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and Population

Procurement of Medicines in Sri Lanka: A Case Study

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June 4, 2021

India Health Systems Project

Working Paper #4

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Preface to the Working Paper Series

The India Health Systems Project is motivated by the goal of advancing health system reforms in India to provide equitable access to good quality of care and financial risk protection for its citizens. The Project adopts a system approach to assess the strengths and weaknesses of India's current health care system, identify underlying causes, propose potential solutions drawing on best practices within India and international experience, and, finally, to monitor and evaluate progress and impacts of reforms.

The Working Paper Series presents products from the project. They include research papers, country cases, and analytical tools for conducting health system and reform analysis. The intended audiences are researchers, health policy analysts and practitioners of health systems reform in India—at the national- and state-level—and worldwide. The Working Papers are available at <https://sites.sph.harvard.edu/india-health-systems/>.

Funding from the Bill and Melinda Gates Foundation (OPP-1181215 and OPP-1181222) is gratefully acknowledged.

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Acknowledgements

The author gratefully acknowledges support from the India Health Systems Project to develop this case study. Professors Winnie Yip and Michael R. Reich provided invaluable guidance, and Betsy Osborn and Rashida Simmons offered key administrative support. The author also appreciates the thoughtful comments on a draft version from Dr. Ravi Rannan-Eliya and Professor Veronika J. Wirtz.

A Note on Data Sources, Methods, and Limitations

This case study was developed through a desk review using a variety of published sources, including academic literature, news articles, and organizational information from key agencies' websites.

Most of the published reports and journal articles cited were a few years old at the time of writing. In the rapidly shifting global health landscape, and particularly in the complex context of pharmaceutical and medical device technology, key players and policies are dynamic. While I sought to be accurate, because the case study is based on available documentation, it may also be somewhat dated.

Any and all errors are my own. Please email alguyer@gmail.com with any suggested corrections.

Executive Summary

For many decades, the nation of Sri Lanka has been providing for the health of its citizens at a level that exceeds what most other countries with similar economic situations have attained. Among other indicators, Sri Lanka has assured relatively good access to medicines while controlling prices. Sri Lanka spends about 1.6% of GDP on health, with about one-quarter of the total health budget spent on medicines. Its achievements in access to medicines stem from the government's well-established system for procurement and distribution of medicines. For health systems in low- and middle-income countries, Sri Lanka's example demonstrates the benefits of investing strategically and extensively over long periods of time in building a strong system for the procurement of necessary medicines, in useful formulations and appropriate quantities. The case study provides details on Sri Lanka's model, which offers lessons for other governments working to improve medicines procurement policies and practices.

In order to procure medicines effectively, a list of required medications must be drawn up, manufacturers or suppliers of each medicine must be identified and vetted, funds must be provided to pay for them, and the physical commodities must be purchased, received and their quality verified. Then they must be transported to the facilities in time to be available to patients who need them. Each step in this process is complicated on its own—and coordinating the various steps to work in concert with each other adds complexity to the system.

While Sri Lanka's system is far from perfect, it is overall relatively strong and has proven to be flexible enough to adapt and improve over time while maintaining its commitment to improving health equity in the country. The system has developed and changed over time, with key principles and goals related to providing for access to medicines for all Sri Lankans made clear from the outset. Structures established early on to support the vision remain in place, most notably the State Pharmaceuticals Corporation (SPC), through which all purchasing of pharmaceuticals for use in Sri Lanka is conducted. Having a single, government-controlled, purchaser does create bottlenecks that can slow down timely procurement. However, by issuing worldwide tenders and enabling bulk purchasing, SPC manages to control its own costs and the prices paid by consumers. Sri Lanka's long-standing insistence on using the generic names of medications when prescribing has also contributed to bolstering the use of cheaper generics. By controlling costs, Sri Lanka has managed to expand its Essential Medicines List and formulary in order to supply a wide array of products to citizens.

Thanks to its long tradition of principled health care delivery, Sri Lanka is well-positioned to build on its previous successes as it continues to develop its approaches to health care delivery overall and access to quality medicines in particular. It also provides an informative example for other health systems seeking to rationalize their pharmaceutical policy and delivery systems to better serve populations in need.

Procurement of Medicines in Sri Lanka: A Case Study

Case Objective

This case study describes how the health sector in Sri Lanka procures medicines for public and private health care facilities and pharmacies. The centralized medicines procurement component of its health system is one contributing factor in Sri Lanka's overall success in providing for the health of its citizens. The objective of the case study is to provide readers with details on Sri Lanka's model, which offers lessons for other governments seeking to reform, reorganize, and improve medicines procurement policies and practices. The intended audiences for this case study include government officials and technical advisors working in health sector policy and planning and other students of public health policy and health systems strengthening.

Introduction

For decades, the Asian island nation of Sri Lanka (see Box 1) has successfully provided for the health of its citizens at a level that exceeds that which most other countries with similar economic situations have attained. Among many other strong public health indicators, Sri Lanka has assured relatively good access to medicines while controlling prices.

These achievements stem from, among other factors, the government's well-established system for procurement and distribution of medicines. Sri Lanka spends about 1.6% of GDP on health, and about one-quarter of the total health budget (35 billion Sri Lankan rupees, or over US\$ 250 million) was spent on medicines in 2015.¹

In a study published in 2007 on the availability of selected essential medicines for NCDs in six low- and middle-income countries, Sri Lanka had four times the availability of four other countries (Bangladesh, Malawi, Nepal and Pakistan; Brazil had higher availability). That study found that the availability of a packet of essential medicines in Sri Lanka's public sector health facilities was 28%, although it was higher in the private sector.² Six years later, a 2013 national survey

Box 1: Facts about Sri Lanka

Population (2018): **21.67 million people^a**
GDP per capita (2019): **US\$ 3852^b**
Urban population (2012): **18.2%^a**
Population under 5 years (2012): **8.6%^a**
Aging Index [ratio of 60+ years population/1-14 years population] (2018): **49.2^a**
Life expectancy at birth (2013): **78.6 years for females, 72.0 years for males^a**
Deliveries attended by a skilled provider: **99.5%^a**
Population with access to safe water (2012): **81.1%^a**

Sources: a) Ministry of Health, Sri Lanka. 2018 Annual Health Bulletin. Colombo: Medical Statistics Unit, Ministry of Health. b) World Bank Group. The World Bank in Sri Lanka. <https://www.worldbank.org/en/country/srilanka> (accessed 29 January 2021).

found that availability of selected essential medicines for NCDs ranged between 50 and 80% in the public and private sectors.³

A 2015 situational analysis conducted by the World Health Organization (WHO) and the Government of Sri Lanka cited over 90% availability of key essential drugs in teaching hospitals and 72-79% availability in lower-level facilities.⁴ And a study conducted in 2016 on the availability of essential medicines in a rural district of Sri Lanka similarly found 71% of medicines available in a secondary care facility and 81% at a primary care facility. However, two central dispensaries surveyed had availability less than 50%.⁵ Overall, most studies find relatively high availability of essential medicines in Sri Lanka's health facilities in the public sector, reflecting a general consensus that the country performs well on this important indicator.

Medications are provided to patients in the public system free of cost—when they are available. When they are not, Sri Lankans head to government- or privately-owned pharmacies. (This approach is typical of Sri Lanka's approach to health systems organization overall—the government provides public services to a great extent, but also fosters a parallel private sector that offers more costly options to people with the means to pay for convenience and customer service.) The prices charged in pharmacies generally are higher than in neighboring India, but are significantly lower than the international reference prices. The prices paid by individual consumers mirror the procurement costs to pharmacies. For example, in a 2015 comparison of unit procurement prices, Sri Lankan unit prices for 24 medicines were approximately 53% higher than the prices paid by an Indian government hospital but 96% lower than the buyer median prices in the 2014 edition^a of the MSH *International Drug Price Indicator Guide*.⁶

Policy makers and health care providers in Sri Lanka are engaged in continuous efforts to improve Sri Lanka's system of financing, procuring and distributing medicines. However, from an historical perspective, Sri Lanka has achieved important successes in creating a functional and stable system to get medicines to the patients served by the public health system. This case study summarizes how Sri Lanka's system works and suggests lessons that may be relevant for other health systems seeking to deliver medicines to patients effectively and at reasonable cost.

Overview of Sri Lanka's Health System

Sri Lanka's health system has both a long and a strong performance record. One observer writes: "For at least 50 years [Sri Lanka] has achieved much better outcomes in

^a In recent years, the name of the guide has changed to *The International Medical Products Price Guide* to reflect the inclusion of a wider variety of products. Guides from 1996 to the present are available at the website: www.mshpriceguide.org.

