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PART I : SECTION (I) — GENERAL

Government Notifications

NATIONAL IMMUNIZATION POLICY OF SRI LANKA

NATIONAL Immunization Policy of Sri Lanka is approved by the Cabinet of Ministers, and it is effective from 16th October 2014 onwards, it is a long felt need of the country which will provide the policy guidance and directions to the national and provincial authorities, and other relevant stakeholders for effective implementation of the National Immunization Programme.

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Colombo 10,
23rd December 2015.

Preamble

With the vision of a country free of vaccine preventable diseases of public health importance and by creating an enabling environment for immunization of all eligible citizens of Sri Lanka against vaccine preventable diseases of public health importance, Cabinet of Ministers has approved the National Immunization Policy of Sri Lanka.

Sri Lanka has achieved significant improvement in human development index in 2014, securing the 73rd place globally and has become the 1st in the South East Asian Region. Some health indicators of this country is at a level to be compared with that of developed countries in the world.

National Immunization Programme of Sri Lanka has made great progress by providing quality immunization services covering the whole country with special emphasis on infants, children and pregnant mothers in a sustainable and equitable manner through a comprehensive island wide network of free health care services. The National Immunization Programme is aiming to ensure the availability of efficacious safe vaccines, provision of services efficiently, maintaining vaccines at optimal temperatures, timely distribution of logistics through the system, rational introduction of new vaccines, availability of trained skilled workers, availability of surveillance for vaccine effectiveness and safety, adequate funding



and due recognition for research. All these will reflect on the essential components of a well-functioning immunization programme in the country. The main objective of introduction of the National Immunization Policy is to ensure the optimal functioning of all said components of a well-functioning immunization programme. Successful implementation of the National Immunization Policy will help to strengthen the free immunization services provided by the public sector while strengthening the quality and standards of the immunization services the private sector.

NATIONAL IMMUNIZATION POLICY - 2014

MINISTRY OF HEALTH

THE CABINET OF MINISTERS OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA APPROVED THE NATIONAL IMMUNIZATION POLICY ON 16TH OCTOBER 2014

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 vaccine.

The main components of a well-functioning immunization programme include : availability of efficacious, safe and quality vaccines, efficient service deliver ; 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, programme 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 and evidence base, recognize the importance of private public partnership, have a multidisciplinary and multisectoral approach and be mindful of ethical considerations.

National Immunization Programme

All vaccines in the National Immunization Programme 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 objective of the NIP.

Immunization for vulnerable groups/high risk categories (immunosuppressed, 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 disease exposure of travellers) 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 stake holders. Many stakeholders including the National Advisory Committee on Communicable Diseases, Epidemiology Unit, National Medicines 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 Programme.

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 areas. 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 quality immunization service by both public and private sector service providers.

Over 90% of the total cost of the state immunization programme is borne by the Government of Sri Lanka. This is 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 vaccine 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 Programme 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 Programme 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 Programme.
7. To implement the National Immunization Policy in a systematic manner, inclusive of all stakeholders and the training of all immunization service providers.

STRATEGIES TOWARDS ACHIEVING OBJECTIVES

Objective 1 - Immunization Services

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

- 1.1 All citizens of Sri Lanka shall receive all vaccine recommended in the EPI in the National Immunization Programme 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 programme managers and the National Advisory Committee on Communicable Diseases (NACCD).
- 1.5 All immunization related activities should be carried out at centres which are registered and accredited by the Ministry of Health. The Ministry of Health will ensure all immunization clinic centres 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 Centers of 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 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 rules, regulations and 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, vaccine received as donations should go through the required quality assurance and registration process.
- 1.15 In accordance with the country specific requirements and international regulations 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 Programme 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 Programme 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 Welfare of vaccine recipients with proven evidence of permanent disability or death due to immunization will follow the Health Ministry response procedure.
- 1.23 Will ensure the availability of safe and efficacious passive immunization products (e. g. immunoglobulins and hyper immune immunoglobulins) to prevent or treat medical conditions that require them.

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 of 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 Programme 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 NMRA 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 Programme 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 NMRA and programme management institution.
- 2.11 Immunization service providers should ensure that information on risk benefit of vaccines will be made available to the recipient. Any 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 National Medicines Regulatory Authority Act in Sri Lanka.
- 2.13 Efficacy, safety and quality of vaccines will be safeguarded through surveillance, monitoring and evaluation by the NMRA (National Medicines Regulatory Authority), National Control Laboratory (Medical Research Institute) and the Immunization Programme 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 finding among the stakeholders. In addition all vaccine related clinical trials need approval from the NMRA.
- 3.4 Research and development of vaccine is recognized as an important component of the National Immunization Programme.
- 3.5 As part of the vaccine research development effort, the possibility of manufacturing cost effective, safe and efficacious vaccines in a sustainable manner for NIP will be explored to address the country need.

Objective 4 - Implementation of the National Immunization Programme.

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 programme.
- 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 activities shall be in accordance with scientific methods, standard ethical clearance process (through Health Ministry approved ethics committees) and proper/timely dissemination of research finding 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 Programme.

Objective 5 - Financial Sustainability

To ensure the financial sustainability of the National Immunization Programme

- 5.1 The Government of Sri Lanka is committed to maintain the financial sustainability of the immunization programme. The state will provide sufficient funding for timely procurement and supply of quality vaccines and other supportive logistics.

- 5.2 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.
- 5.3 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.
- 5.4 The Government of Sri Lanka will explore the possibility of obtaining donor funding to strengthen the NIP while maintaining the integrity of the programme and programme objectives.
- 5.5 Mechanisms will be in place to regularly monitor the financial sustainability of the NIP.

Objectives 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 healthcare 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 Programme. Child vaccination status at School entry should be evaluated and identified deficiencies will be rectified.
- 6.7 Have a constant dialogue with media organizations 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 marketing 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 and Act of Parliament.
- 7.4 The Director General of Health Services is the competent authority for implementation, monitoring and evaluation of the National Immunization Policy. The Director General of Health Services 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 should 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 should 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 implementation 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 developed 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.

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