Report of the Director General: Roadmap for access to medicines, vaccines and other health products

Information Session
4 December 2018, Geneva
Background

Report by the Director-General on addressing the global shortage of, and access to, medicines and vaccines. 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 Document A71/12.

WHA 71 (8) Decision

1) elaborate a roadmap 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

(2) submit this roadmap report to the Seventy-second World Health Assembly for its consideration in 2019, through the Executive Board at its 144th session.
# Participation and Consultative Process

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>DATE</th>
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<tr>
<td>Member States Online Consultation, including good practices examples</td>
<td>9 July- 14 September 2018</td>
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<td><strong>62 countries provided feedback</strong></td>
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<td><strong>12 Good practices examples were received</strong></td>
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<td>Member States Consultation – Geneva (HQ)</td>
<td>10-11 September 2018</td>
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<td>Informal Discussion with Stakeholders</td>
<td>10 September 2018</td>
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<td>(Non-State Actors in official relations with WHO and UN and related organizations)</td>
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<td><strong>ROADMAP DISCUSSIONS - REGIONAL COMMITTEES</strong></td>
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<td>AFRO (Dakar, Senegal)</td>
<td>27-31 August</td>
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<td>SEARO (New Delhi) (Ministerial Declaration)</td>
<td>3-7 September</td>
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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. The contributions received are available on the Website at: [http://www.who.int/medicines/access_use/road-map-medicines-vaccines/en/](http://www.who.int/medicines/access_use/road-map-medicines-vaccines/en/)
Structure of the road map: Activities within the two strategic areas

Ensuring quality, safety and efficacy of health products
- Regulatory system strengthening
- Assessment of the quality, safety and efficacy/performance of health products through prequalification
- Market surveillance of quality, safety and performance

Improving equitable access
- Research and development that meets public health needs and improves access to health products
- Application and management of intellectual property to contribute to innovation and promote public health
- Evidence-based selection and fair and affordable pricing
- Procurement and supply chain management
- Appropriate prescribing, dispensing and rational use
Strategic area: Ensuring the quality, safety and efficacy of health products

• The activities in this strategic area support countries to deliver regulation that protects the public while enabling timely access to, and innovation of, quality products.

• Activities focus on regulatory system strengthening, assessment of the quality, safety and efficacy of health products through prequalification, and market surveillance of quality, safety and efficacy.
### Activity: Strengthening of regulatory system

**ACTIONS**

| Development and implementation of WHO technical guidelines, norms and standards for quality assurance and safety of health products | Support improvement of regulatory systems, promoting reliance and collaboration | Strengthen preparedness for entry of medicines, vaccines and other health products into countries experiencing a public health emergency (PHE) or crisis |
**Activity:** Assessment of the quality, safety and efficacy/performance of health products through prequalification

**ACTIONS**

Maintain and expand the prequalification service
Activity: Market surveillance of quality, safety and performance efficacy

ACTIONS

Support strengthening national capacity to ensure the quality, safety and efficacy of health products
Strategic area: Improving equitable access to health products

- Activities under this strategic area will support countries to achieve a continuous supply of quality, safe, effective and affordable.

- Activities focus on research and development that meets public health needs; the application and management of intellectual property standards; evidence-based selection and fair and affordable pricing; procurement and supply chain management; and appropriate prescribing, dispensing and rational use.
**Activity:** Research and development for health products that meet public health needs

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<td>Continue to set priorities for health research and development in areas of compelling health need</td>
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<td>Coordinated actions on health research and development</td>
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<td>Support improved capacity for R&amp;D and clinical trials in countries</td>
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**Activity**: Application and management of intellectual property to contribute to innovation and promote public health

**ACTIONS**

- Foster innovation and access to health products by appropriate IP rules and management
- Provide technical support and capacity building
**Activity.** Evidence-based selection and fair and affordable pricing

**ACTIONS**

Support processes for evidence-based selection, including health technology assessment and their implementation

Encourage more transparent and better policies and actions to ensure fairer pricing and reduction of out-of-pocket payments
Activity: Procurement and supply chain management for quality-assured health products

**ACTIONS**

- Support collaborative approaches to strategic procurement of health products
- Support countries in efficient procurement and supply chain management of health products
- Improve capability and capacity for detecting, preventing and responding to shortages of medicines and vaccines
- Support for adequate supply management and appropriate use of health products in emergencies and crisis situations
Activity: Appropriate prescribing, dispensing and rational use of medicines

ACTIONS

- Interventions that improve use of health products
- Support capacity for monitoring
“Key milestones” have been identified for each Strategic Area in line with the Programme Budget 2018-2019 and the draft Global Goods:

- 2019: Covered in the Programme of Budget 2018-2019
- 2020-2021: Draft Global Goods