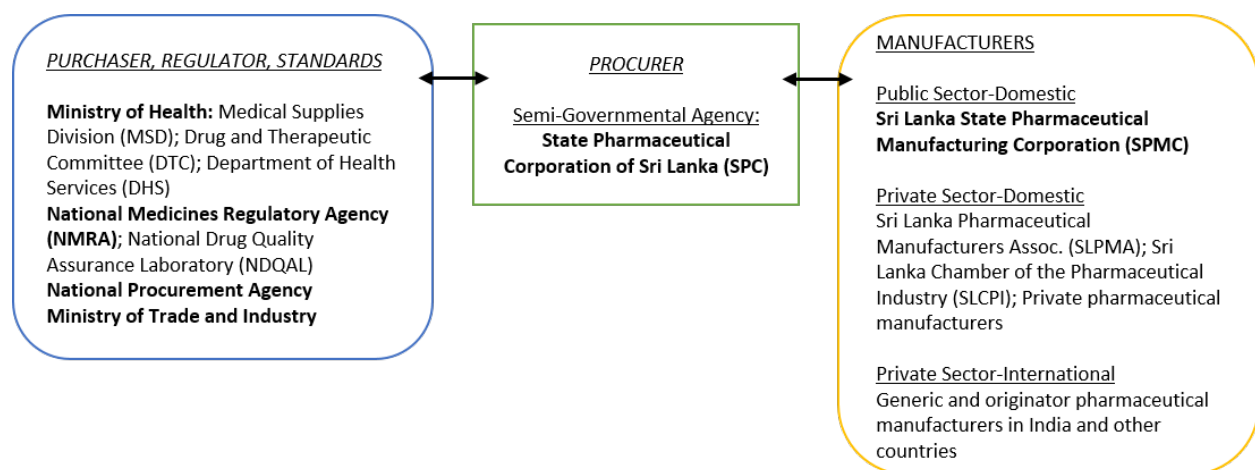
maternal and child health and infectious disease control than would have been predicted by its income level. Health financing indicators also indicate that the health system is both pro-poor and efficient.”⁷ Sri Lanka began providing universal and free access to government health care services in the late 1930s, even before it achieved independence in 1948. The government is the main health service provider in the country, especially for secondary and tertiary care. The government health system comprises 650 hospitals, 500 outpatient facilities, and 325 offices providing preventive and maternal and child health services. An estimated 95% of all in-patient hospital visits, and nearly all preventive health care, are provided at government facilities.⁸ There is also a robust private sector for primary outpatient care. In fact, many physicians work in both government facilities and private clinics, where patients with the means to pay out-of-pocket can receive “more convenient, personalized care.”⁹ Overall, the private sector accounts for about half of all outpatient visits.

The central Ministry of Health (MoH) has a few key functions: it sets national policies and guidelines, coordinates training and deployment of human resources for the health system, and procures all medicines. It also operates some of the government hospitals and other facilities. Most direct management of facilities has been devolved to nine Provincial MoHs and their 26 Regional Health Districts.¹⁰ There is also another parallel system in place to govern the practice of traditional Ayurveda medicine, including 62 public Ayurvedic hospitals and 200 Ayurvedic dispensaries, which also receive government funding.¹¹

Major Players and Policies in the Management of Medicines

Several institutions coordinate with the **Ministry of Health** and play key roles in procuring medicines for Sri Lanka’s citizens (see Figure).

Figure: Overview of key agencies involved in medicines procurement



The **National Medicines Regulatory Agency** (NMRA) (previously known as the Cosmetics, Devices and Drugs Regulatory Authority of Sri Lanka) was made independent by the 2015 National Medicines Regulatory Authority Act. The NMRA is overseen by a 13-member committee and is comprised of several divisions. These include, among others, groups that focus on evaluation of medicines and pricing.¹² Among other functions, the NMRA updates the national Essential Medicines List every few years.¹³ The 5th edition was published in 2013-4.¹⁴ NMRA is also the institutional home of the **National Drug Quality Assurance Laboratory** (NDQAL). The revamping of the NMRA sought to take into account a long-standing lack of sufficient human resources for the agency, which in 2015, had 472 staff, despite having 605 approved positions, and only 30 pharmacists.¹⁵ NMRA has a partnership with the University of Colombo to conduct pharmacovigilance activities.¹⁶

