

Improving the transparency of markets for medicines, vaccines, and other health-related products and other technologies to be discussed at the 72nd session of the WHA to be held on 20-28 May 2019

Draft resolution proposed by Italy, Greece, Egypt, