World Health Organization

SIXTY-NINTH WORLD HEALTH ASSEMBLY **A69/34**
Provisional agenda item 15.2 **11 March 2016**

Global vaccine action plan

Report by the Secretariat

1. The Executive Board, at its 138th session, noted an earlier version of this report.[1] The report has been amended to take account of the requests by Board members for additional information on progress made to date in implementing resolution WHA68.6 (2015) on the global vaccine action plan.

2. In May 2012, the Sixty-fifth World Health Assembly endorsed the global vaccine action plan[2] and requested the Director-General to monitor progress and report annually, through the Executive Board, to the Health Assembly, until the Seventy-first World Health Assembly, on progress towards achievement of global immunization targets, as a substantive agenda item, using the proposed accountability framework to guide discussions and future actions.[3]

3. In May 2013, the Sixty-sixth World Health Assembly noted the report by the Secretariat,[4] including the proposed framework for monitoring and evaluation and accountability, as well as the process for reviewing and reporting progress under the independent oversight of the Strategic Advisory Group of Experts on immunization.[5]

4. In accordance with the monitoring, evaluation and accountability process,[6] the Strategic Advisory Group of Experts on immunization reviewed progress against each of the indicators for the goals and strategic objectives of the global vaccine action plan, based on data from 2014,[7] and prepared the 2015 Assessment Report of the Global Vaccine Action Plan.[8]

5. A summary of the 2015 Assessment Report by the Strategic Advisory Group of Experts on immunization is included in Annex 1.

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[1] See document EB138/32 and the summary records of the Executive Board at its 138th session, ninth and tenth meetings, (document EB138/2016/REC/2).

[2] The global vaccine action plan is available at: http://www.who.int/immunization/global_vaccine_action_plan/en/ (accessed on 10 March 2016).

[3] See resolution WHA65.17 (2012).

[4] Document A66/19.

[5] See document WHA66/2013/REC/3, summary record of the tenth meeting of Committee A, section 2.

[6] See document A66/19, paragraphs 16 and 17.

[7] The Global Vaccine Action Plan Monitoring, Evaluation and Accountability: Secretariat Annual Report 2015 is available at: http://www.who.int/immunization/global_vaccine_action_plan/gvap_secretariat_report_2015.pdf?ua=1 (accessed on 10 March 2016).

[8] The 2015 Assessment Report of the Global Vaccine Action Plan is available at: http://www.who.int/immunization/global_vaccine_action_plan/sage_assessment_reports/en/ (accessed on 10 March 2016).

6. Between March and October 2015, the Strategic Advisory Group of Experts on immunization reviewed progress made in the implementation of the global vaccine action plan. As the data taken into consideration were those available prior to the period under review, the review did not cover progress made in the implementation of resolution WHA68.6, which was adopted in May 2015 by the Sixty-eighth World Health Assembly. A preliminary report summarizing progress made to date in the implementation of that resolution is provided in Annex 2 to the present report. The final report, duly reviewed by the Strategic Advisory Group of Experts on immunization, will be included in the Secretariat's next report on progress towards the achievement of the global vaccine action plan targets.

7. Resolution WHA68.6 was adopted by Member States in response to the fact that limited access to an affordable and timely supply of vaccines is a major barrier to sustainable immunization programmes. WHO has been conducting a range of activities to increase the availability of an affordable and timely supply of vaccines, including activities to: promote vaccine research and development in developing countries; facilitate technology transfer; revise the prequalification process; streamline in-country registration procedures; strengthen procurement processes; promote price transparency; and provide information and technical support to identify the determinants of vaccine shortages. Annex 2 provides a detailed description of these efforts. Nevertheless, it should be noted that the resources available for this work are very limited and unpredictable, preventing a more systematic and comprehensive approach.

8. In April 2015, the Strategic Advisory Group of Experts on immunization endorsed a shared partner strategy to enhance sustainable access to vaccines in middle-income countries. This strategy proposes a comprehensive approach to addressing the challenges identified by countries in implementing sustainable immunization programmes, particularly with regard to access to supply.

9. It should be noted that supply-side interventions should be matched with demand-consolidation activities relating in particular to strengthening national decision-making and the national financing of immunization programmes. Furthermore, immunization should be considered as one part of a package of interventions for health care delivery aimed at preventing, protecting against and treating diseases. Such an integrated approach has already been taken for the prevention of maternal and neonatal tetanus and in the integrated global action plan for the prevention and control of pneumonia and diarrhoea.[1]

ACTION BY THE HEALTH ASSEMBLY

10. The Health Assembly is invited to take note of the report and to consider the recommendations for actions to be taken by the various stakeholders of the global vaccine action plan, in particular by Member States.

[1] See http://www.who.int/woman_child_accountability/news/gappd_2013/en/ (accessed on 23 February 2016).

