

WHO vision and guidance on HTA and access to medicines

INFARMED CONFERENCE - Facing the Challenges: Equity, Sustainability and Access
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www.who.int

“Health is a human right. No one should get sick or die just because they are poor, or because they cannot access the services they need.” – Dr Tedros

Essentials of Universal Health Coverage



Health financing for universal coverage



Service delivery and safety



Health workforce



Essential medicines and health products



Health systems governance



Health statistics and information systems

"Together for a healthier world"

Dr Tedros Adhanom Ghebreyesus



Vision

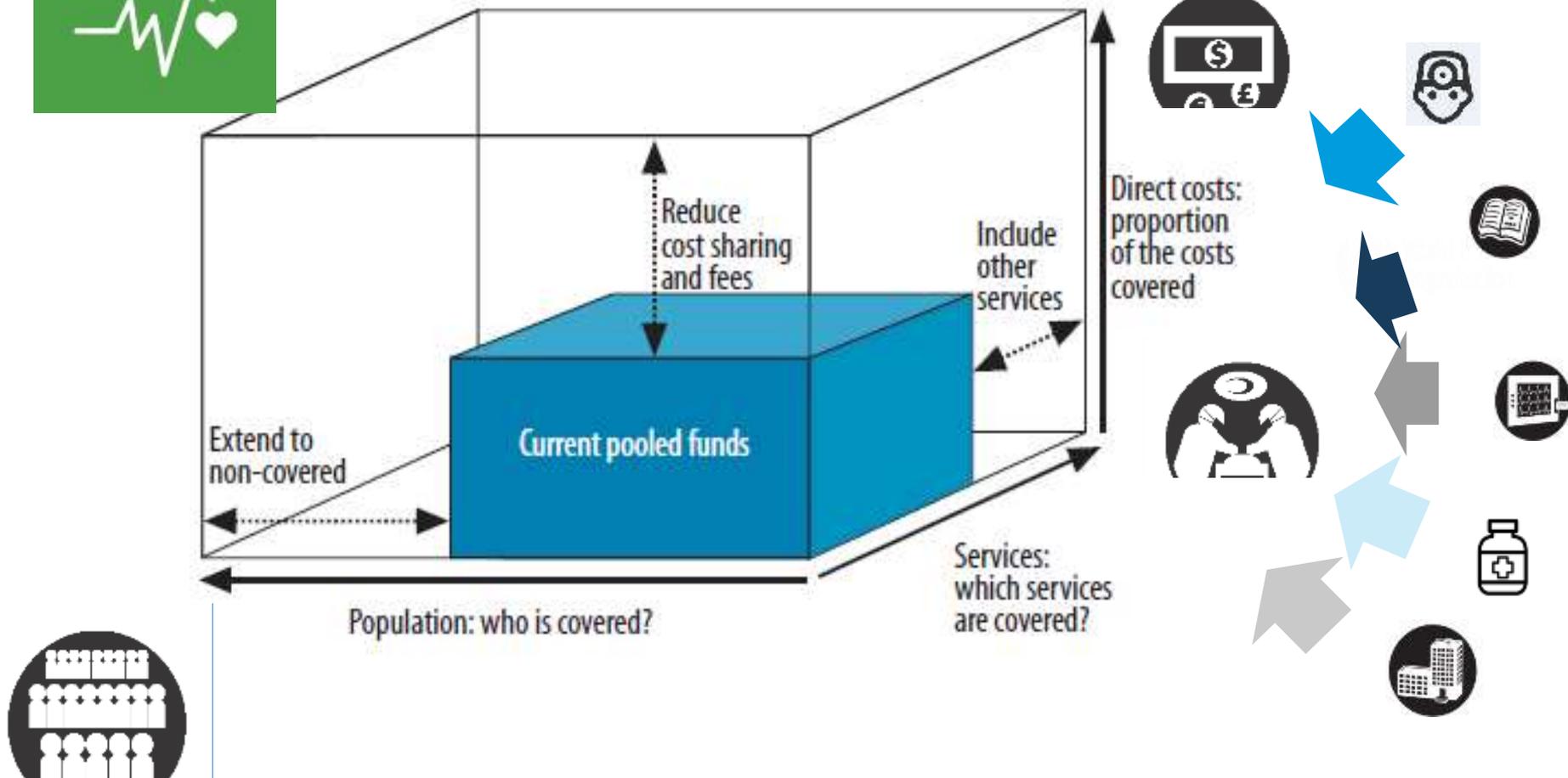
I envision a world in which everyone can live healthy, productive lives, regardless of who they are or where they live. I believe the global commitment to sustainable development – enshrined in the Sustainable Development Goals – offers a unique opportunity to address the social, economic and political determinants of health and improve the health and wellbeing of people everywhere.

