World Health Organization

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Draft global vaccine action plan

Report by the Secretariat

1. In May 2011, a report by the Secretariat on the global immunization vision and strategy was noted by the Sixty-fourth World Health Assembly.[1] During the discussions the vision for the Decade of Vaccines (2011–2020) and the development of a global vaccine action plan were welcomed. Subsequently, the Executive Board at its 130th session in January 2012 considered the draft global vaccine action plan and provided guidance.[2] The Board also adopted resolution EB130.R12 on World Immunization Week.[3] The present document provides an updated draft of the action plan that draws on an extensive consultation process, and invites consideration of a draft resolution in relation to the plan.

INTRODUCTION

2. The draft global vaccine action plan builds on the success of the Global Immunization Vision and Strategy, 2006–2015, which was launched in 2005 as the first 10-year strategic framework to realize the potential of immunization. Developing the plan has brought together multiple stakeholders involved in immunization, including governments and elected officials, health professionals, academia, manufacturers, global agencies, development partners, civil society, media and the private sector, to define collectively what the immunization community wants to achieve over the next decade. In total, the global consultation process reached over 1100 individuals representing more than 140 countries and 290 organizations, and included two special sessions to brief representatives of the Permanent Missions of the United Nations Offices and other Intergovernmental Organizations in Geneva and New York.

3. Immunization is, and should be recognized as, a core component of the human right to health and an individual, community and governmental responsibility. Vaccination prevents an estimated 2.5 million deaths each year. Protected from the threat of vaccine-preventable diseases, immunized children have the opportunity to thrive and a better chance of realizing their full potential. These advantages are further increased by vaccination in adolescence and adulthood. As part of a comprehensive package of interventions for disease prevention and control, vaccines and immunization are an essential investment in a country's – indeed, in the world's – future.

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[1] See documents A64/14 and WHA64/2011/REC/2, summary records of the sixth meeting, section 2, the seventh meeting and the eighth meeting, section 2.

[2] See documents EB130/21 and EB130/2012/REC/2, summary record of the eleventh meeting.

[3] See document EB130/2012/REC/1 for the resolution, and for the financial and administrative implications for the Secretariat of the adoption of the resolution.

4. Now is the time for showing commitment to achieving the full potential of immunization. The collective recognition of this opportunity has led the global health community to call for a Decade of Vaccines, in line with the requests made in resolution WHA61.15 on the global immunization strategy. The vision for the Decade of Vaccines (2011–2020) is of a world in which all individuals and communities enjoy lives free from vaccine-preventable diseases. The mission of the Decade of Vaccines is to extend, by 2020 and beyond, the full benefit of immunization to all people, regardless of where they are born, who they are or where they live.

5. The draft global vaccine action plan reiterates existing goals and sets new goals for the decade, proposes six strategic objectives and the actions that will support their achievement, and provides an initial estimate of resource requirements and return on investment. Annex 1 summarizes recommended indicators to monitor and evaluate progress. Beyond the action plan, country, regional and global stakeholders need to take responsibility for specific actions, translate the action plan into detailed operational plans (updating both the action plan and the operational plans as new information becomes available), complete the development of an accountability framework for the Decade of Vaccines (2011–2020) and mobilize resources to ensure that the vision for the Decade of Vaccines becomes a reality. Accomplishing this will require global and national institutions to innovate and to change the way they work. Annex 2 provides a summary of stakeholder responsibilities.

6. The last century was, in many respects, the century of treatment, resulting in dramatic reductions in morbidity and mortality, with the discovery and use of antibiotics as one of the biggest agents of change in health. This century promises to be the century of vaccines, with the potential to eradicate, eliminate or control a number of serious, life-threatening or debilitating infectious diseases, and with immunization at the core of preventive strategies. Ensuring that the vision for the Decade of Vaccines becomes a reality is a powerful step in that direction.

THE IMMUNIZATION LANDSCAPE TODAY

Important progress in the last decade

7. In the last 10 years, great advances have been made in developing and introducing new vaccines and expanding the reach of immunization programmes. More people than ever before are being vaccinated and access and use of vaccines by age groups other than infants is expanding. As a result of immunization combined with other health care and development interventions – including improved access to clean water and sanitation, better hygiene and education – the annual number of deaths among children under five years of age fell from an estimated 9.6 million in 2000 to 7.6 million in 2010, despite an increase in the number of children born each year.

8. Immunization has helped drive this reduction in child mortality: coverage of vaccines that have been in use since the inception of the Expanded Programme on Immunization has expanded, and new vaccines have been introduced. Vaccines against hepatitis B and *Haemophilus influenzae* type b have become part of national immunization schedules in 179 and 173 countries, respectively; poliomyelitis is nearing eradication; and a large number of deaths from measles are being averted every year. The number of deaths caused by traditional vaccine-preventable diseases (diphtheria, measles, neonatal

tetanus, pertussis and poliomyelitis) has fallen from an estimated 0.9 million in 2000 to 0.4 million in 2010.[1]

9. New and increasingly sophisticated vaccines that have become available in the last decade, including pneumococcal conjugate vaccine and vaccines against infection with rotavirus and human papillomavirus, are currently being rolled out globally. Efforts are being made to shorten the time lag that has historically existed in the introduction of new vaccines between high- and low-income countries. For example, the 13-valent pneumococcal conjugate vaccine was introduced in a low-income country a little more than a year after it had been introduced in a high-income country.

10. Through an innovative international collaboration, an affordable conjugate vaccine against *Neisseria meningitidis* serogroup A was developed and is now in use in the African meningitis belt. There are now licensed vaccines being used to prevent, or contribute to the prevention and control of, 25 vaccine-preventable infections (Table 1).

Table 1: Vaccine-preventable infectious agents or diseases

- Anthrax
- Cholera
- Diphtheria
- Hepatitis A
- Hepatitis B
- Hepatitis E
- *Haemophilus influenzae* type b
- Human papillomavirus
- Japanese encephalitis
- Measles
- Meningococcal disease
- Mumps
- Pertussis
- Pneumococcal disease
- Poliomyelitis
- Rabies
- Rotavirus gastroenteritis
- Rubella
- Influenza
- Tetanus
- Tuberculosis
- Typhoid fever
- Tick-borne encephalitis
- Varicella and herpes zoster (shingles)
- Yellow fever

11. The strengthening by countries of national programmes, aided by improved support from and coordination among local, national, regional and international stakeholders, has succeeded in improving immunization coverage rates. Financing from domestic budgets allocated to immunization programmes has risen over the past decade, as has the flow of international resources dedicated to immunization. According to the immunization programme data for 2010,[2] 154 of the 193 Member States report having a specific budget line item for immunization, and 147 have developed multi-year national plans to sustain the gains achieved, further enhance performance to reach desired goals and introduce appropriate new vaccines.

[1] Sources for estimates: measles and neonatal tetanus, in *World Health Statistics 2012*, Geneva, World Health Organization, 2012; diphtheria and poliomyelitis, for 2000: http://www.who.int/healthinfo/global_burden_disease/estimates_regional_2000_v3/en/index.html (accessed 5 April 2012), for 2008: http://apps.who.int/ghodata/ (accessed 5 April 2012); pertussis, WHO Secretariat provisional data.

[2] http://www.who.int/immunization_monitoring/data/en/ (accessed 13 April 2012).

12. Global and regional immunization initiatives have supported countries in building up their systems and introducing new vaccines. Global goals and milestones established through the Global Immunization Vision and Strategy 2006–2015, the United Nations Millennium Declaration, the United Nations World Summit for Children, the United Nations General Assembly Special Session on Children, and, more recently, the United Nations Secretary-General's Global Strategy for Women's and Children's Health have stimulated expansion of national immunization programmes. In low- and middle-income countries these have been supported by initiatives such as the GAVI Alliance, the Global Polio Eradication Initiative, the Measles Initiative, the vaccine procurement services of UNICEF, and PAHO's Revolving Fund for Vaccine Procurement.

