

SRI LANKA'S SUCCESS: ENSURING AFFORDABLE ESSENTIAL MEDICINES FOR ALL



Executive Summary

“The reduction of 48 drugs is only a first step, and more price reductions will be announced soon.”

**- Dr Rajitha Senaratne,
Minister of Health,
Nutrition and
Indigenous
Medicine,
Sri Lanka**

On 21 October 2016, Sri Lanka transformed the pricing of essential medicines, making drugs more affordable for patients. The Government issued a notice by Extraordinary Gazette setting a price ceiling for 48 essential medicines used to treat noncommunicable diseases (NCDs), such as diabetes, heart disease, high blood pressure, high cholesterol, and other common diseases.

Sri Lanka's pharmaceutical market is estimated to be worth USD \$ 400 million per year. The regulation of the pricing of these medicines has an enormous impact on the health of the population.

The revised drug price formula introduced in 2016 ensures that essential medicines should be sold below a recommended maximum retail price at all times. Upon issuing the gazette notification, the Hon. Minister of Health, Nutrition and Indigenous Medicine, Dr Rajitha Senaratne said that the prices of certain drugs could be reduced up to 85 % as a result.

The revised pricing policy is a major achievement in safeguarding patients' rights to access affordable medicine in Sri Lanka.

“The price reductions on the 48 essential drugs based on the maximum retail price formula, are expected to have a very positive impact on the cost of these essential medicines.”

*- Professor Asitha de Silva,
Chairman of the
National Medicines
Regulatory Authority,
Sri Lanka*

How it was achieved

Sri Lanka was faced with rising costs of medicines since pharmaceutical price controls were abolished in 2003. The increasing burden of NCDs such as heart disease, cancer and diabetes, coupled with the high prices of medicines for treating these diseases, put the need for pharmaceutical price control back in the spotlight.

In 2016, WHO conducted an analysis of Sri Lanka's approach to pharmaceutical price control and explored alternative mechanisms following a request by the National Medicine Regulatory Authority (NMRA). WHO presented this evidence to NMRA and other stakeholders.

This analysis provided valuable insights on the strengths and weaknesses of various pricing formulas to the Ministry of Health, Nutrition & Indigenous Medicine, NMRA, and other key stakeholders.

NMRA conducted extensive discussions and consensus was reached on the need to regulate the price of essential medicines and the appropriate pharmaceutical pricing formula for Sri Lanka.

Sri Lanka's successful regulation of pharmaceutical prices shows how evidence based policies can protect patients' rights, reduce out of pocket expenditure, ensure affordable access to quality assured medicines and advance the principles of Universal Health Coverage.

Challenges

- The abolishment of pharmaceutical price controls in 2003 led to increased costs borne by consumers.
- Even though medicines are exempt from certain taxes in Sri Lanka, this does not always result in lower prices for the patient. Private hospitals have applied 15% V.A.T. on medicines provided to patients.
- In the public sector, patients receive free health care and medicines. However, patients frequently spend out of pocket for prescribed medicines and laboratory tests when these are not readily available. For the past decade, out of pocket expenditure has been consistently above 40 % of the total health expenditure.
- In the past, importers based prices on the Cost, Insurance, and Freight (CIF) value of medicines.

“Facilitating evidence based decision making for better health”

"Sri Lanka has taken an important step which safeguards patient's rights to access affordable medicine. This price control has far reaching benefits, which profoundly impact the health of the Sri Lankan people and further advance Universal Health Coverage and achievement of the Sustainable Development Goals."

**- Dr Jacob Kumaresan,
WHO Representative
to Sri Lanka**

- Any pricing formula based on the CIF value is vulnerable to exploitation because the importers declare the CIF value. It is not independently scrutinized or verified. In 2011, the Consumer Affairs Authority found that mark-ups on the CIF value of medicines were higher than 500 % in certain cases.
- Many factors distort demand and push up drug prices. These include: unethical drug promotion; lack of consumer awareness on generic brands; lack of monitoring of overcharging; irrational selection and use of medicines and; unreliable supply systems.

