World Health Organization
REGIONAL OFFICE FOR Europe

Regional Committee for Europe
68th session

Rome, Italy, 17–20 September 2018

Provisional agenda item 3

EUR/RC68/Inf.Doc./8

16 August 2018
180568

ORIGINAL: ENGLISH

Development of the road map on access to medicines and vaccines

In decision WHA71(8), the World Health Assembly requested 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. The present document, containing an outline of the draft road map being prepared by the WHO Secretariat, is submitted for the consideration of the WHO Regional Committee for Europe at its 68th session. A revised draft of the road map, following consultations, will be prepared for consideration by the Executive Board at its 144th session in January 2019.

WORLD HEALTH ORGANIZATION REGIONAL OFFICE FOR EUROPE
UN City, Marmorvej 51, DK-2100 Copenhagen Ø, Denmark Telephone: +45 45 33 70 00 Fax: +45 45 33 70 01
Email: eugovernance@who.int Web: http://www.euro.who.int/en/who-we-are/governance

World Health Organization

INFORMATION DOCUMENT

HQ/MVP
13 June 2018

Development of the road map on access to medicines and vaccines

BACKGROUND

1. Access to safe, effective and quality medicines and vaccines for all is one of the targets of the Sustainable Development Goals. 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.

2. 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.

3. 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.[1] 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. The Health Assembly then adopted decision WHA71(8), in which it decided to request the Director-General to elaborate a road map, 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 to the Seventy-second World Health Assembly, through the Executive Board at its 144th session.

[1] Document A71/12.

Road map on access to medicines and vaccines

4. In response, the Secretariat is preparing a draft road map on access to medicines and vaccines, with consultations scheduled to begin in July. Based on the priority options for actions presented in the report submitted to the Health Assembly in May 2018, the draft road map outlines the actions and deliverables for the 10 strategic activities set out below.

(i) **Ensuring that research and development for medicines and vaccines meets public health needs.** Actions will be focused on priority setting and coordination.

(ii) **Implementing fair pricing and financing policies for medicines and vaccines.** Actions will be focused on: improving selection and health technology assessment processes and implementing them in countries; improving policies and actions to ensure fairer pricing; and reducing out-of-pocket payments.

(iii) **Applying and managing intellectual property to contribute to innovation and promote public health.** Actions will be focused on building 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 full use of its flexibilities.

(iv) **Improve procurement and supply chain management.** Actions will be focused on supporting strategic procurement approaches, strengthening institutional capacity for procurement and supply chain management and improving capacity for detecting, preventing and responding to shortages.

(v) **Appropriate prescribing, dispensing and use of medicines.** Actions will be focused on improving prescribing and use, and in particular on improving prescribing and use of antibiotics to mitigate risks and impact of antimicrobial resistance and on ensuring that controlled medicines with therapeutic use are accessible, while preventing their divergence and misuse.

(vi) **Strengthening regulatory systems to ensure quality, safety and efficacy of medicines and vaccines.** Actions will be focused on supporting improvement of regulatory systems, promoting reliance between regulatory authorities at regional and subregional levels, as appropriate, and collaboration and maintaining and expanding the prequalification service.

(vii) **Preparedness for emergencies.** Actions will be focused on improving regulatory preparedness for a public health emergency and ensuring adequate supply and appropriate use.

(viii) **Improving good governance.** Actions will be focused on increasing the public availability of timely, robust and relevant pharmaceutical and health product information; reducing undue influence and corrupt practice in pharmaceutical systems; and supporting policy dialogue and policy coherence, particularly with regard to local production.

(ix) **Collecting, monitoring and using key data on medicines and vaccines.** Actions will be focused on supporting regular monitoring of access to medicines and vaccines in countries and improving global monitoring.

(x) **Improving pharmaceutical workforce.** Actions will be focused on improving capacity of the pharmaceutical workforce and monitoring and evaluating development policies.

Next steps

5. Following consultations, a revised draft of the road map will be prepared for consideration by the Executive Board at its 144th session in January 2019.

= = =