ANNEX 1

A SUMMARY OF THE 2015 ASSESSMENT REPORT OF THE GLOBAL VACCINE ACTION PLAN BY THE STRATEGIC ADVISORY GROUP OF EXPERTS ON IMMUNIZATION[1]

1. The Global Vaccine Action Plan (GVAP) set ambitious but achievable goals, to save thousands of lives through vaccination in this Decade of Vaccines to 2020. However The Decade of Vaccines is not on course to achieve its true potential.

2. Performance against key immunization targets remains off-track, though there have been some success stories. These isolated improvements in countries and at the global level as highlighted below will have to become the norm if the plan is to get back on track.

- The GVAP target for introduction of new or under-utilized vaccines is on track worldwide, with 86 low and middle-income countries introducing a total of 128 vaccines since 2010.
- The Ebola candidate vaccines were developed and tested within a short timeframe and showed the potential to protect against a high mortality disease.
- Following the resolution by the World Health Assembly on vaccine pricing,[2] the WHO secretariat has worked with countries to share pricing data. To date, 40 countries have shared information with WHO compared with only one country last year.
- India has been declared free of maternal and neonatal tetanus, demonstrating that it is possible to eliminate this disease even in challenging circumstances.
- Africa has not had a case of wild poliovirus since August 2014 – an enormous achievement. Nigeria is no longer a polio-endemic country.
- Polio resources were utilized in containing the outbreak of Ebola virus in Africa.
- The Americas became the first region to eliminate rubella and congenital rubella syndrome, a major achievement.

3. This assessment report focuses on the need for leadership and accountability systems at all levels, particularly within countries to put progress with the GVAP back on track.

4. Based on countries' achievements, the following common factors that would lead to success are highlighted: improving quality and use of data; community involvement; improved access to immunization services for the marginalized and displaced populations; strengthening health systems; securing and sustained supply of vaccines at all levels; leadership and accountability.

[1] http://www.who.int/immunization/global_vaccine_action_plan/sage_assessment_reports/en/ (accessed on 10 March 2016).

[2] http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_R6-en.pdf (accessed on 10 March 2016).

5. At this critical midpoint of the Decade of Vaccines, **SAGE makes nine recommendations**, focusing squarely on the major issues.

To improve accountability to achieve the GVAP goals, SAGE recommends that:

– Countries have annual plans for immunization consistent with the GVAP and relevant regional vaccine action plans. The Ministries of Health, Finance and other pertinent ministries demonstrate leadership by establishing an annual process for monitoring and accountability at national and subnational levels. Monitoring should be through an independent body, for example the National Immunization Technical Advisory Group (NITAG). Each country should share, every year, with WHO regional offices, its monitoring report which should include monitoring progress towards achievement of outcomes but also sharing of best practices.

– Once regional vaccine action plans are finalised (by December 2015), WHO regional offices establish a process of annual progress review through their regional technical advisory groups and report to the respective Regional Committees. The first annual review should take place in the first half of 2016 for countries already having annual plans consistent with the GVAP. WHO Regional Committees' reports should be made available annually to SAGE as part of the global review process.

– Global, regional and national development partners align their efforts to support countries in strengthening their leadership and accountability frameworks and in implementing their national plans. This should include establishing and/or strengthening partner coordination mechanisms at each level.

– Decade of Vaccines secretariat agencies report to SAGE in 2016 on their supporting activities conducted in the 10 countries where most of the unvaccinated and under-vaccinated children live. This annual reporting mechanism should include discussion of those reports in regional technical advisory groups.

To address the shortfalls in disease-specific areas of the Global Vaccine Action Plan's implementation, SAGE recommends that:

– Given poor progress with elimination of maternal and neonatal tetanus and the relatively small funding gap to achieve this goal, WHO and UNICEF convene a meeting of global partners and the remaining 21 countries to agree on an action plan, resources and respective responsibilities so that the goal is achieved no later than 2017 and thereafter strategies are in place to sustain elimination in all countries.

– Global, regional and national development partners support countries in securing the required resources and in implementing their measles and rubella elimination or control strategies and plans. The recommendations of the mid-term review of the global measles and rubella strategic plan to be conducted in 2016, once endorsed by SAGE, should be taken into account in refining plans and for monitoring and enhancing quality of plan implementation.

To improve immunization coverage especially where many unvaccinated and under-vaccinated children live, including those affected by conflict and crisis, SAGE recommends that:

– Global, regional and country development partners should coordinate and align their efforts to support countries to immunize more children by strengthening their health-care delivery systems, combined with targeted approaches to reach children consistently missed by the routine delivery system, particularly in the countries where national vaccination rates, or subnational rates in larger countries, are below 80%, and to provide services to populations displaced due to conflict (both internally displaced persons and refugees).

