

Seventh report of Committee A

(Draft)

Committee A held its thirteenth meeting on 28 May 2019 under the chairmanship of Dr Silvia Paula Valentim Lutucuta (Angola) and Dr Yasuhiro Suzuki (Japan).

It was decided to recommend to the Seventy-second World Health Assembly the adoption of the attached resolution relating to the following agenda items:

11. Strategic priority matters

11.7 Access to medicines and vaccines

One resolution, as amended, entitled:

- Improving the transparency of markets for medicines, vaccines, and other health products

Agenda item 11.7

Improving the transparency of markets for medicines, vaccines, and other health products¹

The Seventy-second World Health Assembly,

Having considered the report by the Director-General on access to medicines and vaccines² and its annex entitled “draft road map for access to medicines, vaccines, and other health products, 2019–2023” and the report by the Director-General on medicines, vaccines and health products: cancer medicines,³ pursuant to resolution WHA70.12 (2017) on cancer prevention and control in the context of an integrated approach;

Recognizing the critical role played by health products¹ and services innovation in bringing new treatments and value to patients and health care systems around the world;

Recognizing also that improving access to health products is a multidimensional challenge that requires action across, and adequate knowledge of, the entire value chain and life cycle, from research and development to quality assurance, regulatory capacity, supply chain management and use;

Seriously concerned about high prices for some health products, and inequitable access to such products within and among Member States, as well as the financial hardships associated with high prices which impede progress towards achieving universal health coverage;

Recognizing that the types of information publicly available on data across the value chain of health products, including prices effectively paid by different actors and costs, vary among Member States and that the availability of comparable price information may facilitate efforts towards affordable and equitable access to health products;

Seeking to enhance the publicly available information on the prices applied in different sectors, in different countries and the access to and use of this information, while recognizing different national and regional legal frameworks and contexts and acknowledging the importance of differential pricing;

Taking note of the productive discussions at the second Fair Pricing Forum (Johannesburg, South Africa 11–13 April, 2019) regarding the promotion of greater transparency around prices of health products, especially through sharing of information to stimulate the development of functional and competitive global markets;

Noting the importance of both public- and private-sector funding for research and development of health products, and seeking to improve the transparency of such funding across the value chain;

Seeking to progressively enhance the publicly available information on inputs across the value chain of health products, the public reporting of the relevant patents and their status, and the availability

¹ For the purposes of this resolution, health products include medicines, vaccines, medical devices, diagnostics, assistive products, cell- and gene-based therapies, and other health technologies.

² Document A72/17.

³ Document EB144/18.

of information on the patents landscape covering a particular health product as well as its marketing approval status;

Noting the latest Declaration of Helsinki (2013), which promotes making publicly available the results of clinical trials, including negative and inconclusive as well as positive results, and noting that public access to comprehensive data on clinical trials is important for promoting advancement in science and successful treatment of patients, while protecting personal patient information;

Agreeing that policies that influence the pricing of health products and that reduce barriers to access can be better formulated and evaluated when there are reliable, comparable, transparent and sufficiently detailed data¹ across the value chain,

1. URGES Member States in accordance with their national and regional legal frameworks and contexts:

- (1) to take appropriate measures to publicly share information on the net prices² of health products;
- (2) to take the necessary steps, as appropriate, to support dissemination and enhanced availability of, and access to, aggregated results data and, if already publicly available or voluntarily provided, costs from human subject clinical trials regardless of outcomes or whether the results will support an application for marketing approval, while ensuring patient confidentiality;
- (3) to work collaboratively to improve the reporting of information by suppliers on registered health products, such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives;
- (4) to facilitate improved public reporting of patent status information and the marketing approval status of health products;
- (5) to improve national capacities, including through international cooperation and open and collaborative research and development and production of health products, especially in developing countries and low- and middle-income countries (LMICs), including health products for the diseases that primarily affect them, as well as for product selection, cost-effective procurement, quality assurance, and supply chain management;

2. REQUESTS the Director-General to:

- (1) to continue to support Member States, upon their request, in collecting and analysing information on economic data across the value chain for health products and data for relevant policy development and implementation towards achieving universal health coverage;
- (2) to continue supporting Member States, especially LMICs, in developing and implementing their national policies relevant to the transparency of markets for health products, including

¹ Including but not limited to data on: availability, especially in small markets; units sold and patients reached in different markets; and the medical benefits and added therapeutic value of these products.

² For the purposes of this resolution, “net price,” “effective price,” “net transaction price” or “manufacturer selling price” are the amount received by manufacturers after subtraction of all rebates, discounts, and other incentives.

national capacities for local production, rapid and timely adoption of generic and biosimilar products, cost-effective procurement, product selection, quality assurance and supply-chain management of health products;

(3) to support research on and monitor the impact of price transparency on affordability and availability of health products, including its effect on differential pricing, especially in LMICs and small markets, and provide analysis and support to Member States in this regard as appropriate;

(4) to analyse the availability of data on inputs throughout the value chain, including data on clinical trials and price information, with a view to assessing the feasibility and potential value of establishing a web-based tool to share information relevant to the transparency of markets for health products, including information on investments, incentives, and subsidies;

(5) to continue WHO's efforts to biennially convene the Fair Pricing Forum with Member States and all relevant stakeholders to discuss the affordability and transparency of prices and costs relating to health products;

(6) to continue supporting existing efforts to determine the patent status of health products and promote publicly available user-friendly patent status information databases for public health actors, in line with the global strategy and plan of action on public health, innovation and intellectual property, and to work with other relevant international organizations and stakeholders to improve international cooperation, avoid duplication of work, and promote relevant initiatives;

(7) to submit a report on progress made to the Seventy-fourth World Health Assembly, through the Executive Board at its 148th session.

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