Key Milestones

- ➡ Establishment of the State Pharmaceuticals Corporation (SPC) in 1971 to provide high quality, safe, effective and affordable medicines. The SPC imports, distributes and sells pharmaceuticals throughout the country. It is the largest distributor in Sri Lanka. The SPC can secure lower prices through competitive global tenders, generic and bulk purchasing. The SPC has acted as a buffer for drug price increases in the public sector.
- ➡ In 1987, the State Pharmaceuticals Manufacturing Corporation (SPMC) was founded. It is now the largest drug manufacturer in Sri Lanka, providing 43 drugs to the Department of Health Services (MoH) at low profit margins. In 2015, SPMC and local manufacturers accounted for 15 % of the total pharmaceutical market in Sri Lanka.
- ➡ The NMRA was established by the former Minister of Health and current President of Sri Lanka, H.E. Maithripala Sirisena, demonstrating the highest-level political commitment to the provision of affordable, safe, quality medicines. The NMRA appointed a Pricing Committee to carry out this mandate.
- ➡ Technical analysis, high level advocacy and public debate prompted the Extraordinary Gazette issued by the Government of Sri Lanka to put a ceiling on the price of 48 essential medicines in October 2016.

Way Forward

- Ongoing measures are needed to ensure that essential medicines for NCDs and other common illness are affordable and accessible for the entire population in Sri Lanka. Practices such as unethical drug promotion by the pharmaceutical industry remain a concern.

- Further mechanisms are needed to ensure that any tax reductions or exemptions on medicines result in lowered prices to the patient, particularly in the private sector.
- The new pricing policy is a helpful measure which sets a maximum cap on the price of core essential medicines for NCDs and other common conditions. For many of the essential medicines, cheaper generic medicines are already available below the maximum retail price. However, the public are often reluctant to purchase them because of concerns about their quality. In 2017, WHO is supporting the NMRA to develop new guidelines which will help ensure the quality of generic medicines, and encourage greater utilization of generics by the Sri Lankan public.
- Making medicines affordable requires adoption of a comprehensive approach: promoting rational use of medicines; promoting generic prescription and substitution; banning inappropriate medicine promotion; strengthening quality control and assurance; raising consumer awareness and strengthening medicine supply, procurement and forecasting of future needs.
- WHO will continue to support the Government of Sri Lanka to achieve the goals for access to essential medicines set out in the global NCD targets and the SDGs.

References

- Jaime Espin Joan Rovira, Margaret Ewen, Richard Laing. Mapping External Reference Pricing Practices for Medicines Working Paper September 2014
- World Health Organization. Country Office for Sri Lanka. Country Cooperation Strategy: Sri Lanka 2012 – 2017.
- Fink. C. "How Stronger Patent Protection in India Might Affect the Behavior of Transnational Pharmaceutical Industries," The World Bank Policy Research Working Paper Series, 1999.
- World Bank. "Prevention and Control of Selected Chronic NCDs in Sri Lanka: Policy Options and Strategic Actions" Washington, DC. 2010 <http://siteresources.worldbank.org/HealthNutritionandPopulation/Resources/281627-1095698140167/NCDsSriLanka.pdf>
- Parliament of the Democratic Socialist Republic of Sri Lanka. 2015 National Medicines Regulatory Authority act, no. 5 of 2015.
- Rohini Fernandopulle. "Pricing of Medicines Sri Lanka", Presentation. September 2015.
- World Health Organization. "Medicines in Health Care Delivery Sri Lanka Situational Analysis: 16-27 March 2015 Report prepared using the WHO/SEARO workbook tool for undertaking a situational analysis of medicines in health care delivery in low and middle income countries", June 2015.
- World Health Organization. "Sri Lanka Pharmaceuticals in Health Care Delivery Mission Report 23-30 July 2010", 31st December 2010.
- Consumer Affairs Authority. Pricing of Pharmaceuticals, Final Report, Consumer Affairs Council, Consumer Affairs Authority, 2012.
- Minutes of the meeting of the Ministry of Internal Trade and Cooperatives, 9 November 2011.
- Ministry of Healthcare and Nutrition. "National Medicinal Drug Policy for Sri Lanka", "Suwasiripaya" Colombo 10, 2005.
- Progress on Project on price regulation of Pharmaceuticals, Presentation by Dr. Mahanama Rajamanthre
- Jacqueline Cumming et al. How New Zealand has contained expenditure on drugs BMJ 2010;340:c2441, 2010
- Parliament of the Democratic Socialist Republic of Sri Lanka. National Medicines Regulatory Authority act, no. 5 of 2015
- Modi. S. "Pharmaceutical price control in India: A case of missed opportunities?", Unpublished manuscript, 2006.