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State of the Economy Report 2011

Chapter 16
A Rational Drug Policy: An Imperative of 'Health for All'

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16. A Rational Drug Policy: An Imperative of 'Health for All'

16.1 Introduction

The provision of essential drugs - which are accessible and affordable to all - is one of the critical means to achieve the ultimate goal of 'health for all'. Sri Lanka's current demographic transition is a reflection of its success in providing good health services over many decades. Nevertheless, emerging disparities in status, income and access to resources have led to inequalities in health services and outcomes within the country. While health disparities within a population are common to any country, what is important is the recognition that restoration of equity in health care service delivery is critical for sustained and equitable socio-economic development of a country. In this respect, an essential element in the health policy paradigm is equitable access to drugs and equitable health outcomes resulting from access to drugs.

> ***"Access to essential life saving medicines has become a crucial issue in recent times, requiring policies that build an institutionally sound and transparent pharmaceutical system"***

Policy making in the provision of essential drugs cannot be examined and studied in isolation, but has to be approached as an integrated function of a health system. Sri Lanka's health policy covers a system that contributes specific services such as health administration, promotion, preventive, curative, and rehabilitative care. Among these, the most important in the provision of health care services - i.e., curative care and community care - are laboratory services and pharmaceutical services. All these services have specific policies as integral parts of a national health policy. In this context, pharmaceutical services play a pivotal role in health service delivery which meets an essential element in health care needs of the population. This discussion aims to examine the main policy issues linked to usage of pharmaceuticals (drugs) and identify gaps in making available essential drugs at affordable prices and its rational usage through a well defined drug policy. It remains a critical area of policy concern given the rising burden of disease and experiences of drug shortages.

16.2 Burden of Disease

After World War II, the disease picture in Sri Lanka was dominated by infectious diseases like tuberculosis (TB) and malaria. As a result of improved health advisory and hygiene, and the availability of life saving medicines, such as penicillin, other antibiotics and various vaccines, infectious diseases declined. Improvement made over time in primary care, reproductive health, and efforts to reduce maternal and infant mortality resulted in increasing life expectancy at birth. These trends led to a dramatic advance in health status and fertility reduction in the country. From the 1960s, Sri Lanka entered the third stage of demographic transition, namely, the phase of declining fertility.[1] As a result, the country is experiencing a rapid increase in the elderly cohort. It is estimated that the above 70-year age category will double over the next 20 years.

As NCDs emerge as the most prevalent diseases, the direct and indirect costs of treating such patients are currently estimated to be about US$ 420 per person per year.[2] This provides an indication of the magnitude of the cost of medi-care needed for the population for similar illnesses. As the prevalence of chronic diseases increases with age, the burden of NCDs can be heavy on the poor and marginalized population.

In addition, preventable communicable diseases such as Dengue are also on the rise. Dengue is the most common mosquito-borne illness and is endemic in Sri Lanka, spread by rapid urbanization - characterized by densely populated areas and widespread mosquito breeding grounds. Other emerging diseases in Sri Lanka include, HIV-Aids. According to the Aids Prevention Division of the Ministry of Health, registration of Aids patients was up by 3,000 in 2009, with 1,249 new registrations in 2010.

The seriousness of the burden of diseases is also evident by the rising demand for treatment for multiple illnesses by different age/gender groups, and by different communities of varied income levels. Data on out-patient visits and in-patient admissions in public and private hospitals reveal that there had been around 43 million out-patient visits to government hospitals, in addition to annual clinic visits of 16 million, and in-patient admissions of 4.6 million in 2007.[3] Of the patients who obtained indoor treatment in government hospitals, bed occupancy rates in differently categorized hospitals provide a cross-sectional view of the degree of demand for long term care in non-fee levying government hospitals - i.e., estimated bed occupancy rates in provincial hospitals stood at 101 per cent, national hospital (101 per cent), teaching hospitals (90 per cent) and base hospitals (82 per cent).[4]

Further, in 2007, 5.7 million out-patient visits and 221,000 in-patient admissions have been reported by private hospital facilities.[5] This does not include the out-patient treatment delivered by around 2,000 General Practitioners (GPs) spread throughout the country. In the late 1990s for instance, when the number of GPs stood at 900, an estimated 12.7 million patients were seen by them annually.[6] Indeed, private Western

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1 Indralal De Silva "Beyond Twenty Million: Projecting the Population of Sri Lanka 2001-2081", Research Studies: Demographic Transition and Pension Series No.6, Institute of Policy Studies.

