irrational prescribing and wastage.

4. DONATIONS OF MEDICAL SUPPLIES

With the severe shortages experienced from early 2021, several donor agencies and other well-wishers, both local and overseas, stepped in to provide medical supplies to the hospitals. Some of the medicines supplied as donations include essential medicines such as insulin, enoxaparin, warfarin, thyroxine, streptokinase, tenecteplase, immunosuppressants for transplant patients and some anticancer medicines, to name a few. Donations supplied in varying quantities contributed towards meeting the demands, at least partially. Many professional colleges such as the College of Physicians and the College of Pediatricians rose to the occasion to obtain donations through their overseas contacts and donor agencies. While improving the medicines situation unfortunately some donations also brought problems which were similar to those encountered by the GOSL during the 2004 Tsunami period (24). After the Tsunami, large stocks of expired or unwanted medicines had to be destroyed at an enormous cost to the country. The impact of the donations during the current economic crisis remains to be analyzed.

Considering the evolution of events since the economic crisis it is the opinion of this Committee that “donations” are here to stay, at least for some time. We have come to a state where the Government has to actively solicit donations of medical items throughout the year. However, as the recipient of donations the GOSL need not accept anything and everything that is donated. The recipient (*ie*. The GOSL) should also have a say. The way out of this situation would be for the GOSL (in this case represented by the MSD) to declare upfront its requirements in detail and give information about the procedure for making donations and persons to be contacted and their contact information.

There are medicines donation guidelines developed by the WHO (25) and Sri Lanka has also developed guidelines for accepting donations. Unfortunately, there were donations which did not follow any of these guidelines.

4.1 Challenges and barriers relevant to donations

1. Lack of a regularly updated publicly available information on the list of shortages of medical supplies for which donations are required. Donors therefore initiate and select what items to be donated without knowing the requirements. The GOSL also has little say in negotiating what items are required as donations in such a situation, when items are brought to the country and need to be cleared by the customs.
2. Unfortunately stocks of expired or short expiry medicines, those which are not needed, medicines labeled in foreign languages, inappropriate dosage forms are still received as donations. Some products are unfamiliar to the healthcare workers and patients and these lead to medication errors and other difficulties (24).
3. Although donated medical items are free of charge, the GOSL has to still spend a considerable amount of money, effort and time pertaining to freight, clearance, storage, transport etc. Donations also disturb the normal functioning in certain locations.
4. Donations influence the local estimates and procurement schedules. Therefore, a dedicated person at the MSD and the SPC has to keep track of them.
5. Clearing donations at the Sri Lanka customs has caused difficulty and the GOSL has used the WOR option to clear them. This is also unsatisfactory.

4.2. Recommendations about donations

1. The MSD to identify a list of its requirements in detail on a monthly basis and make it available online on the ministry website and give information about the procedure for making donations and persons to be contacted and their contact information.
2. Donations should be according to the WHO and/or the Sri Lanka guidelines of accepting donations. These guidelines should be available to the donors in the relevant websites.
3. Streamline the donations by publicizing the focal point in the MoH. Donors must communicate with the local focal point before shipment.

5. LOCAL PURCHASE (LP) OF ITEMS AT HOSPITAL LEVEL

The hospitals purchase out of stock and urgently needed items at local level after approval of the hospital administration. The Committee is not sure as to whether there are any limits to such purchases by institutions but it noted that hospitals are local purchasing large number of items, sometimes at very high prices. Sometimes medicines bought as LP from the open market have been unregistered products. This also raises the question as to how unregistered products are sold in the market. There is a need to analyse the LP data and take steps to address concerns of the hospital administrators and pharmacists. The LP items should be discussed at the hospital DTCs and observations forwarded to the national DTC.

6. OBSERVATIONS AND RECOMMENDATIONS OF THE GOVERNMENT TREASURY, MINISTRY OF FINANCE

This Committee met officials of the Government Treasury Operations Division, the Public Enterprises Department and the National Planning Department. The issues highlighted by them and our recommendations based on these discussions are given below.