– WHO should provide guidance for countries and partners on implementation of immunization programmes and immunization strategies during situations of conflict and chronic disruption.

The 2016 GVAP assessment report will also serve as a mid-term review of progress in the Decade of Vaccines and SAGE recommends that:

– This report should be presented at the World Economic Forum in Davos where the Decade of Vaccines was launched. The 2016 report should also aim to highlight those activities that were game-changers at global, regional and country levels.

ANNEX 2

ACTIVITIES BEING CONDUCTED BY WHO TO ADDRESS THE CHALLENGES COUNTRIES ARE FACING IN RESPECT OF ACCESS TO VACCINE SUPPLIES

1. VACCINE RESEARCH AND DEVELOPMENT IN DEVELOPING COUNTRIES

1. The global vaccine action plan's monitoring, evaluation and accountability framework reviews research capacity in low- and middle-income countries in each region on a biennial basis. The Secretariat's 2014 progress report on the action plan[1] includes data on the number of registered vaccine clinical trials by region.

2. In 2015, WHO convened a broad coalition of experts to develop a research and development blueprint for action to prevent epidemics.[2] The blueprint presents options for reducing the time lag between the identification of a nascent outbreak and the approval of the most advanced products that can be used to save lives and prevent the escalation of crises. Its third workstream, on global coordination and expansion of capacity, includes activities to increase the involvement of low- and middle income countries in vaccine research and development.

3. The development processes for vaccines that specifically target diseases prevalent in developing countries, such as malaria, epidemic meningococcal A meningitis and Ebola virus disease, have been taken as an opportunity to strengthen research and development capacities in low and middle-income countries.

2. TECHNOLOGY TRANSFER

4. WHO has been providing technical and financial support and facilitating technology transfer to 14 countries since 2006 to establish or enhance their capacity to produce influenza vaccines. These countries are Brazil, China, Egypt, India, Indonesia, Islamic Republic of Iran, Kazakhstan, Republic of Korea, Mexico, Romania, Serbia, South Africa, Thailand and Viet Nam. Five manufacturers have achieved licensure of their influenza vaccines as a result of this support. For the period 2015–2016, support is being focused on helping those manufacturers with influenza vaccines that are already at the clinical development stage to advance towards licensure, as well as on providing the adjuvant technology to allow for the development of dose-sparing strategies for pandemic response. As a result of these activities, it is anticipated that, by the end of 2016, this support will have resulted in an increase in global pandemic influenza vaccine capacity of at least 500 million doses.

5. In addition, financial and technical support has been provided to enable the establishment of the African vaccine manufacturing initiative. WHO, in collaboration with UNIDO and African vaccine manufacturers, has conducted an assessment of Africa's needs and opportunities for regional vaccine production. As a result of this assessment, a business plan for African vaccine production is being prepared.

[1] http://www.who.int/entity/immunization/global_vaccine_action_plan/gvap_secretariat_report_2014.pdf?ua=1 (accessed on 10 March 2016).

[2] http://www.who.int/csr/research-and-development/en/ (accessed on 10 March 2016).

6. In the regions, WHO, with partners, is implementing solutions to ensure technology transfer in the area of vaccines. These include the solutions described below.

– In the African Region, the Meningitis Vaccine Project – a partnership between WHO and PATH – joined forces with the Serum Institute of India and public health officials across Africa to develop an affordable, tailor-made vaccine for use against meningitis A in sub-Saharan Africa. A vaccine was developed in record time, at less than one tenth of the cost of a typical new vaccine.

– In the South-East Asia Region, WHO has been coordinating applications for the transfer of technology to Indian manufacturers for the production of an inactivated poliovirus vaccine from Sabin poliovirus seed strains.

– In the Eastern Mediterranean Region, WHO is supporting the transfer of technology for the influenza vaccine and inactivated poliovirus vaccine to Egypt and the Islamic Republic of Iran.

Other examples of successful technology transfer by partner agencies include the development of rotavirus and oral cholera vaccines in India and initiatives to develop a novel pneumococcal vaccine and a candidate rotavirus vaccine in Indonesia.

3. PREQUALIFICATION PROCESS

7. WHO prequalification provides assurance of the quality, safety and efficacy of vaccines for international procurement. Driven by the stringent quality requirements of donors and procurers, WHO prequalification offers manufacturers a well-established and robust means of accessing markets for products that meet internationally accepted quality norms and standards.

8. WHO has recently revised the prequalification process to reduce target time frames for prequalification once an application has been submitted. Accordingly, it has published a revised collaborative procedure for the registration of prequalified pharmaceutical products and vaccines, which was implemented on a pilot basis for the registration of inactivated poliovirus vaccines as part of the polio endgame strategy. In addition, WHO initiated a rotational fellowship programme to provide support to developing countries in building their regulatory capacity for vaccines.

