# National Medicinal Drug Policy for Sri Lanka

**Certification of Authorisation**

The National Medicinal Drug policy for Sri Lanka had been published 2005, by the Ministry of Health Care and Nutrition.

Accordingly, The National Medicine Regulatory Authority Act (Act No 05 of 2015) has been approved by the Parliament of the Democratic Socialist Republic of Sri Lanka, and certified on 19th March 2015.

## Preamble

Sri Lanka had a partly written Drug policy from the 1960s. it was "written" as elements of a policy, beginning from selection of drugs for the government drug supply and the Ceylon Hospitals formulary in early 1960s, the Bibile Wickremasinghe report in 1971, the Cosmetics Devices and Drugs Act (1980). However, there was no comprehensive document.

There were attempts to develop a NMDP in 1991 & 1996; while the documents were accepted by the Ministry of health, they did not reach the final step of cabinet approval. Hence no comprehensive document exists at present. The present effort building upon previous efforts brings together the elements of a National Medicinal drug Policy all stakeholders. It is hoped that this effort will see a formal National Medicinal drug Policy being adopted by the cabinet for the country.

The objectives of the Sri Lanka National Medicinal Drug Policy are;

1. To ensure the availability and affordability of efficacious, safe and good quality medicines relevant to the health care needs of the people in a sustainable and equitable manner.
2. To promote the rational use of medicines by healthcare professionals and consumers.
3. To promote local manufacture of Essential Medicines.

The Sri Lanka National Medicinal Drug Policy;

1. Will be within the overall health policy of the country
2. Will be based on the Essential Medicines concept
3. Will be focused on the health sector but include/ coordinate with relevant areas such as education, finance, agriculture, animal husbandry, pharmaceutical industry and trade
4. Will safeguard the rights of the patients/ consumers.

An NMDP should cover all systems of medicine including allopathic, homeopathy, Ayurveda, sidda, unani and any other systems recognized in the country. The primary concern of this policy is allopathic medicines; however policies for the others systems of medicines will be developed later in consultation with stakeholders of those systems.

The Sri Lanka NMDP will have the following elements.

1. Selection of essential medicines
2. Affordability and Equitable Access
3. Financing options
4. Supply systems and Donations
5. Regulation and quality assurance
6. Quality use of Medicines
7. Research
8. Human resources
9. Viable Local Pharmaceutical Industry
10. Monitoring and evaluation

There shall be a National Standing Committee appointed by the Ministry on the recommendation of the DGHS, comprising all stakeholders to oversee the implementation of the National Medicinal Drug policy.

## Selection of essential medicines

The selection of an Essential Medicines List Prioritizes the medicines that are important. The medicines will be selected according to valid scientific evidence, the disease pattern in the country and cost-effectiveness.

A standing committee comprising all stakeholders will be established to define and regularly update the National Essential Medicines List. It will formulate, review and update Standard Treatment Guidelines, Drug Index, the Sri Lankan Formulary and Government Drug procurement Documents.

## Affordability and equitable access

A pricing policy/ mechanism should be adopted to ensure affordability. Retail pricing should be based on a dispensing fee rather than cost markup. Legislation requiring generic prescribing and allowing cost effective generic substitution with the consent of the patient (and where possible informing the doctor) should be enacted. There shall be a policy for licensing pharmacies which among others would incorporate the needs and requirements of the communities.

Medicines including raw materials (both local and imported) should be free of any taxes, other tariffs and excise duties. The public health provisions of the Doha Declaration (parallel Imports, compulsory licensing) should be authorized by the Regulatory Authority.

Rational self-medication will be facilitated by appropriate scheduling of the medicines.

## Financing options

The state should provide sufficient funding for procurement and supply of necessary medicines with priority for essential medicines, monitor appropriate use and prevent waste. Public and private sector health insurance schemes will be encouraged to develop reimbursable lists of medicines.

## Supply systems and donations

The responsibility for ensuring a continuous availability of Essential Medicines in the country is a shared public/private sector responsibility. The state should continue centralized bulk purchase and supply to it's institutions. Preference should be given to local manufacturers in supply of medicines to the state sector. Good pharmaceutical procurement practices and management of the supply chain should be enacted for both the public and private sector.

