

Access to medicines and vaccines

Report by the Director-General

1. The Executive Board, at its 144th session in January 2019, noted an earlier version of this report.¹ The draft road map has been revised and a new Appendix 2 has been added to indicate the linkage between the Thirteenth General Programme of Work, 2019-2023 and the activities, actions, deliverables and milestones set out in the road map. The milestones have been updated to reflect the global goods planning process, and information has been added on the Organization's mandate with regard to the actions required by the road map and on the distribution of road map activities across the programme budget. The revised draft also reflects issues raised by the Executive Board relating to providing health products for primary health care, monitoring access, optimizing the use of biosimilars, addressing the challenges faced by small island States, and supporting countries transitioning from donor funding.²

2. In May 2018, the Seventy-first World Health Assembly considered a report by the Director-General on addressing the global shortage of, and access to, medicines and vaccines.³ The report focused on a list of priority options for actions to be considered by Member States and presented a comprehensive report by the Director-General on access to essential medicines and vaccines.

3. Having considered the report, the Health Assembly adopted decision WHA71(8), in which it decided 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 for the period 2019–2023, including activities, actions and deliverables. The Health Assembly also requested the Director-General to submit the road map report to the Seventy-second World Health Assembly, through the Executive Board at its 144th session.

4. In July 2018, the Secretariat initiated a process to consult Member States and an online consultation with Member States on the zero draft road map was conducted in the period July–September 2018, during which 62 countries provided feedback. In addition, a consultation with Member States on the zero draft was conducted on 10 and 11 September 2018 in Geneva, preceded by an informal discussion with representatives of the United Nations and other international organizations and non-State actors in official relations with WHO. The draft report was updated based on the feedback obtained by these consultation processes, including broadening of the scope to include medicines, vaccines and health products.

¹ See document EB144/17 and summary record of the Executive Board at its 144th session, ninth and tenth meeting.

² See the summary records of the Executive Board at its 144th session, tenth meeting.

³ Document A71/12.

5. The revised draft road map for access to medicines, vaccines and other health products, 2019–2023, based on existing WHO mandates in key Health Assembly resolutions of the last 10 years related to access to safe, effective and quality medicines, vaccines and health products, and also reflecting the Thirteenth General Programme of Work, 2019–2023, is contained in the Annex.¹

ACTION BY THE HEALTH ASSEMBLY

6. The Health Assembly is invited to note the draft road map for access to medicines, vaccines and other health products, 2019–2023, as contained in the Annex.

¹ In line with resolution WHA69.19 (2016) on the global strategy on human resources for health: workforce 2030, a health workforce impact assessment was carried out for the draft road map for access to medicines, vaccines and other health products, 2019–2023 (see https://www.who.int/hrh/documents/WHA72_HRHlinks_160119-EMP.pdf, accessed 21 March 2019).

ANNEX

DRAFT ROAD MAP FOR ACCESS TO MEDICINES, VACCINES AND OTHER HEALTH PRODUCTS, 2019–2023

Comprehensive support for access to medicines, vaccines and other health products

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I. Introduction and rationale

1. Equitable access to health products is a global priority, and the availability, accessibility, acceptability, and affordability of health products of assured quality need to be addressed in order to achieve the Sustainable Development Goals, in particular target 3.8.¹ Every disease management strategy requires access to health products for prevention, diagnosis, treatment, palliative care and rehabilitation.

2. Access is a global concern, given the high prices of new pharmaceuticals and rapidly changing markets for health products that place increasing pressure on all health systems' ability to provide full and affordable access to quality health care. The high percentage of health spending on medicines (20–60% as demonstrated in a series of studies in selected low- and middle-income countries) impedes progress for the many countries that have committed to the attainment of universal health coverage.² Furthermore, it is known that a large proportion of the population in low-income countries who spend for health do pay out-of-pocket for medicines. With the rise in noncommunicable diseases – many of which are chronic conditions that require long-term treatment – the financial burden on both governments and patients will become even greater.

3. Improving access to health products is a multidimensional challenge that requires comprehensive national policies and strategies. These should align public health needs with economic and social development objectives and promote collaboration with other sectors, partners and stakeholders; they also need to be aligned with legal and regulatory frameworks and cover the entire product life cycle, from research and development to quality assurance, supply chain management and use.

