

# Annex 3. Template for a New Vaccine Introduction Plan

This is a generic template to guide countries in developing a practical plan for introducing a new vaccine. This template is intended to provide suggestions for key areas to be considered, and as such, may be missing some items relevant to a particular country or to a particular vaccine introduction, or equally may contain some items that are not relevant. Each country and vaccine introduction will have different characteristics and requirements, and thus each country's introduction plan will need to be adjusted accordingly. The overall recommended length for this plan is 10-20 pages.

The introduction plan should build on plans, strategies and activities outlined in the country's own broader strategic plans, e.g. the National Immunization Plan, National Health Plan or Comprehensive Multi-Year Plan. Additionally, countries may want to consider developing an introduction plan for lower administrative levels in the country that translates goals and activities articulated at the national level into ones more relevant at sub-national level.

Section numbers in footnotes refer to sections of the main document, *Principles and Consideration for Adding a Vaccine to a National Immunization Programme*.

## Executive Summary

Summarize key aspects of the introduction plan, such as:

- Justification, goals, and objectives (short-, intermediate- and long-term) of the new vaccine introduction, with reference to the National Health (or Immunization) Plan or the Comprehensive Multi-Year Plan, as well as expected impacts on the immunization programme and health system
- The vaccine and presentation to be introduced, the specific target populations, phased or nation-wide implementation of introduction, and delivery strategies
- Coordination mechanisms and key partnerships for overseeing the introduction
- Opportunities provided by the new vaccine introduction to improve the immunization programme and health system, e.g., key issues and weaknesses to be addressed by the vaccine introduction
- Major activities of the introduction, e.g., expanding health worker capacity, reaching the hard-to-reach with social mobilization, improving the cold chain and logistics system, etc.
- Costs and financing of the short- and intermediate-term new vaccine introduction activities and the associated operational costs
- Sources of funding and the contribution of the Government

## 1. Background and Country Context

- Brief background information about the country (e.g., geography, population size, health status of children)
- Brief background on the national immunization programme, such as:
  - Goals, plans and vaccines currently in the current immunization programme.
  - Programme performance and achievements (e.g., trends in coverage rates, accelerated disease control efforts) disaggregated by sex, geography and wealth quintile, to the extent possible.
  - Past experience with new vaccine introductions and lessons learned, key findings from a recent EPI review, post-introduction evaluation, EVM assessment or other analyses and how identified issues and recommendations are being addressed by the immunization programme
  - Recent improvements made to the immunization programme and health systems that will facilitate introduction of the new vaccine (e.g., increase in cold chain capacity)
- Burden of the targeted disease in the country (e.g., summary of local data or regional or global estimates of disease burden, estimates of the economic burden of the disease)
- Decision-making process regarding the new vaccine introduction such as the decision-making body involved (e.g., NITAG, special task force), types of evidence reviewed and rationale for the decision (e.g., contribution to national and/or global disease prevention and health goals; cost, affordability and cost-effectiveness of the vaccination vs. other prevention and control measures), involvement of stakeholders and experts from different agencies and sectors of society, government review and approval process (e.g., HSCC, ICC, other health departments)

## 2. Goals, objectives and expected impact and challenges of the vaccine introduction

- Goals, objectives and targets (e.g., short-, intermediate- and long-term), and alignment with regional and/or global timelines (if applicable)
- Expected impact of the vaccine (e.g., on disease incidence and mortality, on equity related to gender, wealth and geography, among other factors on the overall immunization programme and health system)
- Major challenges and risks of the new vaccine introduction (e.g., programmatic, financial, cultural/societal) and the country's ability to address them. An equity analysis (gender, wealth, geography) should be conducted that includes suggested actions to mitigate any equity-related barriers that are identified.

