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## **Addressing the global shortage of, and access to, medicines and vaccines**

### **Report by the Director-General**

1. In January 2018, the Executive Board, at its 142nd session, noted an earlier version of this report<sup>1</sup> and adopted decision EB142(3) in which it recommended to the Seventy-first World Health Assembly the adoption of a draft decision to request the Director-General to elaborate a road map report, in consultation with Member States, outlining the programming of WHO's work on access to medicines and vaccines, including activities, actions and deliverables for the period 2019–2023; and to submit that road map report to the Seventy-second World Health Assembly for its consideration in 2019, through the Executive Board at its 144th session.

#### **BACKGROUND**

2. In May 2017, the Seventieth World Health Assembly noted the report on addressing the global shortage of, and access to, medicines and vaccines and agreed to include the subject on the agenda of the Board at its 142nd session.<sup>2</sup> The current report is based on a review of: progress reports on related resolutions from across the Organization; reports considered by Health Assemblies and sessions of the regional committees; work on access to medicines and vaccines by other United Nations bodies, including the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines;<sup>3</sup> and work carried out by partners and non-State actors in official relations with WHO. Attention is drawn to the Director-General's report on the overall programme review of the global strategy and plan of action on public health, innovation and intellectual property.<sup>4</sup>

3. This report contains three sections: (i) an executive summary (paragraphs 4–11) of the report on access to medicines and vaccines, focusing on a list of priority options for actions to be considered by Member States; (ii) an update on the progress made in implementing those elements of resolution WHA69.25 (2016) pertaining to the global shortage of medicines and vaccines (paragraphs 12–15); and (iii) a comprehensive report by the Director-General on access to essential medicines and vaccines (Annex), which includes the following appendices: a list of key resolutions of the Health Assembly and regional committees, and regional committee documents from the past 10 years related to access to safe, effective and quality medicines, vaccines and health products

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<sup>1</sup> See document EB142/13 and the summary records of the Executive Board at its 142nd session, sixth meeting.

<sup>2</sup> See document A70/20 and the summary records of the Seventieth World Health Assembly, ninth meeting, section 2.

<sup>3</sup> Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: promoting innovation and access to health technologies. Geneva: United Nations High-Level Panel on Access to Medicines; 2016 (<http://www.unsgaccessmeds.org/final-report>, accessed 19 February 2018).

<sup>4</sup> See document A71/13.

(Appendix 1); a list of documents reviewed for the purposes of preparing this report (Appendix 2); a review of the recommendations of the report of the High-Level Panel on Access to Medicines and WHO's activities in the area of access to medicines (Appendix 3); and a non-exhaustive list of bodies in the United Nations system and related organizations, WHO collaborating centres, partners and non-State actors in official relations with WHO that carry out work on access to medicines (Appendix 4).

## EXECUTIVE SUMMARY

4. Access<sup>1</sup> to safe, effective and quality medicines and vaccines for all is one of the targets of the Sustainable Development Goals.<sup>2</sup> Achieving universal health coverage requires access to safe, effective, quality and affordable essential medicines and vaccines. Access is a global concern in view of the: rising prices of new medicines that place increasing pressure on the ability of all health systems to provide full and affordable access to health care; persisting problems of shortages and stock outs of essential medicines, especially for noncommunicable diseases, and vaccines; and increasing numbers of substandard and falsified medical products that pose an unacceptable risk to public health. In addition, problems such as antimicrobial resistance and opioid misuse highlight the need to improve appropriate use of medicines.

5. WHO plays a fundamental role in ensuring access to safe, effective and quality medicines and vaccines around the world through its strategic and normative work and technical support at the global, regional and national levels. The Organization takes a comprehensive health-systems approach that addresses all stages of the pharmaceutical value chain, including: needs-based research, development and innovation; public health-oriented intellectual property and trade policies; manufacturing processes and systems; pricing policies; integrity and efficiency in procurement and supply chain management; and appropriate selection, prescribing and use. WHO supports good governance and strengthening of regulatory capacity, monitoring systems and workforce capacity, and collaborates with a multitude of stakeholders.

6. Increasing access to medicines and vaccines is a complex issue. Although many activities contribute to improving access to medicines and vaccines, there is a need to prioritize and invest in those where WHO has an advantage compared with other organizations and that provide value for money, are fit for purpose, and lead to achievable and sustainable improvements. The Secretariat has undertaken a comprehensive review of the major challenges to ensuring access to safe, effective and quality medicines and vaccines and analysed progress made to date. On the basis of this review and in accordance with WHO's draft thirteenth general programme of work 2019–2023, the Secretariat has identified the actions listed below that could be prioritized for implementation. All these actions fall under WHO's existing mandate (see Appendix 1 to the Annex) and are all, to a greater or lesser extent, currently being undertaken by the Secretariat. Confirmation of this approach would enable the Secretariat to focus its activities on those actions with the greatest potential impact.