6.1 Observations by the Treasury

1. The MoH does not provide accurate estimations for purchase of medicines, devices, reagents and test kits, which makes it difficult to budget for the expenditure.
2. The MoH makes commitments to pay suppliers without a proper ceiling on expenditure. Every year there is excess expenditure over the estimates and the initial allocation and this excess expenditure is becoming unmanageable. This situation is partly due to poor planning.
3. Although a master procurement plan is there on paper, in place no proper annual procurement plan is carried out by the MSD and the SPC. Because of this situation, for this year (2023), by the 25th of April 74% of the annual allocations for pharmaceutical supplies (*ie.* LKR 40 billion from the total annual allocation of LKR 55 billion) has already been spent. Only LKR 15 billion are remaining for all the purchases for the rest of the year.
4. As the MSD and SPC do not limit their requests to the allocated amounts, the SPC takes overdrafts from the banks to make the purchases. Finally, the Treasury is required to find funds for all the Government purchases.
5. The prices set by suppliers can be way above the standard market price or the average global price as the MSD has no reliable mechanism to obtain the average prices of medicines.

6.2 Recommendations

1. The MSD must draw up an annual procurement plan and must implement it.
2. The process of purchasing should be made transparent.
3. There should be effective coordination between MSD, NMRA and SPC to avoid delays.

4. Pricing done by the NMRA needs review. The IQVIA database available to NMRA which currently includes only local data should be upgraded to include full access to global data. Although there will be a significant cost involved, this will enable accurate pricing and it will be cost effective in the long run.
5. The Ministry/MSD needs to consider the annual treasury allocation for medical supplies and prioritise items to keep within the budgetary allocation.
6. Adding of new items to the formulary should not be done in a haphazard manner. Justification for inclusion should be considered in detail including the cost of items and ability to supply continuously before adding new items into the list.
7. A finance ministry/treasury official should be included in the key committees of the NMRA, MSD and the MoH as funding is becoming more and more important and difficult every day.
8. The revised procurement guidelines should be followed without any deviations

7. OBSERVATIONS AND RECOMMENDATIONS FROM THE AUDITOR GENERAL'S REPORTS

The government audit reports which have analysed the procurement processes of selected medicines have given many useful recommendations for improvement of the system by all stakeholders. Most of the recommendations of our committee are not different from those given in the Auditor General's reports, except that the Auditor General's reports have given extensive details on the monetary aspects and the losses to the state. We recommend the NMRA, NMQAL, MSD, SPC and the other relevant parties to address the concerns in the Auditor General's reports.

The audit report by the Auditor General on supplying medical supplies by the MSD for the period of 2011 to 2016 makes 47 recommendations (23). There were many useful recommendations and not addressing the concerns and poor adherence to recommendations was noted.

Some of the observations and recommendations are highlighted below;

1. The communication between agencies such as NMRA, NMQAL, SPC, MSD are far from optimal and the pronto system should be used optimally to share information. The NMQAL should have an established quality assurance surveillance scheme rather than wait for complaint samples to do their testing. It should communicate its findings quickly. In some instances, there is a long delay in communicating quality failure information to end users, and by that time the drug stocks are used up. A system of retention of samples should be developed.
2. It is noted that the number of medicines the MSD has to supply annually has increased progressively and deletions have been few. Attempts must be made to limit the number of medicines. The estimations done by the MSD have not been on a firm factual basis. They are done with lot of guess work. It should be based on real requirements with appropriate adjustments made for stocks at hand, stocks expected and other factors.
3. It was noted that certain expensive medicines were put in a "non-estimated" category. This has to be corrected.

4. Delays in finalising specifications should not occur.
5. It has been noted that the Formulary Committee and the national DTC has not met regularly. In some cases, these committees and the local DTCs have not met for prolonged periods. These meetings should be regularised.
6. MSD should only supply medicines from a pre-identified list (Formulary and other) and should not resort to ad hoc purchases.
7. The procurement committee meetings should be held in a timely manner according to a predetermined schedule. If any delays occur, causes for these delays should be identified and corrected.
8. WOR must be minimized and should follow procedure.
9. It was noted that the same drug has been purchased from the local market at widely differing prices. If proper estimations are done such haphazard purchases should not become necessary. Purchases from the local market should be minimized and when done should be from NMRA registered sources.
10. Reliability of suppliers and their past records are important when awarding tenders and these should be considered rather than only going for the lowest quoted price. If any suppliers are blacklisted, medicines should not be purchased from them during the relevant time period.
11. Because of long procurement lead times, some of the Good Stores Practices such as keeping adequate buffer stock, maintaining minimum re-order levels, minimising short expiry dates and preventing expiry of medicines become impractical.
12. The action plan for procurement of drugs is not working and the procurement time schedule is not functioning. Sometimes the procurement lead time has extended to 28 months!
13. The long procurement lead time inevitably leads to shortages which in turn causes the GOSL to make emergency purchases from the local market at exorbitant prices. These must be minimised. The number of medicines with prolonged supply times is considerable.
14. During 2015-2016 LKR 4 Billion has been spent on purchase of medicines from the local market and this amount comes to about 10-13% of the entire annual expenditure on purchase of pharmaceuticals.