4. Primary health care services rely on access to health products, including medicines, vaccines, medical devices, diagnostics, protective equipment and assistive devices. These products must be of assured safety, efficacy, performance and quality, as well as being appropriate, available and affordable. Ensuring that appropriate health products are available and affordable for primary care depends on policy decisions and processes related to the selection, pricing, procurement, supply chain management, maintenance (in the case of medical devices), prescribing and dispensing (in the case of medicines) and use of health products.

5. WHO's comprehensive health systems approach to increasing access to health products is guided by a series of Health Assembly and Regional Committee resolutions. These resolutions, nearly 100 in number (see Annex, Appendix 1) formed the basis for the previous report by the Director-General on this topic.³ The present document responds to the Health Assembly's subsequent request for WHO to develop a road map describing its activities, actions and deliverables for improving access to medicines and vaccines, for the period 2019–2023.

¹ 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.

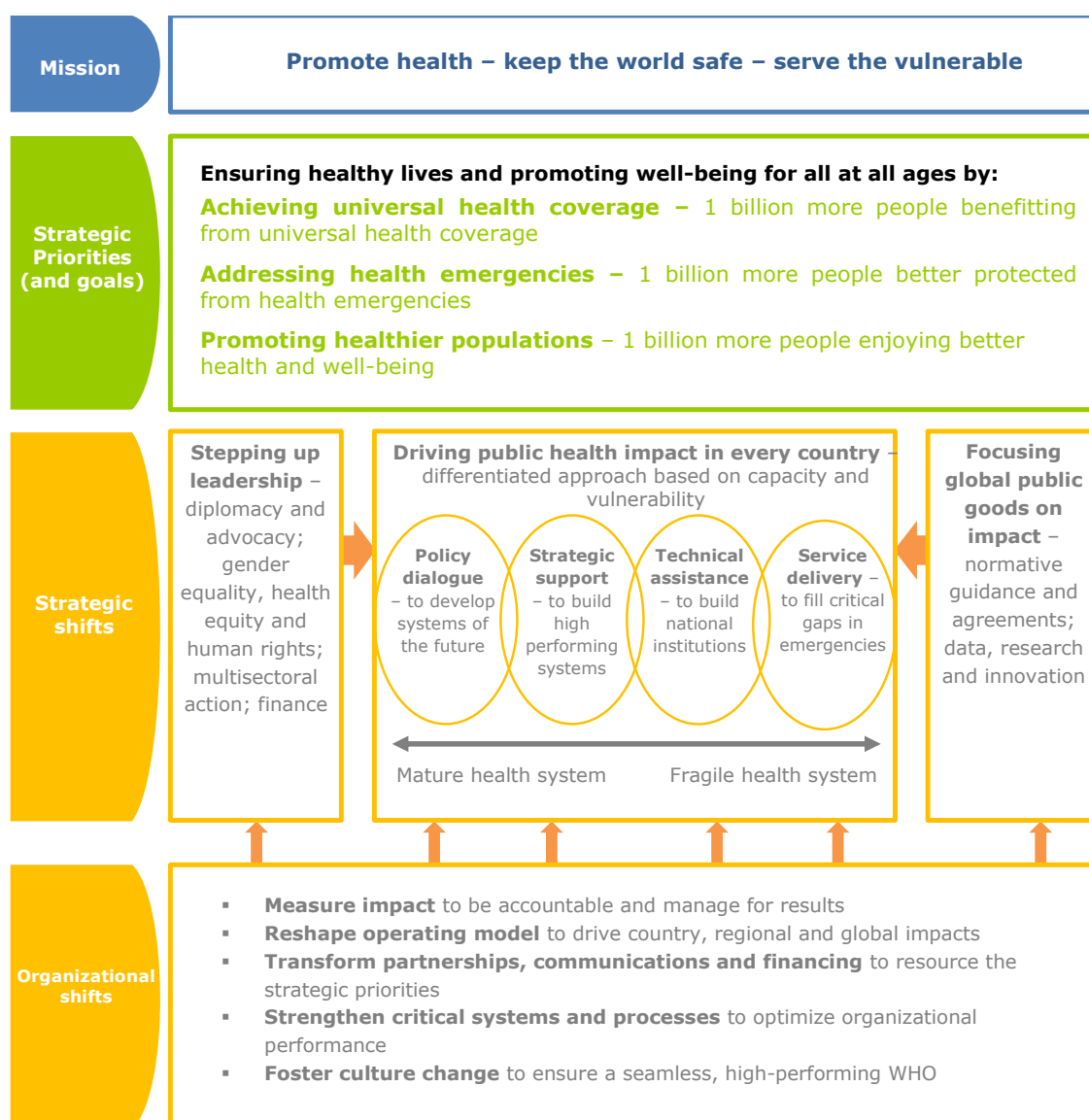
² Reich MR, Harris J, Ikegami N, Maeda A, Cashin C, Araujo EC, et al. Moving towards universal health coverage: lessons from 11 country studies. *The Lancet*. 2016; 387:811–16 ([https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(15\)60002-2.pdf](https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(15)60002-2.pdf)).