Within the MoH, the **Medical Supplies Division** (MSD) takes the lead in procurement, accounting for approximately 95% of total public sector purchases.¹⁷ In addition to operating central and regional storage and distribution warehouses, MSD operates the national **Drug and Therapeutic Committee** (DTC) that creates the national procurement list for medicines and other supplies.¹⁸ MSD's list of medicines to be procured is developed by a team led by the Director General of Health Services. It is based on, but not identical to, the EML.¹⁹ Medicines that do not appear on the EML may be included in the procurement list if requested by physicians and patient advocacy groups knowledgeable about new treatment modalities.²⁰ The list is revised every three years, and the quantities required are generally fixed at 10-15% over past annual consumption.²¹

Once MSD has listed and quantified the medicines required by the health system, the list goes to the **State Pharmaceutical Corporation** (SPC) of Sri Lanka. Created in 1971, SPC is a semi-governmental agency that is Sri Lanka's "sole supplier of pharmaceuticals, surgical consumable items, laboratory chemicals and equipment" to government health facilities.²² SPC's functions include importation, purchasing and manufacturing of products, approximately 80% of which go to the Ministry of Health's Department of Health Services (DHS).^{23, 24} SPC also contributes to retail pharmaceutical sales by operating 105 franchise pharmacies and 11 authorized retailers, and distributing to private retail pharmacies. SPC is a major operation; in 2015, it was procuring more than 900 items, employing over 800 people and managing an annual turnover of 22 billion Sri Lankan rupees (approximately US\$ 160 million).²⁵

Procurement of medicines falls squarely in the public sector. Production of medicines is a different matter—in addition to significant importation and the existence of one public sector manufacturer, there is an active private sector in producing and marketing medicines. The **Sri Lanka Pharmaceutical Manufacturers Association** (SLPMA) was established in 1963 and the **Sri Lanka Chamber of the Pharmaceutical Industry** (SLCPI) in 1999. Both organizations represent and advocate for private Sri

Lankan-owned pharmaceutical companies as well as the multinational companies' local affiliates. SLPMA reports that its 20 members produce about 15% of the pharmaceuticals used in the country.²⁶ The larger SLCPI includes over 60 members, or about 80% of the private pharmaceutical manufacturers in the country.²⁷

Much of the structure and policy underlying Sri Lanka's current system of managing pharmaceuticals and other medical supplies derives from recommendations made in a 1971 report prepared by two people who played important roles in laying the foundation of Sri Lanka's approach to sourcing and managing medicines: Doctors Senaka Bibile and S.A. Wickramasinghe. Dr. Bibile went on to become the founding chair of the SPC and created numerous visionary medicines-related policies. These enshrined, early on, the importance of quality assurance in procurement and the use of generic names for pharmaceutical products in procurement and prescribing, among others.²⁸

Sri Lanka's System of Procurement for Medicines

SPC is the predominant procurer of medicines in Sri Lanka. This semi-governmental organization purchases products from suppliers and manufacturers with its own funds, and is then reimbursed by the Ministry of Health with an additional 10% service charge. Funds for medicines are partially provided by the Ministry of Finance and Treasury to the Ministry of Health based on the budgets submitted by MSD. An estimated 29% of the total pharmaceutical spending in the country is funded through the public sector and mostly covers drugs dispensed through government hospitals. This represented over half of all medicines supplied in the country in the mid-2000's.²⁹ Thus, the population regularly pays out-of-pocket for the rest of the medicines, both when receiving health care in the private sector and when public facilities lack sufficient supplies and they must go to pharmacies to get prescribed medications.³⁰

As noted, the functions of procurement and distribution are divided between the MSD and the SPC. Selection of products to be procured, quantification of the amounts needed and the dates by which they are needed are determined by MSD. Once these have been determined, the lists of required items is handed over to SPC, which manages sourcing, negotiating prices, purchasing and importation. Once they have been received, the supplies are handed over to MSD for storage and distribution to health facilities and pharmacies throughout the country.³¹

SPC's approach to procurement is guided by both the National Procurement Agency's 2007 general governmental Standard Procurement Guidelines³² and the 2006 Guidelines for Procurement of Pharmaceuticals & Medical Devices.³³ This latter policy states its strategic objectives as: to "procure the most cost-effective Pharmaceuticals and Medical Devices in the right quantities; ensure supplier reliability with respect to service and quality; arrange timely delivery to avoid shortages and stock outs; and achieve the lowest possible evaluated cost."³⁴ Per government procurement guidelines, pharmaceuticals and other medical supplies were eligible to be procured by