There should be a private/public mix of suppliers to the private sector.

A policy for acceptance of donations of medicines should be developed based on WHO Guidelines for Drug donations. Until this policy is developed the WHO guidelines should be followed.

The state should take the responsibility for the availability of "orphan" drugs and incentives to be given to suppliers of such items.

## Regulation and quality assurance

Legislation should be enacted to provide a sound legal basis for regulating activities in medicines. A statutory body called the National Medicinal Drug Regulation Authority (NMDRA) accountable to the Ministry of Health through the National standing committee should be established. This authority will be solely responsible for regulation and control of manufacture, importation, registration, promotion, sale and distribution of medicinal drug and devices, nutraceuticals and functional foods. It should have transparent mechanisms and adequate human resources.

Medicines should be registered based on the criteria of quality, safety, efficacy, need and cost effectiveness. These criteria should be established by the NMDRA. The NMDA should have the authority to limit the number of new chemical entities of a particular class of drugs, as well as the number of products. Official drug information will be instituted through approval of product information Leaflets/summary of product characteristics and where relevant patient information leaflets.

The authority should be funded by the state and through statutory levies on services rendered. An accredited drug quality Assurance Laboratory should function within the authority with appropriate fees for services.

Good Manufacturing practices (GMP) compliant with WHO Guidelines should be required for registration of medicines. Good pharmacy practices (GPP) and good Distribution practices (GDP) should be developed and implemented.

The promotion of medicines should be regulated based on the Sri Lanka Medical association Ethical Criteria for Medicinal Drug promotion. Promotion and sale of medicinal drug based on financial or other incentives should be prohibited. Post-marketing surveillance and pharmacovigilance systems should be established.

## Quality use of medicines

Appropriate education in the quality use of medicines should be included in the training of healthcare professionals. The state should fund a national medicines information center and Drug information Bulletins through the medicines budget, to provide independent and unbiased information to healthcare professionals and consumers.

The rational use of drugs should be promoted, and irrational use should be discouraged. There should be public education programs about medicines especially through the school curricula.

## Research

There should be resources and incentives for operational research on issues such as access to medicines, pricing mechanisms, cost-effectiveness and other areas of pharmaco-economics, quality, storage and utilization. The research findings should be incorporated into clinical practice.

Clinical research into drug for neglected diseases which are prevalent in Sri Lanka should be encouraged and funded.

Contract research in drug development should be in keeping with WHO Good Clinical practice Guidelines.

## Human resources

There should be a special focus on the development of the pharmacy profession with degree programs in pharmacy. The pharmacy council should be established as a priority with sole responsibility for accreditation of pharmacists.

The NMDRA should undertake human resource development it’s staff. There is a necessity for external technical cooperation for the development of human resources in the pharmaceutical sciences. Expertise in clinical pharmacology/clinical pharmacy needs to be developed and utilized in the health care sector.

## Viable local pharmaceutical industry

The state should encourage and facilitate a viable sustainable local pharmaceutical industry by fiscal and other incentives. This will allow better monitoring of quality; improve availability, affordability, employment of skilled personnel and development of technical and human resources.

The state pharmaceuticals corporation (SPC) and the state pharmaceuticals Manufacturing Corporation (SPMC) should be amalgamated into one comprising of technical experts in the relevant fields and official from the Ministry of Health and Treasury.

This corporation should facilitate training for the pharmaceutical sector. The Medical supplies Division should give preference to pharmaceutical manufactured by this corporation at procurement.

## Monitoring and evaluation

An inspection system should be established at the NMDRA for GPP, GMP, and GDP by the appropriately qualified personnel. Regular monitoring of the pharmaceutical sector through indicator-based surveys should be conducted by the National Standing committee.

## Implementation

Once the NMDP is adopted, it will be the responsibility of the Minister of Health on the recommendation of the Director General of Health Services, to appoint the National Standing committee within three months to oversee the implementation of the policy.

This policy will be reviewed, and revised if necessary, in five years.