7. The extension and broadening in scope of the following actions is considered by the Secretariat as having the greatest potential impact on access to safe, effective and quality medicines, with the least complexity and requiring the fewest resources to implement.

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<sup>1</sup> <http://www.who.int/medicines/areas/policy/en/> (accessed 22 February 2018).

<sup>2</sup> Target 3.8 of the Sustainable Development Goals: Achieve universal health coverage, including financial risk protection, access to quality essential health care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

- Engender and facilitate the development of political will at the national and regional levels to ensure the affordability and availability of safe, effective and quality medical products through effective regulation and policy implementation, particularly the implementation of pricing and financing policies that encourage fair pricing and domestic investment in universal coverage schemes that reduce out-of-pocket payments.
- Support increased interorganizational, regional and country collaboration, networking and training on specific topics such as: governance; regulation; quality and safety; intellectual property and trade policies, including action through WHO's trilateral collaboration with WIPO and WTO; pricing; procurement; reimbursement; and appropriate use.
- Consolidate and enhance the Secretariat's contribution to product development across different diseases, including effective prioritization of research and development needs through the Global Observatory on Health Research and Development and building on the success of existing research and development models such as the Global Antibiotic Research and Development Partnership.<sup>1</sup>
- Support expansion of the Medicines Patent Pool to include all antimicrobial medicines and patented medicines from the WHO Model List of Essential Medicines.
- Build capacity, in collaboration with other partners, for the implementation of intellectual property laws that are in line with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and that make adequate use of its flexibilities.<sup>1</sup>

8. In addition, the continuation of WHO's normative work to specify standards and guidance for the development, regulation, production, selection, pricing, procurement, distribution, prescription and use of medicines and vaccines is likewise considered as having a high impact on access to safe, effective and quality medicines, with low complexity and requiring resources for implementation that are mostly available.

9. The extension and broadening in scope of the following actions is considered as having a potentially high impact on access to safe, effective and quality medicines, but involves greater complexity and requires additional resources.

- Support the development and implementation of systems at national levels for collecting and monitoring key data on medicines and vaccines, such as availability, price, expenditure, usage, quality and safety, and ensuring use of these data for better evidence-based policy-making.
- Develop policies that promote transparency throughout the value chain, including the public disclosure of clinical trial data, research and development costs, production costs, procurement prices and procedures, and supply chain mark-ups.<sup>2</sup>
- Provide support to Member States to develop collaborative approaches for strategic procurement based on existing models.

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<sup>1</sup> See also document A71/13.

<sup>2</sup> See recommendation 4.3.4. and 4.3.5 in Appendix 3 to the Annex.

- Develop a more systematic approach to providing technical support for improving the skills of the pharmaceutical workforce and monitoring its size, composition, skill sets, training needs and performance.

10. The continuation of WHO's support to ensure that regulatory systems have the capacity to provide access to safe, effective and quality medicines and vaccines in addition to support for the development of international regulatory convergence and harmonization initiatives are considered as having a potentially high impact on access to safe, effective and quality medicines and vaccines, but involve greater complexity and require additional resources. WHO will continue to support the availability of good-quality generic products for procurement by global agencies and countries through its Prequalification of Medicines programme, which will evolve to meet the changing health needs of countries.

11. Lastly, there are numerous actions that have a potentially high impact, but are also highly complex and require significant additional resources. Examples of such actions are shown below.

- Support the development, implementation and monitoring of national medicines policies to reinforce strategies for the appropriate use of medicines.
- Tackling undue influence and corruption in the pharmaceutical system, particularly in procurement and supply chain management.
- Facilitate discussion on unifying principles for biomedical research and development.<sup>1</sup>

## **PROGRESS IN IMPLEMENTING THOSE ELEMENTS OF RESOLUTION WHA69.25 PERTAINING TO THE GLOBAL SHORTAGE OF MEDICINES AND VACCINES**

12. In May 2016, the Sixty-ninth World Health Assembly adopted resolution WHA69.25 addressing, inter alia, the global shortage of medicines and vaccines. In the resolution, the Director-General was requested "to develop an assessment of the magnitude and nature of the problem of shortages of medicines and vaccines", to develop "a global medicine shortage notification system that would include information to better detect and understand the causes of medicines shortages" and "to report on progress on, and outcomes of, the implementation of this resolution to the Seventy-first World Health Assembly".

