

Global vaccine action plan

Report by the Director-General

1. In January 2018, the Executive Board at its 142nd session noted an earlier version of this report.¹
2. In May 2012, the Sixty-fifth World Health Assembly adopted resolution WHA65.17, in which it endorsed the global vaccine action plan² and requested the Director-General, *inter alia*, “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. In May 2013, the Sixty-sixth World Health Assembly considered and noted the report by the Secretariat,³ including the proposed framework for monitoring, 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.
4. In May 2017, the Seventieth World Health Assembly adopted resolution WHA70.14, in which it urged Member States and requested the Director-General to take appropriate actions to strengthen immunization systems to achieve the goals of the global vaccine action plan.
5. In accordance with the monitoring, evaluation and accountability process,⁴ 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 2016.⁵ It prepared

¹ See document EB142/35 and the summary records of the Executive Board at its 142nd session, thirteenth meeting, section 3.

² WHO. Global vaccine action plan 2011-2020. Geneva: World Health Organization; 2013 (http://www.who.int/entity/immunization/global_vaccine_action_plan/GVAP_doc_2011_2020/en/index.html, accessed 13 March 2018).

³ See documents A66/19 and WHA66/2013/REC/3, summary records of the Sixty-sixth World Health Assembly, Committee A, tenth meeting, section 2.

⁴ Document A66/19, paragraphs 16 and 17.

⁵ Global Vaccine Action Plan Monitoring, Evaluation & Accountability: Secretariat Annual Report 2017 (http://www.who.int/immunization/global_vaccine_action_plan/previous_secretariat_reports_immunization_scorecards/en/ (accessed 13 March 2018)).

the 2017 assessment report of the global vaccine action plan,¹ a summary of which and the recommendations of the Strategic Advisory Group of Experts for action by the various stakeholders of the global vaccine action plan, in particular by Member States, are contained in Annex 1. The actions taken by WHO and other partner agencies in response to the requests in resolution WHA70.14 are summarized in Annex 2.

ACTION BY THE HEALTH ASSEMBLY

6. The Health Assembly is invited to take note of the report.

¹ Strategic Advisory Group of Experts on immunization. 2017 Assessment Report of the Global Vaccine Action Plan. Geneva: World Health Organization; 2017 (http://www.who.int/immunization/web_2017_sage_gvap_assessment_report_en.pdf?ua=1, (accessed 13 March 2018)).

ANNEX 1

EXECUTIVE SUMMARY OF THE 2017 ASSESSMENT REPORT OF THE GLOBAL VACCINE ACTION PLAN AND RECOMMENDATIONS BY THE STRATEGIC ADVISORY GROUP OF EXPERTS ON IMMUNIZATION¹

1. In 2016, some progress was made towards the goals set out in the Global Vaccine Action Plan. The year saw the fewest number of cases of [poliomyelitis due to] wild poliovirus ever reported, and three more countries were certified as having achieved maternal and neonatal tetanus elimination. Nine additional countries have introduced new vaccines. Overall DTP3 vaccination coverage increased, but by only 1% to 86%. Progress therefore still remains too slow for most goals to be reached by the end of the Decade of Vaccines in 2020.
2. Furthermore, multiple global, regional and national issues threaten further progress, and have the potential to reverse hard-won gains. Economic uncertainty, conflicts and natural disasters, displacement and migration, and infectious disease outbreaks all pose major challenges to immunization programmes. At the same time, there are concerning signs of complacency and inadequate political commitment to immunization – as well as a global lack of appreciation of its power to achieve wider health and development objectives.
3. Additional risks include growing levels of vaccine hesitancy and the worrying rise in stock outs disrupting access to vaccines – related primarily to shortcomings in vaccine procurement and distribution but also to some extent to vaccine production. The continued marked underperformance of certain countries relative to others within their region – “outlier” countries – remains of grave concern.
4. The potential impact of the phase-out of funding for polio eradication is also of concern. It is vital that the polio transition remains sufficiently flexible that it does not jeopardize ongoing outbreak control efforts or critical surveillance activities and post-eradication certification processes. Furthermore, there is a significant risk that wider surveillance activities and routine immunization programmes, and hence global health security, could be compromised during the polio transition. The potentially simultaneous phasing out of polio and funding from The GAVI Alliance and technical support is of further concern.
5. These risks threaten to slow the extension of vaccines to neglected populations and heighten global inequalities in vaccine access. As the Decade of Vaccines draws to a close, there is a need to intensify global efforts to promote immunization and to address the systemic weaknesses that are limiting equitable access to life-saving and life-changing vaccines, particularly in outlier countries and middle-income countries.
6. The recommendations made in the Strategic Advisory Group of Experts on immunization (SAGE) 2016 Assessment Report informed the development of World Health Assembly resolution WHA70.14, approved in May 2017, and remain a high priority.

