

# National Immunization Policy

## Certification of Authorisation

The Cabinet of Ministers of Democratic Socialist Republic of Sri Lanka has approved the National Immunization Policy on 16<sup>th</sup> October 2014 as per Cabinet Memorandum No 14/1017/509/050

## BACKGROUND

Governments have the authority and responsibility to ensure vaccination of all citizens. To this end, the world over, National Immunization programmes are being developed which are relatively autonomous, sustainable and effective. The national immunization programme (NIP) of Sri Lanka has been implemented to prevent priority vaccine preventable diseases in the country. The NIP has an excellent record, with extremely low incidence of vaccine preventable diseases (VPD) which are covered by the expanded programme on immunization (EPI) and high coverage of all EPI vaccines.

The main components of a well-functioning immunization programme include: availability of efficacious, safe and quality vaccines; efficient service delivery; capacity to maintain vaccines at the right temperature (cold chain) and timely distribute these through the system (logistics); surveillance on vaccine effectiveness and immunization safety; assessing burden of VPD in order to introduce of new vaccines; trained skilled health workers; research; adequate funding; advocacy; effective communication; program planning and management.

The main purpose of introducing an immunization policy is to ensure that all components of the NIP function optimally to achieve its set goals and objectives.

In addition, the immunization policy has to be considered with all other relevant policies of the country, recognizing equity, have an evidence base, recognize the importance of public-private partnership, have a multi-disciplinary and multi-sectoral approach and be mindful of ethical considerations.

## NATIONAL IMMUNIZATION PROGRAMME

All vaccines in the National Immunization program follow the immunization schedules approved by the National Advisory committee on communicable diseases (NACCD) of the Ministry of Health. Timing and the type of vaccines to be included in the NIP is based on the disease burden, affordability and feasibility of implementation and in achieving the objectives of the NIP.

Immunization for vulnerable groups/high risk categories (immune-suppressed, premature infants, pregnancy, increased risk of occupational disease exposures etc.) and during special situations (exposure to infectious diseases following disasters, during disease outbreaks, risk of diseases exposure of travelers) are an essential component of the NIP. Special vaccines or immunization schedules are recommended for those vulnerable populations in order to protect them against vaccine preventable diseases.

The implementation of National Immunization policy is a continuous process, the responsibility for which will be shared by many stakeholders. Many stakeholders including the National Advisory committee on communicable Diseases, Epidemiology unit, Medical Technology and supplies Unit (cosmetics Devices and drugs Authority/National Regulatory Authority), Family Health Bureau (FHB), Health Education Bureau (HEB), Medical Research Institute (MRI), education sector, private sector health institutions, medical professional bodies, universities/other training and teaching institutions and international Agencies (WHO, UNICEF, GAVI etc.) are involved in the implementation of the National Immunization program.

The NIP provides its services through a wide network of service delivery points to ensure easy accessibility to the public. Vast majority of the public get their immunization services free of charge through the state hospitals and clinics. Over the years, a gradual expansion of the availability of private sector immunization services has taken place especially in the urban area. The Government of Sri Lanka recognizes the importance of public-private partnership in delivering efficient immunization services to the public while ensuring the sustainability of state sector free immunization services. Proper regulatory mechanisms will be placed to ensure the delivery of a safe and quality immunization service by both public and private sector service providers.

Over 90% of the total cost of the state immunization program is borne by the Government of Sri Lanka. This is a good evidence for the stability of financial sustainability. At present the WHO, GAVI and UNICEF are the leading international donors providing funding to the country NIP.

Future expansion of immunization activities, including the introduction of new vaccines and safer vaccination technologies, may require a significant increase in funding.

## **VISION OF THE IMMUNIZATION POLICY**

Sri Lanka a country free of vaccine preventable diseases of public health importance

## **MISSION OF THE IMMUNIZATION POLICY**

To ensure the provision of an enabling environment for immunization of all eligible individuals in the country

## **GOAL OF THE IMMUNIZATION POLICY**

To protect all citizens against vaccine preventable diseases of public health importance as determined by the National Immunization program and work with regional / global initiatives

## **OBJECTIVES**

1. To ensure the availability and affordability of quality immunization services in a sustainable and equitable manner.
2. To have a country free of vaccine preventable diseases of public health importance by ensuring the use of efficacious, safe and quality vaccines relevant to the health care needs of the people, in a sustainable and equitable manner.

3. To ensure the rational and evidence-based introduction of new vaccines.
4. To ensure the implementation of the National Immunization program by all service providers by monitoring, evaluation, information management and research in the field of immunization.
5. To ensure financial sustainability of the National Immunization programme.
6. To ensure advocacy, promotion, awareness, protection and support for the National Immunization programmer.
7. To implement the National Immunization policy in a systematic manner, inclusive of all stakeholders and the training of all immunization service providers.

## **STRATEGGIES TOWARDS ACHIEVING OBJECTIVES**

### **OBJECTIVE 1-Immunization services**

To ensure the availability and affordability of quality immunization services in a sustainable and equitable manner.

- 1.1. All citizens in Sri Lanka shall receive all vaccines recommended in the EPI in the National Immunization program within the specified age limits as a minimum requirement within the rights of individuals and the public, except for valid medical reasons.
- 1.2. All immunization services provided to the community shall be in an equitable and an affordable manner.
- 1.3. All immunization services provided by the NIP shall be made available and accessible to all individuals in Sri Lanka through a comprehensive island wide network of health care services.
- 1.4. The Ministry of health shall act as the sole decision-making authority for all immunization related activities in the country. Technical aspects on the NIP will be periodically reviewed and necessary recommendations will be made by the program managers and the National Advisory committee on communicable Diseases (NACCD).
- 1.5. All immunization related activities should be carried out at centers which are registered and accredited by the Ministry of Health. The Ministry of Health will ensure all immunization clinic centers have minimum required facilities to deliver effective, safe and quality immunization services to the public.
- 1.6. All private sector immunization clinic centers providing immunization services should be registered and accredited as “Immunization clinic Centre’s for NIP” under the Ministry of Health, in accordance with the private Medical institutions (Registration) Act/private Health services Regulatory council.
- 1.7. All citizens seeking immunization services shall be provided with appropriate immunization through provision of quality vaccines administered in a safe and an effective manner.

- 1.8. All immunization service providers should ensure that cold chain of the vaccines is maintained during the transport, storage and up to the administration of vaccines.
- 1.9. All used vaccine vials, syringes and other accumulated medical waste related to the immunization process shall be handled safely in compliance with the policy adopted on safe disposal of medical waste in accordance with the National Environmental policy of the country.
- 1.10. All immunization service providers should adhere to the guidelines related to the provision of quality and safe immunization services formulated by the NIP.
- 1.11. All immunization service providers are expected to share all immunization related information with the NIP.
- 1.12. Vulnerable groups and high-risk categories should be adequately protected against vaccine preventable diseases appropriate to the situation
- 1.13. During special situations such as disasters and disease outbreaks ensure adequate protection to the affected populations against possible vaccine preventable diseases by timely provision of appropriate immunization services.
- 1.14. During a disaster or disease outbreak situation, vaccines received as donations should go through the required quality assurance and registration process.
- 1.15. In accordance with the country specific requirements and international regulation all cross-border emigrants and immigrants should be protected from required vaccine preventable diseases.
- 1.16. Occupation related vaccine preventable diseases risk shall be minimized by provision of appropriate immunization services for relevant occupational categories as recommended by the NACCD.
- 1.17. The National immunization program requires close collaboration and coordination among the relevant stakeholders.
- 1.18. All service providers involved in provision of immunization services should be competent to discharge their expected tasks.
- 1.19. Immunization service providers shall not be held liable for any adverse events following immunization as long as they comply to the National Immunization program guidelines.
- 1.20. Ensure that all vaccine recipients receive age appropriate and correct dose of vaccine by using the correct technique indicated according to available scientific evidence.
- 1.21. The immunization service provider should ensure that information on vaccine efficacy and safety is made available to the recipient.
- 1.22. Ministry of Health will attend the welfare of vaccine recipients with proven evidence of permanent disability or death due to immunization.