8. CONCLUSIONS

It is not a secret that right now there is very adverse publicity against the MoH and the health directorate. Some of the issues raised in the print and electronic media are given below.

1. Supply of pharmaceuticals that do not meet the recommended standards (quality failures). This is a vast subject, but it is the view of the Committee that the indiscriminate use of the WOR pathway has contributed to this situation. Steps must be taken to restrict use of the WOR pathway.
2. Lack of a proper laboratory to test the quality of pharmaceuticals. This is an issue that has been long overdue.
3. Allegations of widespread corruption at the different points of the supply chain. These are not new. Lack of transparency in the processes is the most common problem. Examples of allegations against the NMRA include giving preferential treatment to certain companies while dossiers of others are long delayed, large numbers of dossiers from certain importers are given registrations over short time spans and abuse of the WOR pathway. Allegations against the MSD and SPC include not placing orders in time, precipitating shortages enabling emergency procurements to be made, preferential treatment to certain bidders and irregularities in tender procedures etc. The members of this Committee are unable to comment on the veracity of these allegations. Yet the MoH should investigate where there is substantial reason.
4. The country is going through a period where the state health care system is in danger. In that milieu the authorities should be taking steps to strengthen the existing system and processes. Yet certain actions that the MoH and health directorate has taken recently can be taken as steps to weaken the system. Such practices should not be done.
5. There are a large number of MoH specialists, those of the university system and other institutes and other individuals who are giving their expertise to the MoH by serving in various expert committees and doing other work with very little remuneration. They are also members of various professional colleges and associations. They are serving in the committees to help to keep the free health care system going. However certain recent actions of the MOH (for example in the NMRA) has hurt the feelings of

the specialists. These actions have made them to question themselves as to why they should be doing work for the MoH any further. We are aware of some members who have already resigned from the committees. By these actions ministry is going to lose the services of interested committed specialists who have given their expertise. Some of these specialists have served for prolonged periods. Replacing some of them is going to be impossible and the MoH is going to suffer. In that process it is not only the MoH the entire country is going to suffer. Hence the high officials of the MoH should re-think this issue.

The Ministry of Health should give due consideration to these concerns raised and try to implement the recommendations given in this report which could address these concerns and improve the confidence that the people of this country and the health care professionals have on the state health system.

9. LIMITATIONS OF THIS REPORT

The short time available to compile the final report resulted in inability to analyze all the data that we planned to analyze. Some of the data requested from the NMRA on details of registration, quality failures, were not made available at the time of preparation of the report. The analysis of data on costs have been based on cost and consumption data given to us by the MSD where some information was not available and there were some discrepancies, which we have tried our best to address. Therefore, the cost calculations are likely to be approximate values rather than exact values. The challenges, barriers and recommendations given in this report are based on information supplied to us at the stakeholder group meetings, data, facts and figures given by them, perusal of Auditor General's recent reports and other sources of information in the public domain.

Some of the recommendations are based on the opinions of the stakeholders and the observations of committee members supporting the functioning of the different institutions such as the NMRA and MSD.

10. CONFLICTS OF INTEREST AND DECLARATIONS

The members of this SLACPT Committee do not see any conflicts of interest pertaining to the preparation and contents of this report. All members of the Committee are (or were) employees of the university system and not affiliated to institutions of the MoH. However, Professors Galappatthy, Fernandopulle and Jayakody have, over the years, served in numerous committees of the NMRA, MSD and MoH. Professor Jayakody served as Chairman of the NMRA and Professor Fernandopulle has functioned as a WHO consultant to the NMRA and currently serves as the Secretary of the MEC of the NMRA and Professor Galappatthy serves as a member of the MEC. We declare our allegiance to the upliftment of the state health care system.