International Competitive Bidding (ICB), National Competitive Bidding (NCB), or Limited/restricted International Bidding (LIB) (for those products with only one or a very limited number of manufacturers).³⁵

All products procured for use in Sri Lanka must be registered with the NMRA (formerly known as the Drug Regulatory Authority).³⁶ Off-patent products available from multiple manufacturers should be reviewed and categorized by their rate of usage and value. According to the national procurement guidelines, there are two acceptable methods of analysis. One option is the “VEN” system, which places all medicines into one of three categories: Vital, Essential, or Nonessential.^b The other option is “ABC Value Analysis,” which places medicines in one of three classes (A, B or C) based on their unit cost times annual consumption.³⁷ For limited source products (i.e., patented products only available from a limited number of manufacturers), SPC and the NMRA can agree to rely on standards set by other government or intra-governmental organizational standards (such as other countries’ stringent Regulatory Authorities, the United Nations, the Pharmaceutical Inspection Convention or Corporation Scheme, or the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use).³⁸

In addition to registration of pharmaceutical products, the manufacturers themselves must also be pre-qualified before they are eligible to bid on tenders; these pre-qualifications should be updated at least every three years.³⁹ Post-qualification can also be carried out in urgent situations provided the manufacturer can demonstrate that it meets the established standards.⁴⁰ Before awarding a contract, SPC can conduct inspections of manufacturers’ facilities once the manufacturer has been “determined to offer the lowest evaluated cost for a particular product/s.”

Procuring the vast array of products needed in the health system is a complex undertaking as it requires purchasing from both national pharmaceutical manufacturers and importing from an array of foreign manufacturers. There is one government-owned manufacturer, the **Sri Lanka State Pharmaceuticals Manufacturing Corporation** (SPMC), which in 2015 was supplying 35 pharmaceutical products.⁴¹ There are at least eleven other, private, registered manufacturers in the country; in 2015 they were collectively supplying 56 pharmaceutical products to the government. In these cases, national pharmaceutical manufacturers were participating in a 5-year “Buy Back” Agreement, in which prices for all products were set at a 20% markup over the

^b The VEN system was originally developed in Sri Lanka for use by SPC. It has been adopted and adapted globally since its inclusion in the 1982 publication *Managing Drug Supply*. (see: Management Sciences for Health. *Managing Access to Medicines and Health Technologies (MDS-3)*. Boulder, CO: Rienner Press, 2013. <https://www.msh.org/resources/mds-3-managing-access-to-medicines-and-health-technologies>)

manufacturing cost.⁴² Prices for medicines purchased from Sri Lanka-based manufacturers are now being set in negotiations among the Ministry of Trade and Industry, SLMA, the NMRA, and SL Standards Institute, with input from MSD and SPC.⁴³

In 2018, about 15% of required pharmaceuticals are manufactured and purchased locally.⁴⁴ All other medicines required for the health system must be imported. Nearly 900 foreign manufacturers were registered to import to Sri Lanka (80% of which were based in India).⁴⁵ In terms of cost, the Government of Sri Lanka spent over 34 billion rupees (US\$ 210 million) for imported products, approximately 4 billion rupees (US\$ 25 million) on purchases from SPMC, and almost 4.5 billion (US\$ 27 million) on products from other local manufacturers.⁴⁶

SPC issues a worldwide tender for each product to be procured that details the product formulation, dosage, quantities required and dates for delivery; manufacturers submit their bids to SPC in response to the tender announcements. As late as 2015, tenders were announced in newspapers and the system had not gone electronic.⁴⁷ However, in the years since, the SPC has begun issuing tenders electronically via its website, www.spc.lk. All issued tenders can be reviewed and searched, including by key word.