13. In July 2017, the Secretariat hosted a technical consultation to review existing systems for reporting medicines shortages, including databases of regulatory authorities, as well as those for substandard and falsified medical products and adverse events. This information will be used in the design of a global reporting system for shortages and stock outs. Given that countries will rely on different sources of information to contribute to a global reporting system, regulatory agencies, national procurement authorities, manufacturers and those programmes that procure and deliver medical products were identified among the entities that could contribute. Inclusion criteria, security and interoperability with other reporting systems were also discussed. The global reporting system will be limited to medicines included on the WHO Model List of Essential Medicines.

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<sup>1</sup> See also document A71/13.

14. In advance of a global reporting system, the Secretariat has been assessing the magnitude and nature of the problem of shortages of medicines and vaccines through literature reviews, analysis of existing national notification databases, and interviews with stakeholders. In consultation with partners, the Secretariat is conducting various surveys to gather additional information, especially from countries without a publicly available national reporting mechanism.

15. Regional work on causes of, and solutions to address, shortages has included discussions and a survey conducted in the Eastern Mediterranean Region in 2016, a survey conducted in the Western Pacific Region in 2017 and a vaccines survey conducted in the European Region in 2016.

#### **ACTION BY THE HEALTH ASSEMBLY**

16. The Health Assembly is invited to adopt the decision recommended by the Executive Board in decision EB142(3).

## ANNEX

**ACCESS TO ESSENTIAL MEDICINES AND VACCINES****Report by the Director-General****Overarching issues and context**

1. Access to safe, effective, quality and affordable medicines and vaccines for all is a specific component of target 3.8 of the Sustainable Development Goals.<sup>1</sup> Access to safe, effective and quality medicines has been recognized as a crucial element for solving numerous important public health problems and features in many Health Assembly resolutions covering work across the Organization (see Appendix 1). Achieving universal health coverage requires access to safe, effective, quality and affordable essential medicines and vaccines.

2. Access to medicines and vaccines is of global concern. There is increasing pressure on health systems to provide affordable access to health care, particularly with the introduction of new high-priced medicines and health products. Up to 90% of the population in developing countries purchase medicines through out-of-pocket payments, making medicines the largest family expenditure item after food.<sup>2</sup> With the rise in noncommunicable diseases – many of which are chronic conditions that require long-term treatment – the financial burden for patients and governments will become even greater. Some countries are reporting difficulties in obtaining both traditional and new vaccines in the quantities needed, as well as in accessing sufficient financial resources to meet the increasing costs of paying for vaccines and their delivery.

3. The availability of medicines and vaccines is still poor in some countries, particularly for noncommunicable diseases. Data collected by the Secretariat over the past two years show that less than 10% of facilities in some countries have a complete “basket” of essential medicines for treating noncommunicable diseases.<sup>3</sup> The supply chain system in many countries continues to underperform, leading to stock outs and the inability to deliver quality services. In addition, increasing numbers of substandard and falsified medical products pose an unacceptable risk to public health.

4. The rise of antimicrobial resistance and opioid misuse has highlighted the need for appropriate prescribing and dispensing to ensure appropriate use. The serious lack of new antibiotics under development to combat the growing threat of antimicrobial resistance calls for greater investment in the research and development of innovative medicines.

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<sup>1</sup> Target 3.8 of the Sustainable Development Goals: Achieve universal health coverage, including financial risk protection, access to quality essential health care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

<sup>2</sup> WHO guideline on country pharmaceutical pricing policies. Geneva: World Health Organization; 2015 ([http://apps.who.int/iris/bitstream/10665/153920/1/9789241549035\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/153920/1/9789241549035_eng.pdf?ua=1), accessed 19 February 2018).

<sup>3</sup> Improving access to medicines in the South-East Asia Region: progress, challenges, priorities. New Delhi: World Health Organization Regional Office for South-East Asia; 2017 (<http://apps.who.int/iris/bitstream/10665/258750/1/9789290225904-en.pdf>, accessed 19 February 2018).

5. Access to safe, effective and quality medicines and vaccines requires above all sufficient political will at the national level. It also requires a comprehensive health-systems approach that addresses all stages of the pharmaceutical value chain, including: needs-based research, development and innovation; public health-oriented intellectual property and trade policies; manufacturing processes and systems, including strategic and sustainable local production that ensures quality products; pricing policies and coverage schemes that contribute to the attainment of universal health coverage; integrity and efficiency in procurement and supply chain management; and appropriate selection, prescribing and use. Strong regulatory systems to oversee the quality, safety and efficacy of medicines and vaccines are also required, as well as effective monitoring systems to inform policy. Strong governance is needed to ensure accountability and tackle vulnerabilities to corruption. In addition, a well-trained workforce is needed throughout the system, as well as collaboration with all stakeholders involved.