Significant unmet needs remain

13. Despite this progress, vaccine-preventable diseases remain a major cause of morbidity and mortality. Adoption of new vaccines by low- and middle-income countries (where disease burdens are often the highest) has been slower than in high-income countries. In 2010, for example, only 13% of the total high-income country birth cohort lived in countries that did not have pneumococcal conjugate vaccines in their immunization schedules. Of the total low-income country birth cohort, 98% lived in countries that did not have pneumococcal conjugate vaccines in their schedules.

14. Coverage gaps persist between countries, as well as within countries. The average coverage with three doses of diphtheria-tetanus-pertussis-containing vaccine and with measles-containing vaccine in low-income countries was 16% and 15% below that of high-income countries in 2010, respectively. However, this represents a positive trend in comparison with the coverage gap of 30% for both vaccines in the year 2000.

15. In some countries, coverage of measles-containing vaccine in rural areas is 33% lower than in urban areas. Similarly, the measles vaccine coverage rate for the richest fifth of the population in some countries is up to 58% higher than for the poorest fifth. Coverage can also be very low in settlements of the urban poor, especially in cities with transitory migrant populations, and in indigenous communities.

16. Geographical distance from health centres is not the only determinant of low coverage; inequities are also associated with other socioeconomic determinants, such as income levels and the educational status of the mother. A special geographic focus is needed on lower-middle-income countries with large populations, where the majority of the unvaccinated live. Reaching underserved populations will be especially challenging, but inequities need to be tackled because these populations often carry a heavier disease burden and may lack access to medical care and basic services, with the fragile economies of individuals and their families suffering a severe disease-related impact as a consequence.

New opportunities and challenges for the Decade of Vaccines (2011–2020)

17. Individuals and communities, governments and health professionals have primary responsibility for exploiting the opportunities and confronting the challenges that this decade will bring. New and improved vaccines are expected to become available, based on a robust pipeline that includes several vaccines for diseases that are not currently preventable through vaccination. The introduction of new vaccines targeted against several important causes of major killer diseases, such as pneumonia, diarrhoea and cervical cancer can be used as a catalyst to scale up complementary interventions. In addition to reducing mortality, these new vaccines will prevent morbidity with resulting economic returns even in countries that have already succeeded in improving mortality rates. Innovations in

existing vaccines will bring additional benefits, such as greater effectiveness, thermostability, easier administration and lower cost.

18. At the same time, the development of vaccines and other immunization innovations is facing increasingly complex manufacturing and regulatory processes, as well as rising research, development and production costs. As new vaccines (for example, against dengue and malaria) become available and underutilized vaccines (for example, those against cholera, human papillomavirus, rabies, rotavirus, rubella and typhoid) are administered more widely, supply and logistics systems – already burdened – will face an even greater need for innovations. Finally, the number of health workers, as well as their knowledge and skills, will need to be enhanced, better coordinated and better supervised. While the challenges are many, the introduction of new vaccines also represents an opportunity to strengthen immunization systems and to act as a catalyst to implement many of the required reforms. As national immunization investments increase, so must government oversight and accountability.

19. Immunization funding needs in the areas of research and development, procurement and delivery are expected to more than double in the coming decade. New and more complex vaccines will bring new funding requirements and countries will be confronted with difficult decisions in dealing with competing health priorities. Resources will need to be allocated more efficiently, with the relevant decisions guided by national priorities, capacity, clear information on the costs and benefits of choices, and improved financial management. Expenditures must be linked to outputs and impacts, showing a clear investment case for immunization.

20. As the economies of many low- and middle-income countries continue to grow, so will their potential to fund immunization. Countries that have relied on development assistance will be able to fund an increasing proportion of their immunization programmes, and may even, eventually, be able to fully sustain them. Some will be able to extend new financial and technical support to global immunization projects. At the same time, vaccine manufacturers in some of these countries will be expected to make an even more significant contribution to the supply of high-quality, affordable vaccines, spreading the sources of production more widely and increasing competition.