2 Price Water House Coopers, 2009, *Pharma 2020: The Vision.*

3 Ministry of Health, *Annual Health Bulletin 2007*.

4 Fernando, Joel, 2002, "Functional Perspective in Health Sector in Sri Lanka: Current Status and Challenges", mimeo.

5 IPS, *Census of Private, Co-operative and Estate Hospitals 2005-2008*.

6 De Silva N., and K. Mendis, 1998, "One Day General Practice Morbidity Survey in Sri Lanka", *Family Practice*, Vol. 15, pp. 32331.

out-patient services were considered to be the fastest growing segment of health services in the country.

When glancing at the profiles of patients seeking health provisions from government health institutions and from private GPs, government hospital facilities have been mostly patronized by the lower-middle class and poor households, while households of almost all income groups make use of GP out-patient facilities when a need arises.[7] Free delivery, quality and confidence are some of the key factors that influence low income groups to obtain drugs from state institutions.

16.3 Sri Lanka's Drug Policy

Drug policy is a branch of health policy that deals with the development, provision and use of medications within a health care system. It embraces drugs (both brand name and generic), biological products, vaccines and natural health products. An effective drug policy aims at ensuring that people get good quality drugs at the lowest possible price, and that doctors prescribe the minimum of required drugs in order to treat the patient's illnesses. As is found commonly in other countries, Sri Lanka too has a three-tiered structure of demand where a physician prescribes, a pharmacist dispense, and the patient consumes free of charge, pays or a third party pays.

Pharmaceutical policy is the part of health policy that aims at addressing problems such as increasing access to safe, effective and affordable medicines for all patients.[8] Obstacles to achieving these goals can arise from financial interests on the side of suppliers and health care providers, who may benefit from charging higher prices and issuing more prescriptions than might be justified from a clinical and economic viewpoint. Obstacles can also arise from unscrupulous suppliers trying to introduce low quality or counterfeit drugs into markets, exploiting regulatory weaknesses. In addition, corruption and ineffective bureaucracies sometimes interfere with well intended programmes to offer access to essential medicines for the poor.[9] Some of the issues raised above have relevance to Sri Lanka's current drug administration system as will be discussed later.

The drug registration and regulatory system in Sri Lanka began in the early1960s. The National Formulary Committee established in 1962, introduced a drug list by reducing the number of drugs from 4,000 to 2,100, to be imported only by the private sector. During this period, the procurement procedure for drugs was biased towards more expensive brand names. Sri Lanka's first National Drug Policy in 1971, aimed at ensuring that people could get good quality drugs at the lowest possible price, and that doctors would prescribe the minimum required drugs to treat illnesses. The new drug policy identified the need for a state buying agency for procurement in accordance with the national formulary, to reduce the costs of drugs while maintaining the quality in order to save foreign exchange, rationalize drug usage, and supply essential drugs to the whole population at an affordable cost. Accordingly, an essential drugs list was introduced by a new formulary that reduced the number of essential drugs to 600.

In 1971, the State Pharmaceutical Corporation (SPC) was established to replace private sector drug importers, and in 1973, the SPC

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7 Fernando, Joel 2002, "Private Sector Community Health Services and Health Sector in Sri Lanka: Current Status and Challenges", mimeo.