Achieving this vision will require a strong, effective WHO that is able to meet emerging challenges and achieve the health objectives of the Sustainable Development Goals. We need a WHO – fit for the 21st century – that belongs to all, equally. We need a WHO that is efficiently managed, adequately resourced and results driven, with a strong focus on transparency, accountability and value for money.

Achieving UHC requires people having access to affordable essential medicines and vaccines



3.8 Achieve universal health coverage (UHC), 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**



- Lancet Commission estimated US\$77.4-\$151.9 billion (\$13-\$25 per capita) to finance basic package of 201 essential medicines
- In 2010, most low-income countries and 13/47 middle-income countries spent <\$13 per capita on pharmaceuticals

BACKGROUND DOCUMENT TOWARDS A

GLOBAL ACTION PLAN

FOR HEALTHY LIVES AND WELL-BEING FOR ALL

Shared SDG priorities and areas of work:
 Institutional target-by-target mapping as of 19 October 2018

SDG Targets	Indicators	WHO	UNAIDS	UNFPA	UNICEF	GAVI	GFF	UNITAID	GFATM	WB	UNDP	UN Women
Goal 3. Ensure healthy lives and promote well-being for all at all ages												
3.8 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	3.8.1 Coverage of essential health services (defined as the average coverage of essential services based on tracer interventions that include reproductive, maternal, newborn and child health, infectious diseases, non-communicable diseases and service capacity and access, among the general and the most disadvantaged population)	A	B	A	B	A	A	A	A	A	A	B
	3.8.2 Proportion of population with large household expenditures on health as a share of total household expenditure or income	A	B	A		A	A	A	A	A	A	

WHO Global Program of Work 2019-2023



Mission

Promote health – keep the world safe – serve the vulnerable

Strategic Priorities (and goals)

Ensuring healthy lives and promoting well-being for all at all ages by:

Achieving universal health coverage – 1 billion more people benefitting from universal health coverage

Addressing health emergencies – 1 billion more people better protected from health emergencies

Promoting healthier populations – 1 billion more people enjoying better health and well-being

Strategic shifts

Stepping up leadership – diplomacy and advocacy; gender equality, health equity and human rights; multisectoral action; finance

Driving public health impact in every country – differentiated approach based on capacity and vulnerability

Policy dialogue – to develop systems of the future

Strategic support – to build high performing systems

Technical assistance – to build national institutions

Service delivery – to fill critical gaps in emergencies

Focusing global public goods on impact – normative guidance and agreements; data, research and innovation

Mature health system

Fragile health system

Organizational shifts

- **Measure impact** to be accountable and manage for results
- **Reshape operating model** to drive country, regional and global impacts
- **Transform partnerships, communications and financing** to resource the strategic priorities
- **Strengthen critical systems and processes** to optimize organizational performance
- **Foster culture change** to ensure a seamless, high-performing WHO

WHA67.23 *Health intervention and technology assessment in support of universal health coverage* (Resolution approved May 2014)