## **OBJECTIVE 2-Efficacious, safe and quality vaccines**

To have a country free of vaccine preventable diseases of public health importance by ensuring the use of efficacious safe and quality vaccines relevant to the health care needs of the people in a sustainable and equitable manner.

- 2.1 Availability efficacious, safe and quality vaccines for the public will govern the state immunization policy and free health care service commitment of the country.
- 2.2 Vaccines used in the National Immunization Program shall be cost effective.
- 2.3 Country recognizes the co-existence of immunization services in the private sector with efficacious, safe and quality vaccines in an affordable manner to the public to ensure a wider range of immunization opportunities.
- 2.4 No vaccine shall be used in the country without registration at the National Regulatory Authority.
- 2.5 Registration of all vaccines is in the best interest of the public. Registration of new vaccines or new formulations used in both government and private sectors will follow the requirements laid down by the cosmetics Devices and Drugs Authority- National Regulatory Authority (CDDA-NRA) on the recommendation of the National Advisory Committee on communicable Diseases (NACCD).
- 2.6 Registration is mandatory for vaccines procured or donated by international agencies or non-governmental organizations.
- 2.7 Vaccines used in the government sector will follow the standard government procurement procedures, giving due attention to the efficacy, safety and quality aspects based on available information.
- 2.8 Regulatory procedure adopted by the CDDA-NRA should be followed for all vaccines used in the private sector giving due attention to the safety and quality aspects based on available information.
- 2.9 All service providers will ensure that all vaccines in the National Immunization Program follow the immunization schedules recommended by the National Advisory committee on communicable Diseases.
- 2.10 Both public and private sector institutions should maintain the cold chain of vaccines from importation to the service delivery point to ensure efficacy, safety and quality of the vaccines. Cold chain operational capacity at both public and private sector will be monitored and evaluated by the NRA-CDDA and program management institution.
- 2.11 Immunization service providers should ensure that information on risk benefit of vaccines will be made available to the recipient. Information material provided in this regard should be with the concurrence of the Ministry of Health.
- 2.12 Disposal of expired or condemned vaccines will follow the policy adopted on safe disposal of medical waste in accordance with the National Environmental Policy and Cosmetic Devices and Drugs Act in Sri Lanka.
- 2.13 Efficacy, safety and quality of vaccines will be safeguarded through surveillance, monitoring and evaluation by the CDDA-NRA (Medical Technology and Supplies), National control Laboratory (Medical Research Institute) and the Immunization program Management Institution (Epidemiology Unit).

### **OBJECTIVE 3 – Introduction of new vaccines**

To ensure the rational and evidence-based introduction of new vaccines.

- 3.1 The National Immunization Programme should be reviewed periodically and updated in accordance with available evidence of the country's vaccine preventable disease epidemiology and regional/global initiatives.
- 3.2 Introduction of new vaccines and changes of the National Immunization Schedule should be performed based on scientific evidence.
- 3.3 All new vaccine introduction related research activities shall be in accordance with scientifically sound methodology, good clinical practice (GCP) standards, ethical clearance process (through the Health Ministry approved ethical committees) and proper/timely dissemination of research findings among the stakeholders. In addition, all vaccine related clinical trials need approval from the CDDA-NRA.

### **OBJECTIVE 4-Implementation of the National Immunization programmer**

To ensure the optimal implementation of the NIP by all service providers, through monitoring, evaluation, information management and operational research in the field of immunization

- 4.1 All immunization service providers shall provide necessary information to the NIP to carry out effective monitoring and evaluation of the immunization programmer.
- 4.2 All health care service providers who attend on patients with adverse events following immunization (AEFI) and patients with clinically suspected vaccine preventable diseases shall notify through the National disease Surveillance System, to the NIP in accordance with the guidelines.
- 4.3 All serious AEFI reported to the NIP shall be investigated. It will also take steps to investigate all clinically confirmed vaccine preventable diseases which have being reported through the National disease surveillance system.
- 4.4 The National Immunization programme activities and performance will be monitored and evaluated by relevant authorities.
- 4.5 Confidentiality of all immunization related information affecting individuals, groups of people or service providers shall be ensured at all levels.
- 4.6 All immunization related research actives shall be in accordance with scientific methods, standard ethical clearance process (through Health Ministry approved ethics committees) and proper/timely dissemination of research findings among the stakeholders.
- 4.7 Scientific research findings, AEFI surveillance data, post licensure data and vaccine preventable disease surveillance data should be shared and utilized when taking decisions on the National Immunization programmer.

## **OBJECTIVE 5-Financial sustainability**

To ensure the financial sustainability of the National Immunization programmer

- 1.1 The Government of Sri Lanka is committed to maintain the financial sustainability of the immunization programmer. The state will provide sufficient funding for timely procurement and supply of quality vaccines and other supportive logistics.
- 1.2 To ensure the financial sustainability, the Government of Sri Lanka will ensure a separate budget line for the NIP within the National Budget. This budget line will be reviewed annually with a view of achieving NIP objectives.
- 1.3 To ensure the smooth functioning of immunization services in accordance with the NIP objectives at provincial levels, all provincial authorities shall ensure timely availability of adequate funds and other resources.
- 1.4 The Government of Sri Lanka will explore the possibility of obtaining donor funding to strengthen the NIP while maintaining the integrity of the programmer and programmer objectives.
- 1.5 Mechanisms will be in place to regularly monitor the financial sustainability of the NIP.

## **OBJECTIVE 6 –Advocacy and promotion**

To ensure advocacy, promotion, awareness, protection and support for the National Immunization programme.

- 6.1 The right of the general public to access vaccine and immunization related information is recognized.
- 6.2 High community awareness should be promoted on the importance, benefits and need of age appropriate immunization.
- 6.3 All health care systems (public and private; western and other) shall engage in promoting, protecting and supporting the NIP.
- 6.4 Capacity building of all healthcare providers for promoting immunization activities of NIP will be encouraged.
- 6.5 The Government of Sri Lanka recognizes the vital role played by the education sector, media institutions, community organizations, NGO's, development partners and other UN agencies in promoting, protecting and supporting the NIP implementation by the Health sector.
- 6.6 All educational authorities including preschools and schools (both public and private) will promote and support activities of the National Immunization programmer. Child vaccination status at school entry should be evaluated and identified deficiencies will be rectified.

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- 6.7 Have a constant dialogue with media organization to encourage reporting of matters related to immunization in a timely, rational and responsible manner for the benefit of the public.
- 6.8 Vendors of vaccines shall adhere to accepted marking ethics relevant to immunization to ensure protection and support for the NIP when promoting all vaccines and immunization services.

## **OBJECTIVE 7- Implementation of the National Immunization policy**

The implementation of the National Immunization policy is a continuous process, the responsibility for which will be shared by relevant stakeholders.

- 7.1 The National Immunization policy will be implemented within the goals, objectives and framework of the National Health policy of the Government of Sri Lanka.
- 7.2 Implementation of the National Immunization policy will be done through a strategic plan.
- 7.3 National Immunization policy will be strengthened through an Act of parliament.
- 7.4 The Director General of Health service is the competent authority for implementation, monitoring and evaluation of the National Immunization policy. The Director General of Health service shall obtain advice and consult the National Advisory committee on communicable Diseases (NACCD) on implementation of the National Immunization policy.
- 7.5 Provincial health authorities will adhere to the National Immunization policy and strategic plan while carrying out all immunization related activities in their respective provinces.



- 7.6 Public Health Veterinary services will adhere to the National Immunization policy while carrying out vaccine preventable disease control activities.
- 7.7 National Immunization policy and strategic plan will be implemented by national and provincial health authorities. Further, policy implemented by national will be done through coordination and collaboration with Government Ministries, public and private institutions, national and international organizations.
- 7.8 The implementation of the National Immunization policy will be monitored and evaluated on a regular basis, through an effective monitoring system. For each area of the National immunization policy, monitoring indicators will be development and the progress of implementation will be monitored accordingly.
- 7.9 The National Immunization policy will be reviewed periodically and updated according to the needs of the country.