¹ The text of paragraphs 1–8 and the recommendations in brief is taken from Strategic Advisory Group of Experts on immunization. 2017 Assessment report of the global vaccine action plan. Geneva: World Health Organization; 2017 (http://www.who.int/entity/immunization/web_2017_sage_gvap_assessment_report_en.pdf?ua=1, accessed 13 March 2018).

7. In light of the risks highlighted, SAGE also calls for a broadening of the dialogue, to align immunization with emerging global health and development agendas, including the sustainable development goals, global health security and International Health Regulations (2005), health systems strengthening and universal health coverage, universal health coverage and the battle against antimicrobial resistance. A concerted effort is also required to address outlier countries, through a multidimensional, system-wide approach, recognizing that complex issues require multifaceted solutions and that civil society organizations have important contributions to make.
8. Through these and other measures, progress can continue to be made towards GVAP goals and the ground laid to exploit the full potential of immunization post-2020.

RECOMMENDATIONS IN BRIEF¹

9. The Strategic Advisory Group of Experts on immunization recommends:
- (a) **Broadening the dialogue:** The immunization community should ensure that immunization is fully aligned and integrated with global health and development agendas, including global health security and International Health Regulations (2005), health systems strengthening and universal health coverage, and the battle against antimicrobial resistance;
 - (b) **Funding transitions:** Until polio eradication is achieved, financial and technical support should be maintained in at least the 16 polio priority countries to ensure the success of eradication efforts and to mitigate the risks to infectious disease surveillance, routine immunization and global health security more generally;
 - (c) **Polio and communicable disease surveillance:** Countries in all regions should ensure they maintain effective poliovirus surveillance capacities through the polio endgame and beyond, and build on the polio surveillance platform to strengthen communicable disease surveillance systems, especially for measles and rubella, and other vaccine-preventable diseases;
 - (d) **Outlier countries:** WHO regional offices should work with countries experiencing the greatest difficulties in achieving global vaccine action plan goals to develop and implement multidimensional remediation plans, integrating existing national improvement plans;
 - (e) **Maternal and neonatal tetanus:** The immunization community should make concerted efforts to achieve elimination by 2020, in particular by exploiting compact pre-filled auto-disable devices to extend the reach of immunization;
 - (f) **Displaced, mobile and neglected populations:** WHO should synthesize existing knowledge on reaching displaced and mobile populations – including individuals escaping conflict zones or natural disasters, economic migrants, seasonal migrants, those moving to urban centres, and traditional nomadic communities – and other neglected populations to identify good practice and gaps in knowledge;

¹ For more detailed versions of these recommendations, see page 27 of Strategic Advisory Group of Experts on immunization. 2017 Assessment report of the global vaccine action plan. Geneva: World Health Organization; 2017 (http://www.who.int/immunization/web_2017_sage_gvap_assessment_report_en.pdf?ua=1, accessed 13 March 2018).

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- (g) **Acceptance and demand:** Each country should develop a strategy to increase acceptance and demand for vaccination, which should include ongoing community engagement and trust-building, active hesitancy prevention, regular national assessment of vaccine concerns, and crisis response planning;
- (h) **Civil society organizations:** Countries should broaden and deepen their engagement with civil society organizations to enhance the performance and reach of their national immunization programmes;
- (i) **Technical capacity-building:** WHO regional offices should work with regional and global partners to support national technical capacity-building, adopting a multidimensional approach and leveraging regional and national institutional capacities and expertise as well as global tools and resources;
- (j) **Vaccine access:** WHO regional offices and UNICEF should work with countries to identify and systematically address procurement and other programmatic issues affecting vaccine access;
- (k) **Vaccine supply:** UNICEF, WHO and global partners should continue and expand efforts to map current and anticipated vaccine supply and demand for routinely used vaccines, with a particular focus on vaccines most at risk of supply shortages;
- (l) **Middle-income countries:** WHO regional offices should support middle-income countries in their regions by leveraging all opportunities to promote the exchange of information, the sharing of lessons learned and peer-to-peer support.

ANNEX 2

A SUMMARY OF WHO'S ACTIVITIES IN RESPONSE TO THE REQUESTS IN RESOLUTION WHA70.14 (2017)

SUPPORT TO MEMBER STATES

1. The Secretariat continues to provide technical support to Member States in achieving the global and regional vaccination goals. The draft thirteenth general programme of work 2019–2023¹ envisages the Secretariat intensifying its support to Member States that host the most vulnerable populations, including those affected by or displaced as a result of conflict.