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Annex 1 - Supplementary Table 1

Reasons for not granting Waiver of Registration (WOR)

Reasons for granting WOR	2018	2019	2020	2021	2022
No reason	0	118	78	12	4
Extended (no reason mentioned)	0	0	20	1	12
No registered product / supplier / manufacturer	29	35	19	0	3
Free of charge / Global fund / ICL	0	0	13	20	14
Orphan drug category	0	7	6	0	0
Granted with conditions (register in future, expedite, register strength)	0	32	9	24	18
Certificates / documentation satisfactory	0	0	4	7	2
Emergency use authorisation / Urgent requirement	39	5	3	3	5
Had Prior registration or WoR	0	0	3	0	0
High demand / Shortage of supply	5	0	3	2	3
Low price / within MRP range	0	1	3	4	2
Named patient basis	1	0	3	2	0
Registered suppliers not quoted / no registered product	0	1	3	5	12
Supplier is registered	0	1	3	0	0
Register as orphan drug category	0	0	0	5	0
Manufacturer and supplier registered	0	2	2	0	4
Registered supplier has violated NMRA rules / quality failures	0	0	2	0	1
Permitted for private market.	1	0	1	0	1
A product listed in BNF	0	0	1	0	1
COVID 19 situation	0	0	1	0	0
Essential drug	0	0	1	0	0
For specific indication only	2	0	1	0	0
Only registered product	0	0	1	1	0
Till locally manufactured	0	0	0	1	0
Army tender	1	0	0	1	0
Registered in NMRA approved authority / at NMRA	4	3	1	0	5
Requested by SPC	0	0	1	0	0
Stability data provided by NMRA	0	0	1	0	0
Tablet colour confusion avoided	0	0	1	0	0
Temporary	0	0	1	0	0

Approved by SEC	0	0	0	1	0
Pack size change / different strength	0	0	0	0	4
Site change	0	1	0	0	6
Local manufacturer is inadequate	0	0	0	0	1
Balance / replacement stock	0	0	0	4	0
For special campaign	14	1	0	0	0
Approved by Sub Committee of MEC	56	0	0	0	0
WHO prequalified site	2	1	0	0	0
Required to be used for analyzing samples of pharmaceuticals.	1	0	0	0	0
As a temporary measure approved to issue WOR (Due to software problem)	1	0	0	0	0
For DHS use only	0	62	0	0	0
Total*	156	270	185	93	98

*exceed the total number of WOR granted due to more than one reason being cited per application. The reasons are given this table as they appear in data received from the MDS

Annex 2

Supplementary Table 2: ABC analysis from 2018 to 2022 – number and percentage of medicines that are using 70%, 20% and 10% of the total consumption cost (MSD data)

	2018 **N = 1392 (%)** V=18, E=712, N=663			**2019** **N = 1401 (%)** V=18, E=715, N=668			**2020** **N= 1487 (%)** V=17, E=717, N=744			**2021*** **N = 1368 (%)** V=18, E=710, N=640			**2022*** **N = 1403 (%)** V=19, E=708, N=676		
70% of total cost (Category A)	116 (8.3)			122 (8.7)			122 (8.254)			120 (8.7)			115 (8.2)		
	V	E	N	V	E	N	V	E	N	V	E	N	V	E	N
	7 (6.0)	82 (70.7)	27 (23.3)	7 (5.7)	77 (63.1)	38 (31.1)	6 (4.9)	75 (61.5)	41 (33.6)	6 (5.0)	66 (55.0)	48 (40.0)	7 (7.2)	59 (60.8)	31 (32.0)
20% of total cost (Category B)	184 (13.2)			200 (14.3)			199 (13.46)			200 (14.6)			196 (14.0)		
	V	E	N	V	E	N	V	E	N	V	E	N	V	E	N
	2 (1.0)	121 (65.8)	61 (33.2)	3 (1.3)	134 (56.3)	63 (26.5)	4 (2.0)	132 (66.3)	63 (31.7)	4 (2.0)	138 (69.0)	58 (29.0)	3 (1.5)	132 (68.0)	58 (29.9)
10% of total cost (Category C)	645 (46.3)			777 (55.50)			805 (54.5)			774 (56.6)			718 (51.2)		
	V	E	N	V	E	N	V	E	N	V	E	N	V	E	N
	6 (0.9)	341 (52.9)	298 (46.2)	6 (0.8)	399 (51.4)	372 (47.9)	7 (0.6)	510 (44.1)	640 (55.3)	7 (0.9)	413 (53.4)	354 (45.7)	8 (1.1)	393 (54.7)	318 (44.3)
Not purchased/ consumed	432 (31.0)			287 (20.5)			332 (0.2)			274 (20.0)			293 (20.9)		
	V	E	N	V	E	N	V	E	N	V	E	N	V	E	N
	3 (0.7)	167 (38.7)	277 (64.1)	2 (0.7)	95 (33.1)	190 (66.2)	1 (0.3)	81 (24.4)	250 (75.3)	1 (0.4)	93 (33.9)	180 (65.7)	2 (0.7)	93 (31.7)	198 (67.6)
Donations	15 (1.07)			15 (1.1)			20 (1.4)			1 (0.1)			81 (5.8)		