As of 2015, SPC was using a single bid system, in which technical and financial documents are submitted and considered together. WHO and other advisors have suggested that they consider revising the system to consider technical information first and pricing information only if a bid has met the technical guidelines.⁴⁸

Once bids are received in response to the tender, they are reviewed by a Technical Evaluation Committee. The committee is typically comprised of at least five members, including “director-level representatives of the Ministry of Health and the SPC, two expert consultants and a representative of the Treasury or National Procurement Agency.”⁴⁹

There are some exceptions to the tendering system. For products manufactured by SPMC, MSD is authorized to negotiate and purchase directly if SPMC’s unit price is lower than the unit price received in the previous tender for the product.⁵⁰ Other alternate procurement methods can be used if the complex and lengthy tendering system is not a feasible option. For example, by soliciting three quotes, preferably from pre-qualified suppliers, “shopping” can be used to procure “small amounts of readily available ‘off the shelf’ Pharmaceuticals.”⁵¹ Another exception is “urgent procurement,” which is used when there are unforeseen shortages, most often due to finding quality problems with purchased products. This method allows the government to source “very limited quantities” to cover the gap until the normal supply can be resumed. This approach can also be used on a case-by-case basis for individual patients facing “a grave/life threatening situation.”⁵²

The final, important, exceptions are urgent/emergency procurements—for use when an emergency has been declared by the government due to manmade or natural disasters or disease outbreaks—and procurement of single-source products. In emergency situations or when there is only one company manufacturing a product, medicines and supplies can be procured directly, up to a specified monetary amount, from state- or United Nations-organizations, pre-qualified or registered suppliers/manufacturers, or other agents, if preferred suppliers cannot provide the necessary materials. In these cases, SPC is expected to ensure “that the suppliers/manufacturers have not overpriced the products” by making comparisons to historical prices, the MSH International Medical Product Price Guide, or prices paid by neighboring countries.⁵³

SPC uses multiple types of contracts, depending on the situation. “Direct contracting” for a fixed or estimated quantity of a given product is used for single-source products, emergency procurements, urgent procurement, direct purchases from SPMC, or procurement via UN Agencies, the WHO, Global Drug Facility Inter-Agency Procurement or the Green Light Committee.⁵⁴ “Long term contracts” can be established for multi-source products, especially those that are widely used and/or have been in use for more than 10 years with publicly available reference standards.⁵⁵

Assuring the Quality of Pharmaceuticals in Sri Lanka

Quality assurance, particularly of imported products that are not inspected before they are received, has posed a challenge to Sri Lanka’s health system. Indeed, because Sri Lanka relies so heavily on imported pharmaceuticals, there is concern that sub-standard-quality medicines may be “dumped” into the country by unethical manufacturers.⁵⁶

Various steps have been put in place to test the quality of both foreign and domestic products once procured by SPC. In addition to the requirements for pre-qualification of suppliers and registration of products with the NMRA, SPC can conduct “visual pre-shipment inspections,” especially when working with a new supplier, as well as conducting post-shipment inspections.⁵⁷ Inspections are conducted by up to five “technically competent officers,” including a representative of the NMRA.⁵⁸

Further quality assurance of products is done by sending samples of purchased products to the NDQAL. This can be done both before and after purchasing, and is mandatory when working with a new supplier.⁵⁹ As is specified in all SPC contracts, if a product fails quality tests, the supplier must either replace the batch from which the sample was taken or repay the value of the batch plus 25%.⁶⁰ However, over the years, due to the limited capacity of NDQAL, some medicines quality problems have not been detected until after most of the batch has already been distributed and even used.⁶¹ As a result, the Government of Sri Lanka has been experimenting with contracting inspections and random quality testing of consignments before they are shipped to Sri Lanka.⁶² In addition to NDQAL, the University of Colombo has facilities to assist with investigations

on a contract basis.⁶³ (The University also monitors adverse drug reactions and compiles the *Sri Lanka Prescriber*, a quarterly information bulletin distributed free to all physicians working in the public sector.⁶⁴) Three private laboratories have also been recognized by the government as having the capacity to effectively test pre-market products.⁶⁵

Post-procurement Management of Medicines

Consignments of procured medicines are shipped by SPC to MSD's central warehouses, which are located around the capital city, Colombo. MSD has its own vehicles, including refrigerated trucks, to distribute the supplies on to 26 Regional Medical Supply Divisions (RMSDs).⁶⁶ Previously MSD used a quarterly "push" system for distribution. However, in recent years, and with the introduction of an electronic medical supplies management information system (e-MSMIS), the system has shifted to a "pull" system, with health facilities ordering and receiving deliveries on a monthly or weekly basis, depending on the size of the facility.⁶⁷ From this point on, medicines are managed and distributed by regional authorities, whose management and transportation capacities are variable.⁶⁸ Health facilities also have limited authority to order medicines from local pharmacies and distributors to deal with stockouts and other emergencies.