### **3. Strategies and policies for introducing the vaccine into the national immunization programme**

- Choice of vaccine product to be introduced and rationale (including availability and acceptance of alternative presentations or products, if relevant)<sup>1</sup>
- Target ages and populations, eligibility for routine vaccination and for catch-up vaccination, if any; size and locations of the target population<sup>2</sup>
- Updated immunization schedule with the new vaccine (including booster doses, if relevant) and any schedule changes for the other routine vaccines<sup>3</sup>
- Delivery strategies to be used, including how to overcome barriers to reach new and hard-to-reach populations, the possible role of other sectors (e.g., education), etc.<sup>4</sup>
- Opportunities for integrating activities related to delivery of the new vaccine with other health interventions<sup>5</sup>
- Phased or nation-wide introduction and planned month of national introduction or time table for a phased introduction<sup>6</sup>

### **4. Resources, costs, financing, and sustainability**

- Overall trend of country immunization financing, including government funding, private sector, and donor funding, as applicable
- Identification of key immunization programme and health system needs for new vaccine introduction such as human resources (e.g., addressing number, distribution, turnover, and skills of vaccinators, nurses, logisticians, supervisors, delivery truck drivers, etc.), equipment, systems, etc.
- Estimated cost of adding the new vaccine to the immunization programme, including non-vaccine operational costs; plans for financing the additional costs of the new vaccine being introduced.
- Overview of the comprehensive multi-year plan (cMYP), highlighting any funding shortfalls and plans to address these, and potential impact on the new vaccine introduction

### **5. Strategies and activities for the vaccine introduction, including opportunities to improve the immunization**

---

<sup>1</sup> See Sections 2.3.1 and 3.3 of the main document.

<sup>2</sup> See Sections 3.2.3 and 3.2.4.

<sup>3</sup> See Section 3.2.3.

<sup>4</sup> See Section 3.2.5.

<sup>5</sup> See Section 3.2.6.

<sup>6</sup> See Section 3.2.1.

## **programme and overall health system during the introduction**

This is the core of the Introduction Plan. It should include all activities that need to take place to prepare for a smooth vaccine introduction. It should incorporate activities that address the issues, challenges and weaknesses of the existing immunization programme that were identified during the last EPI review, post-introduction evaluation, EVM assessment or a situational assessment. Suggested areas to describe and address include:

### **5.1 Coordinating and monitoring the preparation and implementation of the vaccine introduction<sup>7</sup>**

- Groups that will coordinate and oversee the introduction, e.g., steering committee or ICC, technical sub-committees to plan and monitor different aspects of the introduction, and persons to be included on these committees
- How the various committees will function, e.g., frequency of meetings, chairpersons and secretariat, to whom they report, etc.
- Partnerships for the introduction, including sectors and types of organizations to be involved (e.g., education, civil society, medical associations) and how they will participate in the planning and implementation of the vaccine introduction

### **5.2 Planning for procurement and distribution of vaccine<sup>8</sup>**

- National licensure status of the selected vaccine or process and timeframe for licensure
- Forecasted vaccine needs, including estimated size of the target population by year and estimated number of doses and injection supplies required per year (taking into account any catch-up vaccinations in the first year of introduction, or in subsequent years)
- Procurement procedures such as likely source(s) of vaccine and procurement process
- Shipping and distribution, including customs regulations and requirements that may affect timing of vaccine deliveries, and planned frequency of vaccine deliveries to regions, districts, and health facilities

### **5.3 Expanding or upgrading cold chain, logistics, and vaccine management<sup>9, 10</sup>**

- Current cold chain capacity at different levels of the system and source of these data; additional requirements at various levels for cold storage, transportation, and equipment to accommodate the new vaccine; how any gaps will be filled
- Current status of vaccine stock management system, including recent assessments, key issues (e.g., freeze monitoring), and any planned improvements

---

<sup>7</sup> See Section 3.1.2.

<sup>8</sup> See Sections 3.4 and 3.5.

<sup>9</sup> See Section 3.5.