V – Vital, E – Essential, N – Non-essential

*Covid-19 vaccines have been excluded from the analysis

Annex 3

Supplementary Table 3: The top 10 pharmaceutical items that have costed the most during the past 5 years

2018		2019		2020		2021*		2022*	
Item	Cost (%)	Item	Cost(%)	Item	Cost(%)	Item	Cost(%)	Item	Cost(%)
Human Immunoglobulin IV 5g-6g Vial	1,509 (4.1)	Human Immunoglobulin IV5g-6g Vial	1,753 (4.2)	Tenecteplase Injection 40mg Vial	1,675 (3.8)	Human Immunoglobulin IV 5g-6g Vial	1,893 (1.9)	Tenecteplase Injection 40mg Vial	1,747 (3.7)
Disodium hydrogen orthophosphate Powder	1,041 (2.8)	Tenecteplase Injection 40mg Vial	1,500 (3.6)	Human Immunoglobulin IV 5g-6g Vial	1,600 (3.7)	Tenecteplase Injection 40mg Vial	1,794 (1.8)	Human Immunoglobulin IV 5g-6g Vial	1,568 (3.3)
Co-amoxiclav Injection 1000mg/200mg Vial	878 (2.4)	Co-amoxiclav Injection 1000mg/200mg Vial	1,024 (2.4)	Human Albumin Solution 20%, 50mL bottle	1,224 (2.8)	Human Albumin Solution 20%, 50mL Bottle	1,623 (1.7)	Co-amoxiclav Injection 1000mg/200mgVial	1,195 (2.5)
Paracetamol Tablet 500mg	831 (2.2)	Human Albumin Solution 20%, 50mL Bottle	871 (2.1)	Co-amoxiclav Injection 1000mg/200mg Vial	1,165 (2.7)	Co-amoxiclav Injection 1000mg/200mg Vial	902 (0.9)	Human Albumin Solution 20%, 50mL Bottle	898 (1.9)
Tenecteplase Injection 40mg Vial	807 (2.2)	Sodium Chloride for IV Infu.0.9%, 500mL Bottle	865 (2.1)	Dried, Factor VIII fraction200-350 IU Vial	812 (1.9)	Enoxaparin Injection 6000IU/0.6mLPFS/Vial	781 (0.8)	Losartan Potassium Tablet 50mg	877 (1.9)
Sodium Chloride for IV Infusion 0.9%, 500mL Bottle	789 (2.1)	Paracetamol Tablet 500mg	832 (2.0)	Losartan Potassium Tablet 50mg	791 (1.8)	Losartan Potassium Tablet 50mg	781 (0.8)	Sodium Chloride for IV Infusion 0.9%, 500mL Bottle	834 (1.8)

Human Albumin Solution 20%, 50mL Bottle	755 (2.0)	Dried, Factor VIII fraction 200-350 IU Vial	732 (1.7)	Sodium Chloride for IV Infusion 0.9%, 500mL Bottle	755 (1.7)	Sodium Chloride for IV Infusion 0.9%, 500mL Bottle	770 (0.8)	Dried, Factor VIII fraction200-350 IU Vial	725 (1.5)
Metformin Tablet 500mg	689 (1.9)	Metformin Tablet 500mg	631 (1.5)	Metformin Tablet 500mg	734 (1.7)	Metformin Tablet 500mg	734 (0.8)	Paracetamol Tablet 500mg	635 (1.4)
Losartan Potassium Tablet 50mg	636 (1.7)	Losartan Potassium Tablet 50mg	616 (1.5)	Paracetamol Tablet 500mg	673 (1.5)	Dried, Factor VIII fraction200-350 IU Vial	729 (0.7)	Gliclazide Tablet 80mg	621 (1.3)
Atorvastatin Tablet 10mg	587 (1.6)	Atorvastatin Tablet 10mg	576 (1.4)	Ferrous Fumarate +Folic Acid Tablet (182.4mg+400mcg)	662 (1.5)	Meropenem Injection 1g Vial	549 (0.6)	Meropenem Injection 1g Vial	604 (1.3)

The cost is expressed in millions of LKR and the % means the expenditure on each item as a % of the total expenditure on medicines for that year

*COVID-19 vaccines are not included

Annex 4 : Minutes of the meetings held with the stakeholder groups

Annex 5 : Letter of invitation to SLACPT for the assignment

Annex 6: Written submission by the stakeholders

Annexures 4 – 6 are not included in this report. These documents have been handed over to Dr. S Sridharan (DDG, planning) of the MOH.