8 World Bank, 2007, *Practical Approach to Pharmaceutical Policy*, World Bank, Washington, D.C.

9 *Ibid.*

became the sole importer of pharmaceuticals by replacing 134 private pharmaceuticals importers. Subsequently, the SPC introduced an international tendering system with quality control requirements, purchasing of low-cost generic products whenever available, approaching non-patent observing sources for newer patented products, and bargaining with transnational sources for newer patented products that were not available elsewhere. As a result, branded drugs were replaced by generic drugs in the prescription and sale of medicine. In 1972, the SPC is estimated to have imported 52 drugs at a third of their previous prices, and some drug prices dropped by a half or two-thirds.[10] The 1971 National Drug Policy was a part of health reforms that was pro-poor, in line with the government policy of centralization of economic activities more or less within a welfare state.

With the introduction of trade liberalization policies in 1977/78, efforts were made to reduce the monopoly of drug imports by the SPC, and its activities were confined only to import the drug requirements of the public sector while the private sector was given a free hand to import drugs, creating a price distortion in the pharmaceutical market. The new policy stance did not make any changes to the existing formulary or the essential drugs list. Although the State Pharmaceutical Manufacturing Corporation (SPMC) established in 1987 aimed to manufacture commonly needed drugs - such as paracetamol and a few others - the institution was mostly running as a loss making venture.

There were attempts to develop a National Drug Policy in 1991 and in 1996, which were accepted by the Ministry of Health (MOH), but failed to gain Cabinet level approval. The report of the 'Presidential Task Force on Formulation of a National Health Policy for Sri Lanka' - established in 1992 - recognized the need for a national drug policy but it was not fully comprehensive nor was it well defined. In 2005, the MOH, with the assistance of the WHO, worked out a comprehensive draft for a National Medicinal Drug Policy for Sri Lanka. After at least four rounds of talks with all stakeholders, the final draft was approved by the Cabinet in October 2005, but is yet awaiting the ratification of Parliament prior to implementation. The delay is largely assumed to be on account of lobbying by vested interests, opposed to its implementation.

16.4 Why Sri Lanka Needs a Rational Drug Policy

The necessity for a comprehensive drug policy has been warranted due to various issues. The more critical are: emerging profile of disease burden; growing influx of patients seeking treatment from free health care services; availability of around 9,000 varieties of branded, generic, and cheap drugs; rising conflicts in prescribing low cost generics and expensive branded drugs; shortages of life saving drugs in government hospitals and dispensaries; sales of drugs without prescriptions over-the-counter; and affordability to pay from out-of-pocket for procurement of drugs by poor households. Among these, shortage of drugs - against the background of disease burden and influx of patients seeking free treatment at state hospitals to avoid the high cost of drugs and care - is the most significant issue for the majority of people.

Effective pharmaceutical delivery to patients seeking treatment from government hospitals is being hampered by non-availability of adequate stocks, absenteeism of qualified

[10] Lall,S., and S. Bibile, 1977, "The Political Economy of Controlling Transnationals: The Pharmaceutical Industry in Sri Lanka (1972-76)", *World Development,* Vol. 5, pp. 677-98.

pharmacists, and uneven distribution of pharmacists and dispensers in dispensaries across the country. As a result, most patients tend to receive less than the quota of prescribed drugs from these institutions, and are frequently required to purchase more expensive drugs from private pharmacies. The granting of state approval for government health professionals to engage in private practice, and intermittent shortages of essential drugs experienced in state hospitals, in combination, has led to patients having to seek treatment at higher costs through private consultations.

The shortage of drugs is a key health policy concern. Shortages in Dextran 40 (a crucial fluid administered to critically ill Dengue patients), in cancer treatment related vaccines, in supplies of Saline, and other essential drugs critical for patients suffering from diabetes, asthma and heart conditions, as well as expectant mothers, etc., have been noted. Indeed, media reports suggested that "300 essential drugs are in short supply in many of the country's hospitals....Doctors have confirmed that the shortages have affected government hospitals."[11] In some instances, Sri Lanka was compelled to take extraordinary action to address critical shortages. For instance, Saline stocks were replenished by immediately airlifting supplies into the country in 2010.