21. The growing availability of information and penetration of mobile telephone and social networks can boost public demand for immunization, and ensure that people are made aware of both the benefits derived from vaccines and their potential risks. The immunization community can take advantage of social networks and electronic media to more effectively allay fears, increase awareness and build trust.

22. The lessons learnt from past decades, the unmet needs, and the opportunities and challenges that this decade presents have been carefully considered in the formulation of the guiding principles, measures of success and recommended actions that are articulated in the following sections.

SIX GUIDING PRINCIPLES

23. Six principles have guided the elaboration of the draft global vaccine action plan.

- **Country ownership:** countries have primary ownership and responsibility for establishing good governance and for providing effective and quality immunization services for all.

- **Shared responsibility and partnership:** immunization against vaccine-preventable diseases is an individual, community and governmental responsibility that transcends borders and sectors.

- **Equity:** equitable access to immunization is a core component of the right to health.

- **Integration:** strong immunization systems, as part of broader health systems and closely coordinated with other primary health care delivery programmes, are essential for achieving immunization goals.

- **Sustainability:** informed decisions and implementation strategies, appropriate levels of financial investment, and improved financial management and oversight are critical to ensuring the sustainability of immunization programmes.

- **Innovation:** the full potential of immunization can only be realized through learning, continuous improvement and innovation in research and development, as well as innovation and quality improvement across all aspects of immunization.

24. These six fundamental principles can realistically and effectively guide the full spectrum of immunization activities throughout the Decade of Vaccines (2011–2020). Although the draft global vaccine action plan will need to be translated into specific regional, country and community contexts, these guiding principles are universally applicable and relevant to each of the Decade of Vaccines' goals and strategic objectives described below.

MEASURES OF SUCCESS

25. The Decade of Vaccines is about taking action to achieve ambitious goals. Early in the decade, this means achieving already established elimination and eradication goals. It means dealing with the public health emergency constituted by wild poliovirus transmission in order to secure a world free of poliomyelitis. It also means assuring the global or regional elimination of measles, rubella and neonatal tetanus.[1] Completing this agenda has never been more critical. Success will encourage the achievement of additional ambitious goals. Failure will mean that millions of preventable cases of disease and death will continue to occur.

26. Later in the decade, success will be recorded in terms of the expansion of immunization services to meet vaccination coverage targets in every region, country and community. In 2015, the coverage of target populations should reach the goal of the Global Immunization Vision and Strategy, 2006–2015 of at least 90% national vaccination coverage and at least 80% vaccination coverage in every district or equivalent administrative unit (the marker for this being coverage for diphtheria-tetanus-pertussis-containing vaccines). By 2020, coverage of target populations should reach these levels for all vaccines in national immunization programmes unless alternative targets exist. Vaccine introductions should also be monitored, with the goal of at least 80 low- or middle-income countries introducing one or more appropriate new or underutilized vaccines by 2015. These technical accomplishments will not be sustained unless countries take full ownership of their routine immunization programmes (see strategic objective 1 below).

27. During this decade millions of additional deaths and cases of disease should become preventable as a result of the development, licensure and introduction of new and improved vaccines and technologies for high-burden diseases. Specifically, progress towards the licensure and launch of vaccines should be tracked against one or more major pathogens not currently vaccine preventable

[1] By 2015, achieve maternal and neonatal tetanus elimination (defined as less than one case of neonatal tetanus per 1000 live births) in every district, measles elimination in at least four WHO regions and rubella elimination in at least two WHO regions. By 2020, achieve measles and rubella elimination in at least five WHO regions.

(such as, cytomegalovirus, dengue virus, group A streptococcus, hepatitis C virus, hookworm, leishmania and respiratory syncytial virus) and at least one new platform delivery technology.