9. Furthermore, in 2015, WHO published the emergency use assessment and listing procedure for candidate vaccines for use in the context of a public health emergency.

4. NATIONAL REGULATORY AUTHORITIES AND IN-COUNTRY REGISTRATION PROCEDURES

10. WHO has been providing direct support to Member States with the objective of ensuring the functionality of national regulatory authorities. The support is targeted at different groups of countries, taking into account the risk of having non-functional national regulatory authorities in countries producing vaccines and the potential significant impact on the global supply of vaccines. WHO has also been providing support to Member States to strengthen capacity for vaccine regulation through the in-country assessment of national regulatory authorities, the development of plans to strengthen those authorities and the monitoring of progress towards the full functionality of those authorities in vaccine-producing countries.

11. WHO has launched a project to estimate the costs of vaccine regulation for national medical authorities in target countries, identify appropriate fee systems in the regulation of vaccines and improve the financial sustainability of national medical authorities.

12. In the regions, WHO, with its partners, has been conducting activities focusing on specific vaccines or networks, as described below.

- The Dengue Vaccine Initiative's work includes providing technical assistance and training to national regulatory authorities (with the support of WHO) in dengue-endemic countries that have expressed interest in evaluating and licensing the candidate dengue vaccines, and carrying out an assessment of the policy environment and country readiness for the accelerated introduction of dengue vaccines in endemic countries.

- The African Vaccine Regulatory Forum, a regional network of regulators and ethicists, aims to strengthen in-country capacity for the regulation of clinical trials, including ethical approval. Its work focuses on the development of procedures and protocols for the review of clinical trial applications and evaluation. Such procedures are aligned and adopted in all countries of the network. It also focuses on organizing joint reviews of clinical trial applications and on reviewing marketing authorization applications.

- The Developing Country Vaccine Regulators' Network is a global network of regulatory agencies from middle-income countries with fairly advanced capacity. The agencies in the network discuss concerns and the difficulties faced with regard to the evaluation of marketing authorization applications for novel vaccines, such as the dengue vaccine.

5. PROCUREMENT

13. The regional offices for the Americas, Europe and the Eastern Mediterranean have been providing support to countries on demand-consolidation activities such as demand planning and forecasting, on the harmonization of product requirements across countries and on the improvement of procurement legislation. WHO is working with the UNICEF Supply Division on the procurement of vaccines for middle-income countries.

14. As a result of efforts by the Regional Office for the Eastern Mediterranean, a number of middle-income countries have increased the procurement of routine vaccines through UNICEF. Nevertheless, because of the lack of interest from Member States, a central procurement system has not been established. The Regional Office for Europe has been working to promote the sharing of experiences on pooled procurement (for example, in the three Baltic States). Furthermore, in cooperation with the South-eastern Europe Health Network, it plans to document, in 2016, vaccine-supply challenges in upper-middle-income countries and to provide evidence-based recommendations regarding areas of action, including a review of the potential for setting up a joint procurement mechanism for the member countries of the Network. ASEAN, under the guidance of the National Vaccine Institute in Bangkok, together with the Regional Office for South-East Asia and the Regional Office for the Western Pacific, has organized two workshops on opportunities for vaccine security, an issue that is in the process of being included in the ASEAN post-2015 health development agenda. In 2015, the Revolving Fund of the Pan American Health Organization procured, on behalf of 42 countries and territories, 53 different biological products and 21 injection devices worth US$ 545 million from 31 different manufacturers.

6. PRICE TRANSPARENCY

15. In the European Region, WHO organized a subregional workshop inviting experts in the areas of vaccine management, financing and procurement from 11 Member States to share their experience and knowledge on how to access and use vaccine price and market information to improve vaccine introduction and procurement decisions.

16. WHO's vaccine product, price and procurement web platform provides an online and publicly accessible database of vaccine price information. Forty countries are currently sharing price information through the platform. The database contains 1600 vaccine price records on almost 50 different vaccine types, making it the largest international vaccine price database. More than 4000 users accessed the website in 2015, from all over the world. However, 70 Member States, over half of which are middle-income countries, have not yet shared information on vaccine prices.

7. VACCINE SHORTAGES

17. In response to concerns raised by Member States and by the Strategic Advisory Group of Experts on immunization with regard to global vaccine shortages, including shortages of traditional vaccines, WHO is facilitating an information session on pre-empting and responding to vaccine supply shortages, to be held at the April 2016 meeting of the Strategic Advisory Group of Experts on immunization.

18. In many countries, WHO has provided specific technical support to identify the determinants of vaccine shortages. For example, the Regional Office for the Western Pacific has organized meetings with the Philippines Department of Health and Department of Finance and UNICEF to analyse chronic vaccine stock outs.

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