

Civil Society Meeting ahead of WHO EB 144
Geneva, Ecumenical Centre, 23 January 2019



Morning sessions: Selected items on the EB agenda

Medicines, vaccines, health products

- Referring to WHO EB 144, agenda item 5.7
- Initial input: Sarai Keestra, UAEM, PHM WHO Watch
- Guest: Dr Mariângela Batista Galvão Simão
WHO ADG Access to Medicines, Vaccines and Pharmaceuticals
- This session will end at 12.00 hrs



EXECUTIVE BOARD
144th session
Provisional agenda item 5.7

EB144/17
5 December 2018

Medicines, vaccines and health products

Access to medicines and vaccines

Report by the Director-General

1. 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.



EXECUTIVE BOARD
144th session
Provisional agenda item 5.7

EB144/18
26 November 2018

Medicines, vaccines and health products

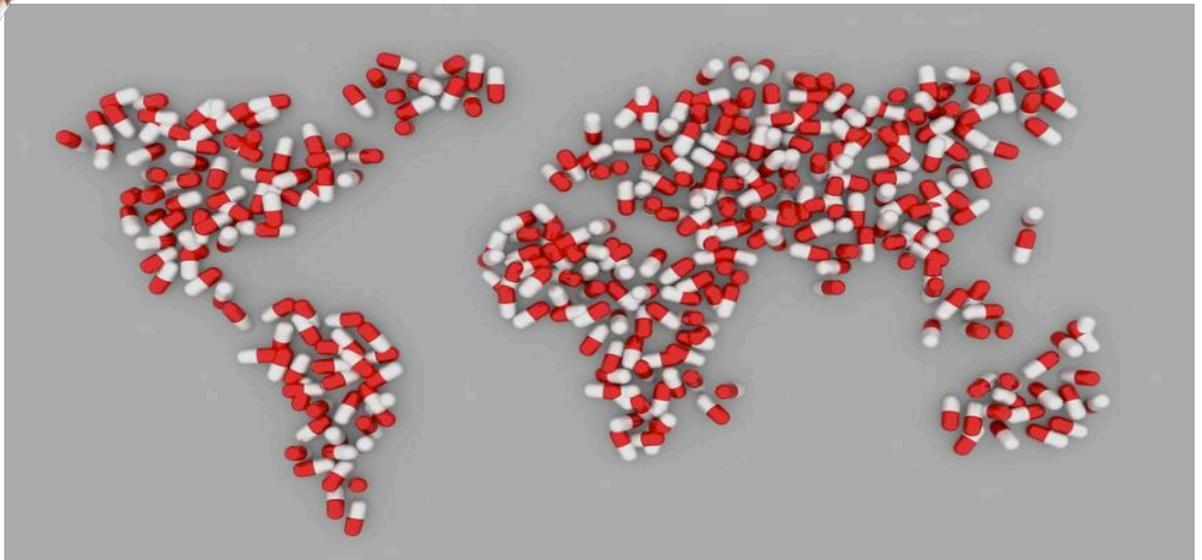
Cancer medicines

Report by the Director-General

1. In 2017, the Seventieth World Health Assembly adopted resolution WHA70.12 on cancer prevention and control in the context of an integrated approach, in operative paragraph 2(f) of which it

Medicines, vaccines & health products WHO EB-144

Analysis presented by WHO-Watcher
Sarai Keestra
(PHM/ National Coordinator UAEM UK)



Why is medicines important in the agenda of EB-144?

- “Equitable access to health products is a global priority” (Roadmap 2019-2023)
- 2 billion people lack access to essential medicines
- 100 million people are pushed into extreme poverty annually due to their inability to pay for their health care expenditures
- “Access depends on having appropriate products available at affordable prices (...) Lack of access can affect patient outcomes if patients go undiagnosed or untreated or receive suboptimal treatment and can contribute to the rise in antimicrobial resistance” (Roadmap 2019-2023)

TARGET

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

Relevant Agenda Points

- **5.5 Universal health coverage**
 - 20-60% of health spending in LMICs goes to the procurement of medicines → impeding progress to universal health coverage
- **5.7 Medicines, vaccines and health products**
 - *Access to medicines and vaccines*
 - *Cancer medicines*
- **5.8 Follow-up to the high-level meetings of the United Nations General Assembly on health-related issues**
 - Antimicrobial resistance
 - Access vs excess
 - No reference to TRIPS-flexibilities
 - Prevention and control of noncommunicable diseases
 - Rise of NCDs → intensify the financial burden of governments and patients to pay for high-priced lifelong treatments
 - Ending tuberculosis
 - Need affordable new treatments, diagnostics and vaccines.
 - R&D funding gap of \$1.3 billion dollars a year
- **6.5 Accelerating cervical cancer elimination**
 - HPV Vaccine affordability and availability

Roadmap 2019-2023

- 71st World Health Assembly
 - Report on the global shortage of, and access to, medicines and vaccines
 - Adopted WHA71/12 → Road map outlining WHO work for 2019-2023 → submit at EB-144
- EB actions required:
 - Consider draft road map
 - Provide further guidance

Roadmap 2019-2023

Ensuring the 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 efficacy/performance

Improving equitable access to health products

Research and development for health products that meet public health needs

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 for quality-assured health products

Appropriate prescribing, dispensing and rational use of medicines

Points of reflection

- Missing from the Road map:
 - Budget estimates
 - Internal division of responsibilities
 - Not every deliverable has a milestone/timeframe
- TRIPS & trade agreements:
 - Currently offers “information” & “technical support” “as appropriate, upon request, in collaboration with other competent international organizations”
 - Could use stronger language on TRIPS-flexibilities as a tool to mitigate high drug prices (as seen in GSPOA)
 - TRIPS+ effect on data exclusivity
 - No mention how harmonisation standards through trade agreements can act as barriers to new market entrants
 - An overemphasis on quality should never be a barrier to access and availability of health products at an affordable price.
- Transparency R&D and delinkage of drug pricing:
 - “Promotion of **transparency in research and development costs**; development of incentive mechanisms that separate/**delink the cost of investment in research and development from the price and volume of sales**; and establishment of additional incentives for research and development of new products where there are market failures. “
 - Breakdown of the relative roles of public and private funding across stages of development → should consequently be reflected in price
 - “There is an increasing need to ensure the sustainable availability of health products through careful management of affordable pricing for health systems **and fair pricing for producers.**”
- No mention of publicly-owned pharmaceutical manufacturing
- No actions or deliverables on access & affordability of biotherapeutics

Cancer report

- WHA70.12: request DG to make a cancer report → 170 pages
- §13: *“Overall, the analysis suggests that the costs of research and development and production may bear little or no relationship to how pharmaceutical companies set prices of cancer medicines. **Pharmaceutical companies set prices according to their commercial goals, with a focus on extracting the maximum amount that a buyer is willing to pay for a medicine.**”*
- §32: *“Given this consideration, some stakeholders have questioned whether pharmaceutical companies can legitimately claim to recover the full costs of research and development by setting high prices for medicines. They see a **need to clarify whether the public has been “paying twice”, or should be paying twice, for medicines developed with at least partial support from public resources.** It is also important to clarify the relationship between the government, industry and universities when pursuing joint research ventures.”*
- EB asked to ‘note’ this report
- It’s up to civil society to ensure that the recommendations of this report are not watered down by encouraging member states to put forward resolutions regarding the implementation