Goals of the Decade of Vaccines (2011–2020)

Achieve a world free of poliomyelitis
Meet global and regional elimination targets
Meet vaccination coverage targets in every region, country and community
Develop and introduce new and improved vaccines and technologies
Exceed the Millennium Development Goal 4 target for reducing child mortality

28. If these immunization-specific goals are achieved, hundreds of millions of cases and millions of future deaths will be averted by the end of the decade, billions of dollars of productivity will be gained, and immunization will contribute to exceeding the Millennium Development Goal 4 target for reducing child mortality (and the target that succeeds it post-2015). For example, it is estimated that if the coverage targets for introduction and/or sustained use of 10 vaccines alone (those against hepatitis B, *Haemophilus influenzae* type b, human papillomavirus, Japanese encephalitis, measles, meningococcus A, pneumococcus, rotavirus, rubella and yellow fever) in 94 countries during the decade are met, between 24 and 26 million future deaths could be averted compared with a hypothetical scenario under which these vaccines have zero coverage (see also paragraphs 89–99 below).

Six strategic objectives

29. Continuous progress towards the following six strategic objectives will enable the achievement of the goals of the Decade of Vaccines (2011–2020).

(i) **All countries commit to immunization as a priority.** Key indicators to monitor progress towards this strategic objective at the country level are the presence of a legal framework or legislation that guarantees financing for immunization and the presence of an independent technical advisory group that meets defined criteria.

(ii) **Individuals and communities understand the value of vaccines and demand immunization as both their right and responsibility.** Progress towards increased understanding and demand can be evaluated by monitoring the level of public trust in immunization, measured by surveys on knowledge, attitudes, beliefs and practices.[1]

(iii) **The benefits of immunization are equitably extended to all people.** Progress towards greater equity can be evaluated by monitoring the percentage of districts with less than 80% coverage with three doses of diphtheria-tetanus-pertussis-containing vaccine and coverage gaps between lowest and highest wealth quintile (or another appropriate equity indicator).

(iv) **Strong immunization systems are an integral part of a well-functioning health system.** The strength of health systems can be evaluated based on dropout rates between the

[1] The Strategic Advisory Group of Experts working group on vaccine hesitancy will develop a definition of vaccine hesitancy and recommend specific questions from surveys (either existing or new) to fully formulate this indicator.

first dose of diphtheria-tetanus-pertussis-containing vaccine and the first dose of measles-containing vaccine. The quality of data is important for monitoring the functioning of a health system. Data quality can be evaluated by monitoring whether immunization coverage data are assessed as high quality by WHO and UNICEF.

(v) **Immunization programmes have sustainable access to predictable funding, quality supply and innovative technologies.** Key indicators to monitor progress towards this strategic objective will be the percentage of routine immunization costs financed through government budgets and globally installed capacity for production of universally recommended vaccines within five years of licensure/potential demand.

(vi) **Country, regional and global research and development innovations maximize the benefits of immunization.** Key indicators of progress towards this strategic objective include proof of concept for a vaccine that shows greater or equal to 75% efficacy for HIV/AIDS, tuberculosis or malaria and the initiation of phase III trials for a first generation universal influenza vaccine. In addition, country research and development capacity can be measured by the institutional and technical capacity to manufacture vaccines and/or carry out related clinical trials and operational and organizational research.

30. Achieving the vision and goals of the Decade of Vaccines (2011–2020) will only be possible if all stakeholders involved in immunization commit themselves to, and take action to achieve, the six strategic objectives; uphold the Decade of Vaccines guiding principles when implementing all the actions; and regularly monitor and evaluate progress towards both strategic objectives and goals using the indicators described above (see also Annex 1).

31. An accountability framework is needed that defines the methodology and source of data for these indicators, identifies which stakeholders will be responsible for what actions, and articulates the process and responsibilities for monitoring and evaluating progress over the course of the Decade. The draft global vaccine action plan lays the groundwork for each of these elements. Further development and implementation of the accountability framework at country, regional and global levels could take place over the course of 2012 by leveraging the findings of the Commission on Information and Accountability for Women's and Children's Health and aligning work, wherever possible, with other accountability efforts and initiatives by all stakeholders at the country level to deliver and monitor progress.

ACTIONS TO ACHIEVE STRATEGIC OBJECTIVES