SPC also distributes supplies directly to its network of pharmacies.⁶⁹ Health facilities can order from the RMSD or may also purchase directly from a local SPC pharmacy.⁷⁰ When medicines are urgently needed, RMSD or the facility itself may arrange for supplies to be provided by another nearby facility that has available stocks.⁷¹

As mentioned, many Sri Lankans purchase medicines out-of-pocket from private or SPC retail pharmacies. Out-of-pocket spending (mostly on lab test fees and pharmaceuticals) has been estimated at almost 40% of total health expenditure—however, unlike in many countries, more than half of this spending is by the richest 10% of the population, who are more likely to use private sector health care providers.⁷² Retail pharmacies tend to be located either near health facilities or in central shopping areas and by law they must have a pharmacist on staff. Retail pharmacies stock anywhere from 300 to 3000 products, depending on their size and location. In addition to purchasing from SPC, they may also be visited directly by representatives from domestic suppliers.⁷³

The use of the e-MSMIS for ordering and tracking supplies has been rolling out gradually since 2009. It was introduced at the central MSD first, and then rolled out to RMSDs and some teaching hospitals.⁷⁴ An expansion begun in 2019 will eventually link an estimated 910 health institutions to be able to order directly from MSD using the system.⁷⁵

Persistent Challenges

One ongoing challenge is the e-MSMIS system, which is still only partially integrated with the procurement system. Persistent problems with the procurement and

distribution systems result in irregular stock outs of various products. These can occur if any step in the procurement process is delayed or interrupted. In particular, a major challenge is the length of process: MSD is required to project the required quantities over a year in advance because the tender process itself is so lengthy. High-value tenders require Cabinet-level approval, which is beyond the control of the lead agencies—this situation often leads to the use of emergency tendering.⁷⁶

Other long-lasting challenges are related to the costs of medicines. This is a perennial cause of public and political debate—one the one hand, the health system faces constant pressure to reduce its costs, while on the other, citizens' demands for medicines continue to increase. These debates have been exacerbated by a lack of data for comparing prices and determining the value of medicines, due to slow progress in adoption of the use of Health Technology Assessment to assess the impact of medicines⁷⁷ and the slow process of creating a viable regional medicines price observatory.

Response to the COVID-19 Pandemic⁷⁸

Like all countries and communities around the world, the arrival of the novel coronavirus COVID-19 in Sri Lanka both highlighted existing challenges in the health system and drove some rapid changes in response. The first case of COVID-19 in Sri Lanka was identified in a tourist on March 10, 2020. A national “police curfew” was put in place on March 20, 2020, and extensive “social distancing” measures were promoted. Among health care service providers, this necessitated reducing non-urgent in-person medical and surgical visits and procedures.

The National Hospital of Kandy (NHK) is a leading Sri Lankan tertiary care hospital with over 2,600 beds, was at the time operating various Non-Communicable Disease (NCD) clinics that served nearly 45,000 people per month. These clients traditionally picked up their medications from clinic pharmacies in person. However, when the new COVID-19-related restrictions were put in place, this was no longer possible, forcing the health system to reconsider how it distributed to medicines to out-patients.

The NHK clinics decided to shift to home delivery of medications. The steps to achieving this goal included: updating contact information for all patients, maintaining cold chains during delivery, accounting for the exam requirements, and paying for deliveries. To manage the process, the clinic first had to update the Hospital Information Management System (HIMS) and Clinic Management System (CMS)—while these were already in use in the Diabetes & Endocrinology clinic, it had to be expanded to include other NCD clinics' clients. To do this, NHK had to provide new hardware and conduct staff training in the clinics, and add systems and printers to the pharmacy. Additional phone lines were also added to the clinics so staff could reach out to clients to verify contact details. The hospital also made announcements in the media asking patients who had not been contacted to get in touch with the clinics.

By April 6, 2020, medical staff began entering all prescriptions into the updated system. Pharmacists could then print out and fill the prescriptions. They packaged them to be sent by mail. Other regular postal services were suspended at the time, so postal staff were able to support the effort. Within two months, 40,150 (or approximately 90% of) NCD clinic clients had been registered in the system and 46,650 prescriptions had been delivered. The main exception was insulin, which could not be sent via the mail due to cold chain requirements. Instead, insulin was distributed, with support from the RDHS Kandy, to its network of 158 hospitals for distribution to clients.⁷⁹

Lessons about Medicines Procurement from Sri Lanka

Overall, Sri Lanka presents an example of what a well-organized, centrally-designed, publicly-financed health system can achieve. Key lessons that Sri Lanka's example can offer other countries are summarized in Box 2.