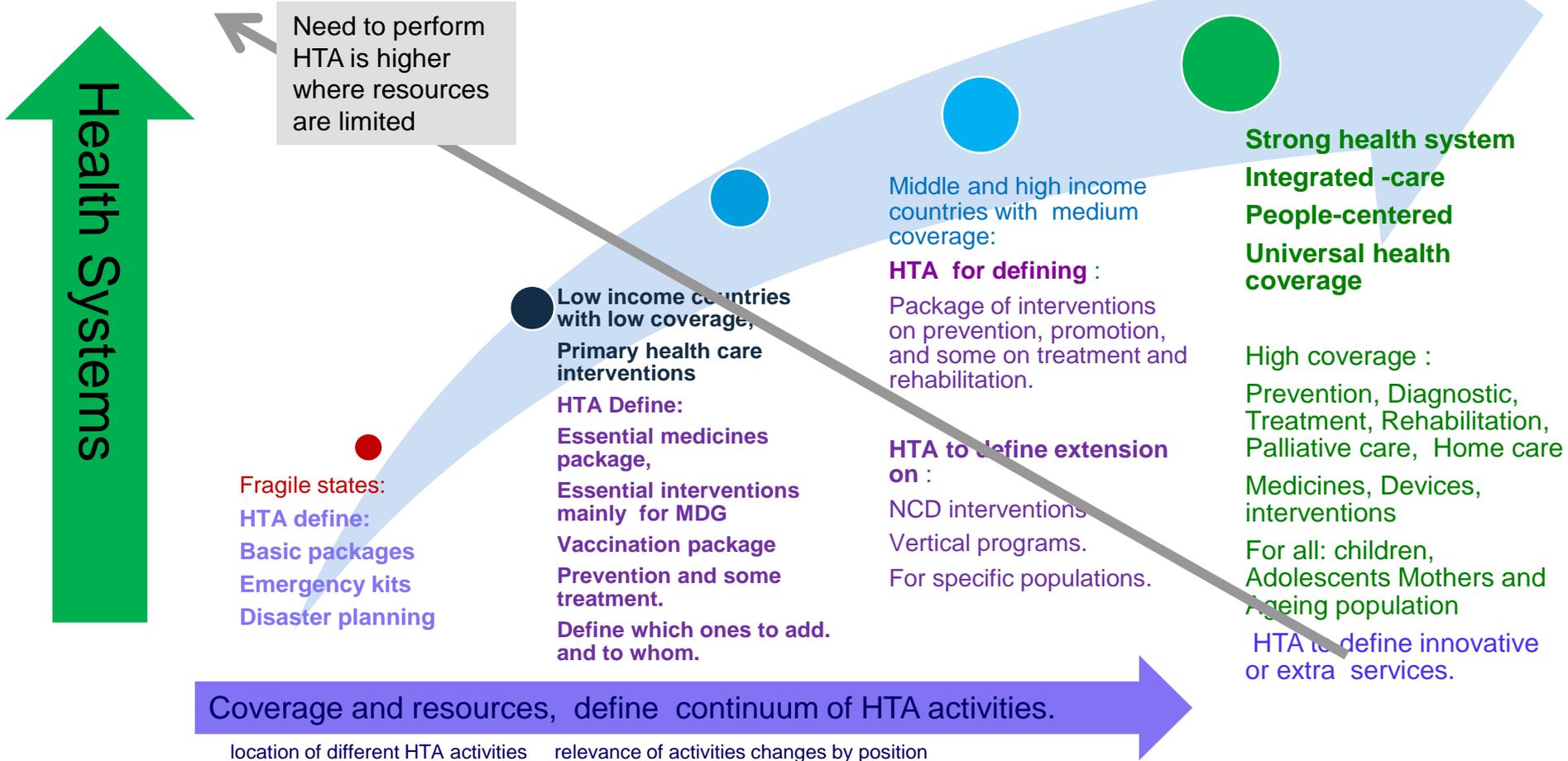
- Requests the WHO Director-General to:
- Assess the status of HTA in Member States
- Raise awareness, foster knowledge and encourage the practice of health technology assessment and its uses in evidence-based decision making
- Provide technical support to Member States to strengthen capacity for HTA
- Support the exchange of information, sharing of experiences and capacity building