Other irregularities in the supply of drugs have also been highlighted. Drug companies have been found to supply drugs prescribed for cancer patients in Sri Lanka to the private sector at higher prices, while failing to supply the same to the MOH throughout 2010. In such instances, the MOH is compelled to purchase drugs locally at higher prices in order to provide effective treatment to patients. Other reported malpractices include instances where despite the presentation of quality drug samples to the National Drug Quality Assurance Laboratory (NDQAL), the subsequent delivered orders are found to be sub-standard drugs. Due to such fraudulent practices, the MOH took action to withdraw 228 kinds of drugs in batches and 58 other items over the period 2006-10.[12] Moreover, it is also the case that the irregularity of drug supplies makes it harder for hospitals to give accurate figures on what drugs are available or in short supply at any given time.

According to the Sri Lanka Chamber of Pharmaceutical Industry, the shortage of drugs in state hospitals is primarily a procurement issue, requiring more transparent tender procedures.[13] The recommendations made are to institute time frames for every step of the tender procedure - i.e., predetermined times for tender boards, awards, indents, letters of credit, etc. - whereby participants are informed within the specific time period. Transparent procedures are also argued to earn greater acceptance and recognition of the SPC, amongst other suppliers. Safeguards against irregular suppliers through the execution of bid bonds and performance bonds on time, subject to a proper evaluation of any reasonable excuses for delays (which should again be limited to a fixed time frame), is also considered important in this regard.

16.4.1 A Case of Shortages: Paracetamol

Paracetamol is a widely used pain reliever, commonly used for the relief of headaches, other minor aches and pains, and is a major ingredient in numerous cold and flu remedies. Paracetamol is also used for relief

[11] *Daily Mirror*, "Essential drugs shortage puts patients and hospitals in a spot", 5 May, 2010.

[12] *Daily Mirror*, "Sickening mismanagement", 19 April, 2011.

[13] The Island, "Shortage of drugs in state hospitals: transparency in procurement vital – Samarasinghe, Ananda, President, Sri Lanka Chamber of Pharmaceutical Industry", http://www.island.lk/index.php?page_cat=article-details&page=article-details&code_title=22356.

of more severe pain such as in post-surgical recovery. In Sri Lanka, the SPMC is responsible for manufacturing a part of the local requirement of paracetamol for state hospitals, while private industry providers and importers supply the same to the pharmaceutical market under brand names (e.g., Panadol, Panadin, etc.). The drugs are made available without a prescription, and have increasingly become a common household drug.

Since 2008, state-run hospitals across the country have been affected by a chronic shortage of Paracetemol. As a result, it is alleged by the Government Medical Officers Association (GMOA), that doctors attached to both government and private hospitals have had no alternative but to prescribe more expensive brands.[14] It is reported that the SPMC has been entrusted to manufacture only 150 million tablets out of a required annual quantity of around 750 million tablets, forcing Sri Lanka to import 600 million tablets.

In February 2011, the MOH initiated inquiries into the purchase of 100 million Paracetamol tablets from the open market at a cost of Rs.37 million under the 'Emergency Purchase' tag, as the SPC holds the monopoly in the supply of drugs to the Medical Supply Division. The inquiries have revealed that the SPC unaccountably delayed supplying the required stocks that led to country-wide shortages of Paracetamol tablets at state hospitals, while there had been ample stocks in the open market manufactured by the SPMC. In March 2011, the MOH instructed the SPMC to take immediate measures to produce 564 million tablets.[15]

16.5 Present Status of Drug Regulatory Regime

Sri Lanka's drug procurement process which follows various stages, including registration, selection procurement, distribution and service delivery, was designed to be transparent. The registration process is expected to guarantee the drug's safety and efficacy, but there are allegations that the credibility of this guarantee is eroded by the pharmaceutical industry lobby. Studies have noted that the registration of new drugs takes almost one year and involves tedious bureaucratic procedures. This has led to an increased circulation of unregistered drugs that undermines the objective of quality regulation to ensure the supply of safe drugs to the public.[16]