Box 2: Summary of key features of Sri Lanka's medicines procurement system

- Clear and consistent vision and values regarding use of medicines
- Significant financing invested over the long term to support the vision
- A single, government-controlled, medicines procurement agency
- A cohort of well-trained technocrats to manage the complexities of the system
- Clear standards and procedures both for selecting medicines to procure and manufacturers to procure from
- Procurement from domestic and international manufacturers through worldwide tenders
- Long-standing policy to use generic names in procuring and prescribing

To low- and middle-income countries in particular, Sri Lanka's experience demonstrates the benefits of investing strategically and extensively, and over long periods of time, in building functioning health systems. In particular, Sri Lanka's system highlights the benefits of having a large cohort of technocrats with relevant professional education and training managing complex aspects of the system.

One of the many critical functions in a health system is the procurement of necessary medicines, in appropriate dosage forms and appropriate quantities, at costs that the health system can bear. Manufacturers or suppliers of each medicine must be identified and vetted, funds must be provided to pay for them, and the physical commodities must be purchased, received and their quality verified. Then they must be transported to the facilities in time to be available to patients who need them. Each step in this process is complicated on its own—and coordinating the various steps to work in concert with each other, while maintaining efficiency and keeping costs under control, adds layer upon layer of complexity to the system.

While Sri Lanka's system is not perfect, it is overall relatively strong and, perhaps just as importantly, is flexible enough to adapt and improve over time. The foundation of the system is its clear and consistent vision, which was first developed and clearly articulated over 50 years ago. Dr. Bibile and colleagues established early on a clear vision for "rational" pharmaceutical policies, including establishing national standards and policies that prioritized public health over industrial concerns, controlling prices and promoting appropriate use. While the specifics of pharmaceutical policies have changed over the years, Sri Lanka's national pride in having had a globally-known visionary leader has helped to keep some of the core tenets of the original principles in place. Further, the vision for medicines is aligned with the country's overall vision for its health sector—it is a public service that forms the foundation of enabling a healthy and successful population and country.

A key structure is the SPC, which purchases all pharmaceuticals for public sector use in Sri Lanka. Having a single, government-controlled, purchaser does create bottlenecks that can slow down timely procurement. However, by issuing worldwide tenders for multi-source products, enabling bulk purchasing by aggregating needs nationally, and authorizing negotiations for single-source products, SPC has multiple opportunities to wield leverage with local and international suppliers and manufacturers, including requiring them to be transparent about product pricing. Sri Lanka's long-standing insistence on using the generic names of medications when prescribing has also contributed to bolstering the use of cheaper generics. Sri Lanka's proximity to India and its strong pharmaceutical industry has also enabled it to purchase directly from generics manufacturers. By controlling costs, Sri Lanka has managed to expand its Essential Medicines List and formulary in order to supply a wide array of products to citizens.

There are, as in any system, areas where improvements and additional capacity development are required. Some of these may entail improving poorly performing aspects of the existing system, while others are responses to changes and developments in the field of health care delivery. For example, Sri Lanka is undergoing a demographic transition resulting in an aging population.⁸⁰ The health system must continue to adapt to better serve the chronic health care needs of older adults, including the need for medicines required to treat chronic non-communicable diseases, including cancers, cardiovascular conditions, diabetes and others. Another example is the need to adjust the system to assure access to new types of medicines and other medical supplies that are being discovered and developed around the world. Finally, COVID-19 has exposed in Sri Lanka, as in all countries, some serious gaps in health care delivery that need to be addressed. Preparing systems to deal with the health and other implications of future pandemics (such as protecting supply chains during global shutdowns) are critical concerns that health systems can begin to anticipate.

Thanks to its long tradition of principled and coordinated procurement of medicines, Sri Lanka is well-positioned to build on its previous successes as it continues to develop its

approaches to health care delivery overall and access to quality medicines in particular. It also provides an informative example for other health systems seeking to rationalize their pharmaceutical policy and delivery systems to better serve populations in need.

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