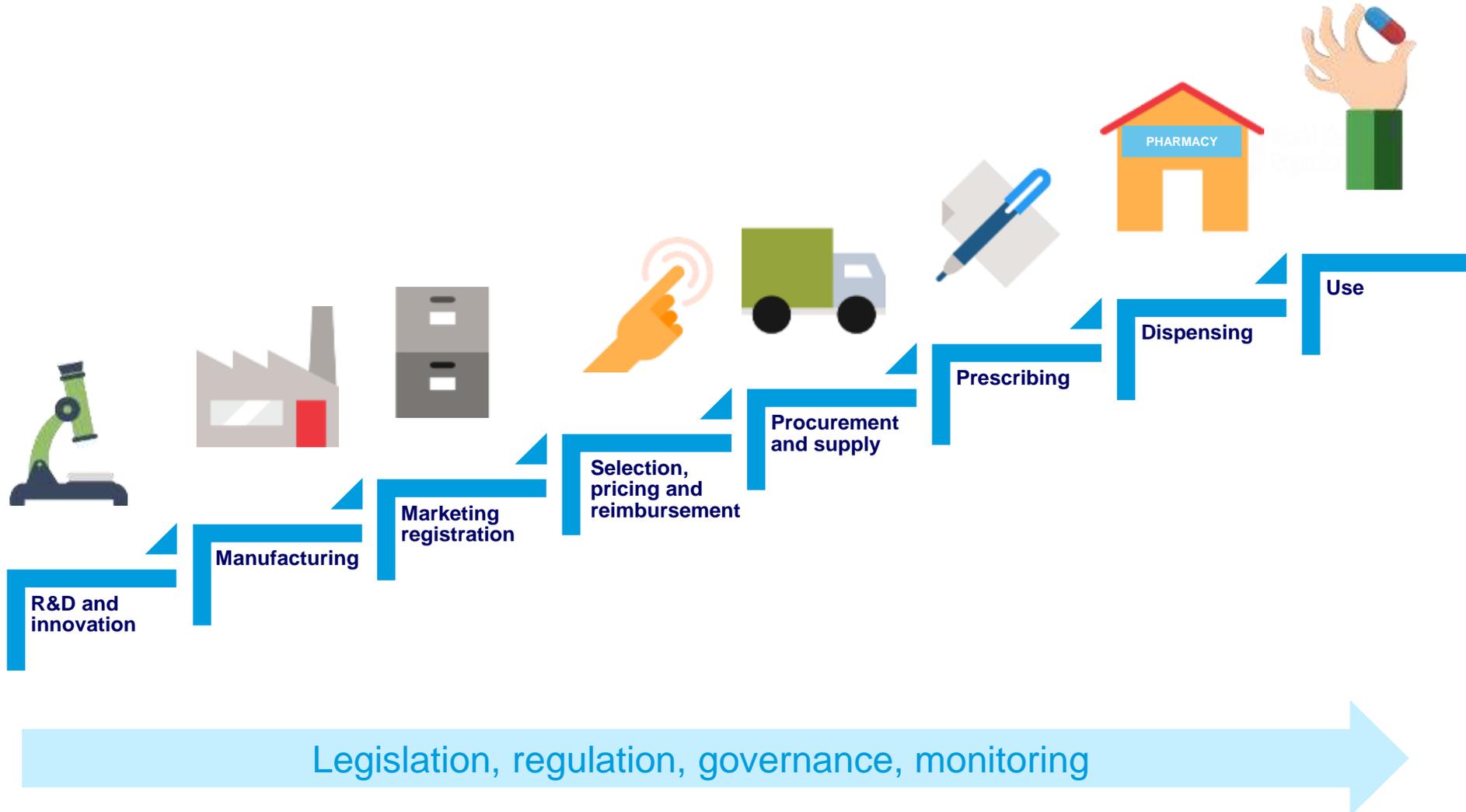
In conclusion, the survey indicated that:

Scope	Main findings
Capacity	<ul style="list-style-type: none"> Formal information gathering process to inform decision making was common among Member States. Most countries reported having more than 6 staff members in the HTA unit/agency and committee.
Methodology	<ul style="list-style-type: none"> HTAs in most responding countries, particularly LMIC, appeared to focus primarily on safety and clinical effectiveness across all types of technologies and interventions, less so for economic and budgetary consideration, and much less for other possible domains of HTAs.
Linkage	<ul style="list-style-type: none"> A majority of countries reported having a national organization that produced HTA reports for the Ministry of Health, with most HTAs initiated from the Ministry. Stronger linkages with agencies and health professionals may enhance the translation of findings from HTAs to clinical practice.
Utilization of results	<ul style="list-style-type: none"> Formal information gathering process to inform decision making was common among Member States, but the use of results from HTAs was often not legally binding.
Interest in and impediments	<ul style="list-style-type: none"> A lack of qualified human resources appeared to be the main barrier for producing and using HTA Most countries do not have academic or training programs to build HTA capacity Providing greater linkages and promote capacity building activities may enhance the utilisation of HTA findings from rigorous analysis into regular process governance.

Spectrum of HTA for priority setting and decision making by income level



WHO work supports the entire technology value chain



WHO Access priorities



1. Provide leadership on ATM policies

2. Setting product quality norms, standards, and their implementation

3. Providing technical support and building institutional capacity on health product regulation and ATM policies

4. Articulating ethical and evidence based policy options

5. Shaping markets through PQ

6. Monitoring and evaluation of ATM including enhancing data systems

Developing policy options to promote access to medicines and health products

Establishing stronger national pharmaceutical systems and capacity

Responding to evolving health product needs

Sustainable access to medicines affects both high- and low-cost products



The Forum has been conceived to:

- Facilitate discussion on strategies that could lead to a fairer price setting and a pricing system that is sustainable for health systems and for innovation.
- Hold preliminary discussions about the wanted but also unwanted consequences of the current business model including ideas about possible alternative business models.
- Explore approaches for high- and middle-income countries to remedy shortages of essential medicines that may be due to low profit margins.
- Expand current networks to include other relevant stakeholders and countries, to facilitate better exchange of experience.
- Identify research gaps, specific to the current innovation and pricing system, including the need for transparency of research and development (R&D) costs, production costs, and profit margins.