6. Access to other health technologies,<sup>1</sup> including medical devices and assistive technologies, is also essential for a well-functioning health system and for achieving the health-related Sustainable Development Goals. Health technologies are essential for screening, diagnosis, treatment, rehabilitation and even palliative care, and are often required for appropriate medicine delivery. Many of the barriers to improving access to medicines are similar to those for medical devices. However, the selection process, training for proper use, maintenance (where appropriate) and infrastructure support, and ensuring sustainable access to medical devices are even more complex. Nevertheless, proposals for the way forward for improving access to medicines and vaccines may be relevant and research and support for improving access to other health technologies has to be further developed.

### **Progress in improving access**

7. WHO plays a fundamental role in ensuring access to safe, effective and quality medicines and vaccines around the world through its strategic and normative work and technical support at the global, regional and national levels. The following is a summary of the main challenges related to access and the activities carried out by WHO to address them, based on a review of progress reports and other documents (Appendix 2).

#### **(a) Political will and governance**

8. Political will is essential for securing the resources required for sustainable access to safe, effective and quality medicines and vaccines and is reflected in the development and implementation of national medicines and immunization policies. The high percentage of health spending on medicines (20–60% in low- and middle-income countries) impedes progress for the many countries that have made a commitment to universal health coverage.<sup>2,3</sup> Strong policies must reflect both an increasing need for financial coverage for health services and the need to ensure equitable access to quality care. Robust processes, including transparency and civil society participation, are needed to decide which services to provide, which patients receive health services, how to reduce out-of-pocket

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<sup>1</sup> The term “health technologies” refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives. See resolution WHA60.29 (2007) on health technologies.

<sup>2</sup> Reich MR, Harris J, Ikegami N, Maeda A, Cashin C, Araujo EC, et al. Moving towards universal health coverage: lessons from 11 country studies. *Lancet*. 2016;387:811-16. doi: 10.1016/S0140-6736(15)60002-2.

<sup>3</sup> WHO guideline on country pharmaceutical pricing policies. Geneva: World Health Organization; 2015 ([http://apps.who.int/iris/bitstream/10665/153920/1/9789241549035\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/153920/1/9789241549035_eng.pdf?ua=1), accessed 19 February 2018).

payments and how to fund health care. Strong governance not only ensures efficient use of funds, but also improves trust in the health care system and contributes to the proper use of quality medicines and vaccines.

9. Weak governance leaves the pharmaceutical system vulnerable to ineffective management, undue influence, corruption, waste, fraud and abuse. Corruption is estimated to lead to losses of up to 6% of the annual global health expenditure, or US\$ 300 billion.<sup>1</sup> In addition, weak governance in the pharmaceutical system continues to be an issue for countries due to a lack of transparency and accountability, unclear roles and responsibilities, and a lack of oversight. Experience in some countries with decentralized health systems showed five or more years of prolonged confusion over roles and responsibilities within their immunization programmes, with inadequate accountability mechanisms and oversight to control how resources were spent and prioritized, making it impossible to achieve improvements in immunization coverage.<sup>2</sup> A question of growing importance is how to manage interactions between governments and the private sector to avoid risks of undue influence. In recent years, there has been an increase in the number and scope of access initiatives being carried out by pharmaceutical companies and there is a need to ensure that public health interests remain at the centre of such initiatives.

10. The Secretariat has supported the development of strong policies, as outlined in the following sections of this report. More work is required to update policy guidance and support countries to develop and implement national policies that reflect the need to improve access to medicines and vaccines as essential to achieving universal health coverage.

11. In October 2017, WHO published a policy brief on responding to industry initiatives to increase access to medicines and other health technologies in order to support Member States in this respect.<sup>3</sup> The Secretariat has field-tested a revised version of the pharmaceutical system transparency and accountability assessment tool.<sup>4</sup>

12. WHO plays a leadership role in the improvement of transparency with regard to immunization and vaccine safety through the establishment of National Immunization Technical Advisory Groups,<sup>5</sup> which provide independent, evidence-informed advice to health authorities on policy issues related to immunization and vaccines. Regional and country collaboration platforms have been established in all WHO regions to share experiences, document evidence and develop a policy dialogue on how countries can use national medicines policies to improve access to essential medicines.

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