ACCOUNTABILITY

2. At the global level, the monitoring and accountability framework provides the mechanism for monitoring progress in the implementation of the global vaccine action plan. The annual reports from the plan's secretariat detail progress achieved towards all the goals and strategic objectives of the global vaccine action plan.² The WHO/UNICEF Joint Reporting Form serves as the unified instrument for collecting the coverage, financial and programme data at the national level that are needed for monitoring progress.

3. Each WHO region has developed independent monitoring and accountability mechanisms, using, for instance, the regional technical advisory groups on immunization. The results of the regional assessments are included in each regional director's report to the respective regional committee. More informal mechanisms, including the annual meetings of national immunization programme managers, are used to provide feedback to countries and to support the development and implementation of corrective actions.

ADVOCACY

4. Key global and regional meetings are forums used to reinforce the urgent need to accelerate the pace of progress towards the goals of the global vaccine action plan. These gatherings include meetings of the regional immunization programme managers and regional technical immunization advisory groups, as well as global disease-specific meetings (for example, on control and elimination of measles and rubella, maternal and neonatal tetanus and rotavirus vaccination).

5. The Addis Declaration on Immunization (Addis Ababa, 25 February 2016) was endorsed by Heads of State and Government at the 28th African Union Summit in January 2017. A road map to operationalize the commitments made in the Declaration has been prepared and an investment case is under development. Plans are under way to establish a secretariat to oversee the implementation of the road map.

¹ Document EBSS/4/2.

² For the annual and assessment reports, see http://www.who.int/immunization/global_vaccine_action_plan/previous_secretariat_reports_immunization_scorecards/en/ and http://www.who.int/immunization/global_vaccine_action_plan/sage_assessment_reports/en/ (accessed 13 March 2018).

SUPPORT TO REGIONAL AND NATIONAL IMMUNIZATION TECHNICAL ADVISORY GROUPS

6. The aim of establishing and/or strengthening the regional and national immunization technical advisory groups is to facilitate evidence-informed decision-making for sustained immunization services, using optimized and cost-effective delivery strategies, and to provide independent oversight and advice to regional and national immunization programmes.

7. The Secretariat continues to provide technical support to regional and national immunization technical advisory groups. Acceleration of progress and intensification of efforts are particularly noteworthy in the African and Western Pacific regions. Several country-specific workshops have been held, focusing on strengthening national immunization technical advisory groups (NITAGs) and evidence-based review processes. Plans include the convening of a regional workshop of national immunization technical advisory groups in the Western Pacific Region in the last quarter of 2017.

8. The Global NITAG Network successfully held its second meeting in Berlin in June 2017. The WHO Secretariat has, as of October 2017, taken over the management of that network and the NITAG Resource Center, an interactive web platform that gathers in one place all information related to national immunization technical advisory groups. WHO continues to support financially the attendance of chairpersons or members of those groups at the biannual meetings of the Strategic Advisory Group of Experts on immunization.

COLLABORATION WITH CIVIL SOCIETY ORGANIZATIONS

9. The secretariat of the GAVI Civil Society Constituency contributes to the monitoring and accountability of implementation of the global vaccine action plan and participates in meetings of the Strategic Advisory Group of Experts on immunization Decade of Vaccines Working Group, at which progress towards the goals of the global vaccine action plan is reviewed. It is developing, with the active involvement of a broad range of immunization stakeholders, a framework for engagement of civil society and reporting on attributable contributions to national immunization plans.

VACCINES FOR NEW AND RE-EMERGING DISEASES

10. The research and development blueprint for action to prevent epidemics has produced substantial progress. WHO has updated its list of priority pathogens likely to cause major epidemics. Ebola virus disease vaccines have progressed to the stage of regulatory assessment for licensure. For the Middle East respiratory syndrome coronavirus, WHO has issued a road map for research and development and vaccine target product profiles; one candidate vaccine is currently undergoing clinical evaluation. A target product profile for Zika virus vaccines has been published¹ and numerous vaccine candidates are in early-phase clinical evaluation. Other target product profiles that have been drawn up include those for vaccines against Nipah virus and Lassa fever.

¹ WHO/UNICEF Zika virus (ZIKV) vaccine target product profile (TPP): vaccine to protect against congenital Zika syndrome for use during an emergency; updated February 2017 (http://www.who.int/immunization/research/development/WHO_UNICEF_Zikavac_TPP_Feb2017.pdf?ua=1, accessed 13 March 2018).