The next stage of the process is the selection of drugs which ensures that the most cost-effective and appropriate drugs for a population's health needs are chosen fairly. Unfortunately, the cost effectiveness is not considered often, and as a result, around 9,000 varieties of (mostly expensive) drugs are imported. These drugs are imported by the SPC as well as by the private sector. The SPC is responsible for procurement of drugs for the Medical Supplies Division of the MOH. The Medical Supplies Division overlooks the distribution of drugs to government health institutions, while private sector importers distribute drugs to private pharmacies. Sri Lanka's NDQAL does not have the capacity to quality test all the drugs that are being brought to the country, and there are weaknesses in post-marketing surveillance due to limitations in capacity.

The ineffectiveness of the NDQAL for quality testing has created two issues, namely:

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[14] *The Island*, "Paracetamol causes headache for Health Dept.", 20 May, 2008.

[15] *Daily Mirror*, "SPMC asked to make more Paracetamol available", 10 March, 2011.

[16] Knight-John, Malathy, P.P.A.Wasantha, Andrew Perumal, Pubudini W. Rupasinghe, Avanthi Gunathilake, 2003, "Cross- Border Competition and Implication for Sri Lanka: Case Studies of Pharmaceutical, Cement Markets and Shipping Line Sector", IPS/LST.

(i) unlicensed individuals and/or entities conducting illegal trade of pharmaceutical products containing controlled substances, and (ii) licensed individuals and/or entities contravening laws to sell controlled drugs, such as pharmacists who sell controlled drugs without a prescription. Due to these areas of weaknesses, it has become common that pharmacies market drugs not registered in the country, employing under-qualified persons as pharmacists, failing to store drugs under specified temperature, and storing foods and drugs in the same refrigerators - which are against the set standards for selling pharmaceutical items.

16.6 Conclusion

The call for a national medicinal drug policy in Sri Lanka has spanned several decades since the liberalization of trade in the late 1970s. The MOH was involved in the preparation of a National Medicinal Drug Policy in 2005, which is yet to receive Parliamentary approval for implementation. Given the number of years that has lapsed since the report was first drafted, it may be that the report itself needs to be revisited to ascertain whether it reflects the key features of a viable drugs policy and best practices, prior to completion of passage of legislative ratification.

Various countries, including both drug manufacturing and drug importing nations, have adopted features in their drugs policy that fit in to national needs. Among these, the key features that could be seen are equitable access, safety, affordability, sustainability, evidenced-based decision, transparency, impartiality, participation and inclusiveness. As Sri Lanka is highly dependent on imported drugs - importing around 90 per cent of requirements - the most important features amongst these are: (i) equitable access which involves individual access to approved drugs and accessibility to a speedy new drug approval process; (ii) safety which requires appropriate pre-market evaluation and post-market surveillance, (iii) affordability applicable to both individuals and the health system, so that no one should suffer undue financial hardship in accessing needed drug therapies, (iv) sustainability which ensures that drugs are evaluated in the context of the overall burden of illness, and of their impact on direct and indirect illness costs and health system sustainability, and (v) participation and inclusiveness of all stakeholder engagement for meaningful involvement in the development and implementation of a proposed national drug policy.

Another issue that is needed to be looked at is the present controversy over generics versus branded drugs, which is closely related to the economics of the pharmaceutical industry. Brand name drugs are several times more expensive than equivalent generics which are feely available in the global market. In the ongoing debate, several questions have been raised whether branded drugs are worth the extra cost, or whether generic alternatives give the same results at a lesser cost. What is important is the ability of patients to understand the difference between generics and brands, recognize the generic name of a drug, and find a good quality variety of that particular drug. A rational drug policy resolves this intricate issue as it is based on drug use, in which patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them.

Access to essential life saving medicines has become a crucial issue in recent times and it is the responsibility of governments to ensure a policy that builds an institutionally sound and transparent pharmaceutical system, with appropriate mechanisms in place to avoid the likelihood of denial of life saving medicines to those in need, especially the poor and marginalized population.