³ Document A71/12.

II. Thirteenth General Programme of Work, 2019–2023

6. The Thirteenth General Programme of Work, 2019–2023¹ sets out three strategic priorities for ensuring healthy lives and well-being for all at all ages: achieving universal health coverage, addressing health emergencies and promoting healthier populations. These strategic priorities are supported by three strategic shifts: stepping up leadership; driving public health impact in every country; and focusing global public goods on impact (see Fig. 1).

Fig. 1. Overview of WHO's Thirteenth General Programme of Work, 2019–2023: strategic priorities and shifts²



¹ Document A71/4.

² Previously issued in document A71/4.

7. The planning framework for the Thirteenth General Programme of Work provides a structure for identifying priorities at the country level and for the planning and budgeting of the work of WHO. It will ensure that the programme budget reflects the needs of the countries and that work at all three levels of the Organization is geared towards delivering country impact. This road map for access to medicines, vaccines and other health products, 2019–2023, aligns with the following outputs that have been identified within this framework:

- provision of authoritative guidance and standards on the quality, safety and efficacy of health products, including through prequalification services, essential medicines and diagnostics lists;
- access to essential medicines, vaccines, diagnostics and devices for primary health care improved;
- country and regional regulatory capacity strengthened and supply of quality-assured and safe health products improved;
- research and development agenda defined and research coordinated in line with public health priorities;
- countries enabled to address antimicrobial resistance through strengthened surveillance systems, laboratory capacity, infection prevention and control, awareness-raising and evidence-based policies and practices.

III. How the road map was developed

8. The previous report (document A71/12) proposed priority actions based on the comparative advantage of WHO, whether the action provides value for money and if the actions lead to achievable and sustainable improvements. These prioritized actions form the basis for the activities, actions and deliverables outlined in the zero draft road map. It was developed based on input from all levels of the Organization, taking into consideration existing governing body documents, the Programme budget 2018–2019 and relevant departmental and Regional Office strategies.

9. The road map builds on the numerous regional and national initiatives and commitments undertaken to improve access to safe, effective and quality medicines, vaccines and health products, several of which, including the Delhi Declaration on improving access to essential medical products in the South-East Asia Region, have been cited in the report by the Director-General on addressing the global shortage of, and access to, medicines and vaccines.¹

10. This revised road map takes into consideration the feedback received through the drafting and consultative processes described in paragraph 4 above of the report by the Director-General. All written contributions from the survey and other written submissions are available on http://www.who.int/medicines/access_use/road-map-medicines-vaccines/en/.

¹ Document A71/12.

IV. Structure of the road map

11. The road map outlines the principles of WHO's work on access to health products, including essential health system components. It is structured around two interlinked strategic areas that are necessary to support access to health products:

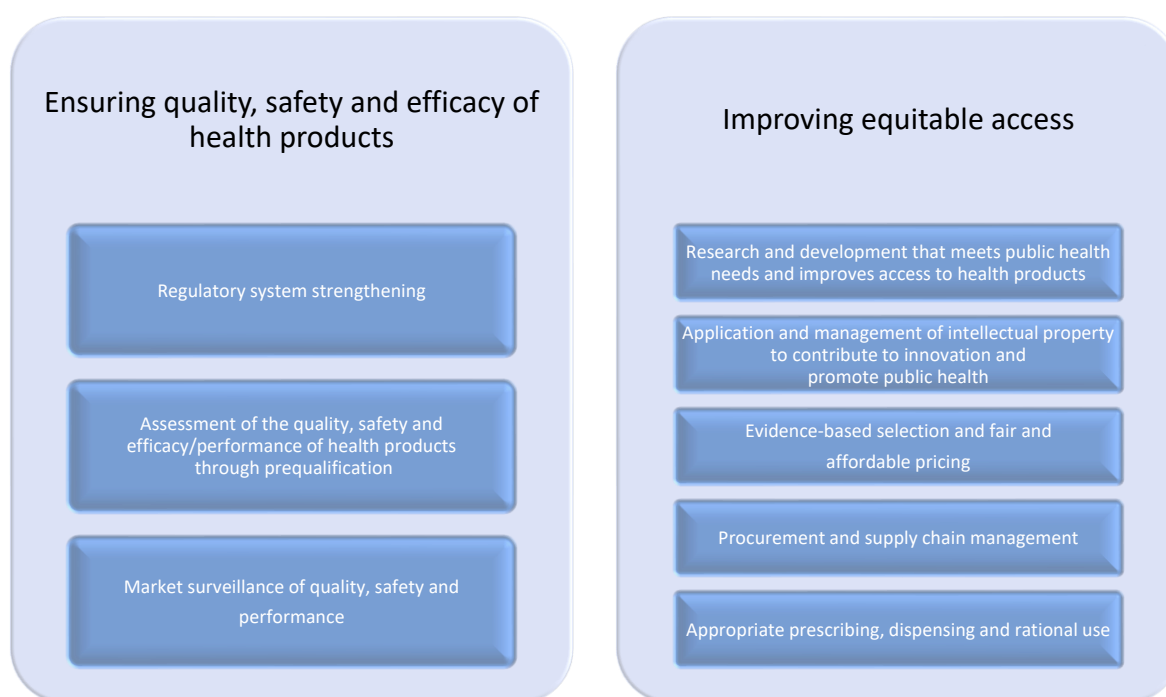
- ensuring the quality, safety and efficacy of health products;
- improving equitable access to health products.

Under each strategic area, the road map describes activities and puts forward the specific actions and deliverables for the period 2019–2023.

12. Fig. 2 shows the activities included under each strategic area; the activities are listed in sequential order of the product life cycle.

13. Appendix 2 indicates the linkage between the 13th General Programme of Work and the activities, actions, deliverables and short-, medium- and long-term milestones.

Fig. 2. Activities within the two strategic areas



V. A health systems approach to improving access to health products

14. The six components of a well-functioning health system outlined in the WHO document “Key components of a well-functioning health system”¹ include: Leadership and governance, health information systems, health financing, human resources, essential medical products and technologies,

¹ http://www.who.int/healthsystems/publications/hss_key/en/ (accessed 11 November 2018).

and service delivery. Ensuring access to health products depends on all of these, in particular governance, health information, financing and human resources. There is no one-size-fits-all approach to ensuring a functional health system and tailored strategies are required to adapt them to the local context.

15. Four key health system components of improving access to health products are detailed below; specific actions to address them are included in relevant activities under the two strategic areas of the road map provided in Sections VI and VII.

Financing of health products

16. Inadequate financing of health products, high prices of new health products and ineffective policy interventions and processes to manage expenditure, such as the ineffective use of policies for generic and biosimilar medicines, contribute to the challenges facing the health system in achieving universal health care. Evidence indicates that up to one fifth of health spending could be channelled towards better use by avoiding waste that occurs (a) when health products are priced higher than is necessary, (b) when less expensive but equally effective alternatives are not used and (c) when purchased products are not used at all.

17. Countries that are transitioning away from receipt of donor funding, such as from the GAVI Alliance and the Global Fund to Fight AIDS, Tuberculosis and Malaria, need particular support to strengthen their health systems, allocate resources more effectively and sustain financing.

18. Activities in this road map support countries' ability to allocate resources more effectively through evidence-based decisions to ensure that cost-effective health products are included in a country's essential medicines list, essential diagnostics lists or reimbursement lists and through more efficient procurement and supply processes and rational use of medicines. Support for fair pricing¹ and policy implementation to reduce out-of-pocket expenditures will also be provided.

Governance of health products

19. The need for good governance is increasingly recognized as a major hurdle on the road to achieving universal health coverage. Weak governance complicates access to health products by fuelling inefficiencies, distorting competition and leaving the system vulnerable to undue influence, corruption, waste, fraud and abuse. Given the large role of health products in the provision of health care and the proportion of health spending they represent (as high as 60% for medicines in some countries),² improving governance will help prevent the waste of public resources needed to sustain health systems

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