11. To foster an enabling environment for research on vaccines, medicines and diagnostics for outbreak response, several tools have been developed, including draft material transfer agreements for sample sharing and an agreement with stakeholders for rapid sharing of data. A global coordination mechanism has been established to map stakeholder activities and priorities and to ensure coordinated research and development activities during outbreaks.

VACCINE PREQUALIFICATION

12. WHO's prequalification of medicines offers manufacturers a well-established and robust means of accessing markets for products that meet internationally accepted quality norms and standards.

13. For cold-chain equipment and vaccine-delivery devices, the Secretariat carried out an external review of the standards development, prequalification and laboratory accreditation processes in 2017 in order to identify potential areas of improvement in the regulatory process for these devices and equipment. The review identified the need to strengthen post-market monitoring of these technologies, and plans are being put in place for a robust post-market monitoring system for immunization equipment.

14. In a further development, phased introduction of operational efficiencies reduced WHO's timelines for vaccine prequalification by half in comparison with the 2010 baseline.

15. Through its highly participatory and collaborative activities, the Secretariat has used these well-established processes to increase the capacity of manufacturers and regulators to implement stringent quality standards. One successful initiative is the WHO rotational fellowship programme on assessment of vaccines prequalification with inspections, in order to provide support to developing countries through building the capacity and expertise of their regulators.

16. During the recent disease outbreaks of yellow fever and of meningitis in the African belt, the supply of vaccine was insufficient to meet the needs for an adequate public health response. Moreover, the rapid introduction of inactivated polio vaccine on the global scale also resulted in a temporary global shortage of vaccine. These examples underscore the urgency of allocating additional resources to ensure oversight of supplies from existing manufacturers, identifying possible future manufacturers, implementing fast-track prequalification processes, and prioritizing the allocation of supplies, while also developing and implementing dose-sparing strategies for use in supply-constrained situations.

17. Additionally, through its work on the regulation of medicines and other health technologies WHO is strengthening its processes for regulatory preparedness to face public health emergencies. Activities include revision of its Emergency Use Assessment and Listing procedure, provision of support to Member States for the review of clinical trials of Ebola virus disease vaccines through the African Vaccine Regulatory Forum, facilitation of collaboration between relevant regulatory agencies and ethics committees, and the development of standards for pharmacovigilance preparedness.

JOINT PROCUREMENT TO INCREASE SUSTAINABILITY OF VACCINE SUPPLY

18. UNICEF is a key partner that provides technical assistance and capacity-building to countries so as to secure both supplies of vaccine for national immunization programmes and an uninterrupted and sustainable supply of quality-assured, affordable vaccines. This work includes providing support to countries in their transition from funding from the GAVI Alliance to financial self-sustainability by strengthening procurement-planning processes. For countries that want to procure vaccines

themselves, support is given for improving their procurement systems, including contracting, strategic procurement and supplier negotiations, access to relevant market data, and awareness of global supply markets and product presentations (for instance, single-dose and multidose vials).

VACCINE SUPPLY AND DELIVERY

19. The Secretariat has concentrated on ensuring that a growing number of countries gains access to the latest solar cold-chain technologies and continuous temperature-monitoring systems for use in the last links of the supply chain in order to improve availability of potent vaccines in the most remote communities.

20. In addition, progress has been made on the thermostability of vaccines, such that additional vaccines are showing promise for licensure for use and administration outside the standard cold-chain but still in a controlled temperature chain.

21. Also, with regard to vaccine administration technologies, progress has been made in the early-phase development of three different formats of microarray patches with measles-containing vaccine. Clinical studies are expected to start in 2018.

PROCUREMENT AND ACCESS TO AFFORDABLE VACCINES

22. WHO has been working with relevant stakeholders (including governments, UNICEF, non-State actors, industry and the GAVI Alliance) on the following initiatives:

(a) to develop policies and programmes to enhance availability and affordability of supply (for example, through the dialogue on fair pricing for medicines and vaccines, WHO's Vaccine Shortage Project, and the Humanitarian Mechanism – recently launched jointly by WHO, UNICEF, Médecins Sans Frontières International and Save the Children – for providing access to pneumococcal conjugate vaccines at around US\$ 3 per dose for use in humanitarian emergencies);

(b) to collect data to inform policy-making and countries' procurement choices (for instance, the Vaccine Price, Product and Procurement initiative, which is currently collecting information from 144 countries, as well as from UNICEF and the Pan American Health Organization (PAHO) Revolving Fund for Vaccine Procurement, and which provides transparent information on vaccine prices for 95% of the world, by birth cohort);

(c) to provide some limited support to countries to strengthen their forecasting and financial planning, procurement and information use for improving timely access to affordable vaccines.

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