<sup>10</sup> See Section 3.5

- Plans to increase supervision for vaccine management as part of the vaccine introduction

#### 5.4 Planning for increased waste management and injection safety needs to accommodate the new vaccine<sup>11</sup>

- Current waste management capacity and practices and injection safety practices and their adequacy; changes needed to accommodate additional volume of wastage due to new vaccine, and plans for upgrading the waste management system

#### 5.5 Revising health and immunization management information/data collection forms and systems<sup>12</sup>

- Revisions to add the new vaccine and any additional or innovative improvements to be made to the forms or information systems, including Child Health or Vaccination Cards/Booklets, to improve data quality and to take advantage of the new vaccine introduction; coordination with the persons or departments responsible for revising, printing and distributing the various forms or improving the information system, and the estimated timeline

#### 5.6 Planning for the monitoring and evaluation of the new vaccine introduction

- Monitoring the vaccine introduction and programme performance (e.g., plans for monitoring short-, intermediate-, and long-term targets and objectives); also for monitoring the new vaccine coverage<sup>13</sup>
- Planning and implementing pre- and post-introduction evaluations using available tools, (e.g. Annex 4 to this document – “New Vaccine Introduction Checklist”, and WHO’s “New Vaccine Post-Introduction Evaluation (PIE) Tool”)
- Updating or enhancing AEFI surveillance and reporting (e.g., current national AEFI monitoring policy and practices and planned improvements)<sup>14</sup>
- Supportive supervision and pre- and post-introduction monitoring, including plans for supervision activities before, during and after the introduction of the new vaccine (e.g., pre-introduction visits to assess readiness for introduction; immediate post-introduction monitoring visits; post-introduction evaluation or EPI review, etc.)<sup>15</sup>
- Measuring the impact of the new vaccine , e.g., description of any current disease surveillance plans for monitoring vaccine impact and timeframe<sup>16</sup>

#### 5.7 Training of health workers (or other professionals involved in vaccination)<sup>17</sup>

- Types and numbers of personnel who provide or assist with vaccination and need to be trained, results of any recent assessments of health worker skills and knowledge

---

<sup>11</sup> See Section 3.6.

<sup>12</sup> See Sections 3.9 and 4.1.

<sup>13</sup> See Sections 3.1 and 4.1.

<sup>14</sup> See Section 4.3.

<sup>15</sup> See Sections 3.7.2 and 4.4.

<sup>16</sup> See Section 4.2.

<sup>17</sup> See Section 3.7.

- Training plan with strategy (e.g., cascade training), numbers and types of people to be trained at national and district levels, duration and content of training at each level, materials to be developed, monitoring and evaluation of training, and timeline
- Updating or creation of training modules to be used to train the trainers and health workers

#### 5.8 Planning and conducting social mobilization, communications and advocacy activities<sup>18</sup>

- Considerations for handling and obtaining informed consent for vaccination, if required
- Description of any community assessments of Knowledge, Attitude, Practice and Behaviour (KAPB), focus group discussions or formative research for the disease or vaccine that have or will take place and how the findings will inform the messages and strategies for information, education, communication, and training
- Advocacy plans to sensitize opinion leaders and the media at national, regional, and district levels regarding the introduction and benefits of the new vaccine and to obtain their active support
- Development of a communication strategy and a crisis communication plan

### **Suggested Annexes:**

1. New Vaccine Introduction Checklist and New Vaccine Introduction Activity List and Timeline (see Annex 4)
2. Budget (see example of following budget and resource table)

---

<sup>18</sup> See Section 3.8.

## Sample budget and resource table for vaccine introduction activities

			Non-Government Support		Total Support Secured	Shortfall in Support	Comment
Activity	Total Cost	Government Support	Name	Amount			
Programme management & coordination							
Planning & preparation							
Social mobilization, IEC & advocacy							
Training & meetings							
Materials production and data management							
Human resources and incentives							
Cold chain equipment							
Transport for implementation & supervision							
Immunization session supplies							
Waste management							
Surveillance & monitoring							
Post-introduction evaluation							
Technical assistance							
Other (specify)							

Total							
-------	--	--	--	--	--	--	--