A fair price is one that is affordable for health systems and patients and that at the same time provides sufficient market incentive for industry to invest in innovation and the production of medicines. In this context, fairness implies positive incentives/benefits for all stakeholders, including purchasers and those involved in the research and development and manufacture of medicines.



Ministry of Health, Welfare and Sport



Amsterdam, 10-11 May
**Fair Pricing
Forum 2017**

WHO has received further requests to assist Member States with HTA



SEVENTY-FIRST WORLD HEALTH ASSEMBLY
Provisional agenda item 11.6

A71/13
15 March 2018

Global strategy and plan of action on public health, innovation and intellectual property

Report by the Director-General

1. In January 2018, the Executive Board at its 142nd session noted an earlier version of this report¹ and adopted decision EB142(4).²
2. This report is submitted at the request of the Executive Board in accordance with decision EB140(8) (2017), in which it approved the terms of reference of the overall programme review of the global strategy and plan of action on public health, innovation and intellectual property.
3. In resolution WHA68.18 (2015), the Sixty-eighth World Health Assembly requested the Director-General to establish a panel of 18 experts to conduct an overall programme review of the global strategy and plan of action as a complement to the comprehensive evaluation to be commissioned by the Secretariat. The executive summary of the evaluation was presented to the Executive Board at its 140th session³ and the full report of the evaluation is available on the WHO website.⁴
4. The terms of reference of the overall programme review suggested that it should be a more policy-oriented, forward-looking exercise than the evaluation. Although the expert review panel should be guided by the evaluation, it should take into account other evidence and involve relevant stakeholders.
5. As part of the review process, a survey on the way forward for the global strategy and plan of action was conducted, as well as interviews, with Member States and a wide range of stakeholders, including United Nations bodies, and intergovernmental, civil society and private sector organizations.



SEVENTY-FIRST WORLD HEALTH ASSEMBLY
Provisional agenda item 11.5

A71/12
19 March 2018

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 report¹ 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.² 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;³ 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.⁴

Background

WHA 71 DG's Report

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.

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 & affordable pricing

Procurement and supply chain management

Appropriate prescribing, dispensing and rational use

Current activities

- A **retreat** was held to discuss the development of a strategic plan for HTA
- **Resource mobilisation**
- **Aligning HTA with WHO transformation** of norms and standards, which includes many aspects of HTA-activity
- **Providing guidance** on ‘institutionalising’ a process for evidence-informed decision making, including ways to disinvestment decisions
- **Developing HTA methods** in lower income or data-poor settings, including how to develop health benefits package
- **Horizon scanning**
- **Disinvestment**

Requests from Member States

- Investment case for HTA
- Political economy, advocacy, governance
- Norms and standards on procurement
- Defining “benefit package” linking health products and money
- How to set up HTA “institution”
- Divestment/budget impact technical assistance
- Procurement support
- Optimizing efficiency
- Retrofitting package
- Global vs. local evidence (decisions, lists)
- Added value of regional institutions
- Market shaping
- Disinvestment
- Horizon Scanning

Who WHO works with on HTA

(Non-exhaustive)

Collaborating centres

- **University of Ottawa:** WHO Collaborating Centre for Knowledge Translation and Health Technology Assessment in Health Equity (Canada)
- **Instituto de Efectividad Clinica y Sanitaria (IECS):** WHO Collaborating Centre for Health Technology Assessment (Argentina)
- **Health Care and Welfare Directorate, Emilia-Romagna Region:** WHO Collaborating Centre for Evidence-Based Research Synthesis and Guideline Development (Italy)
- **Centro Nacional de Excelencia Tecnologica en Salud CENETEC:** WHO Collaborating Centre for Health Technology (Mexico)
- **Imperial College London** (in progress)

Other organizations

Non-state actors in official relations

- HTAi
- Cochrane Collaboration
- iDSI (in progress)
- ISPOR (in progress)

Memorandum of understanding

- INAHTA
- EuroScan

**If you want to go fast, go alone.
If you want to go far, go together.**

African Proverb



*(Framework of Engagement with Non-State Actors (FENSA) permitting)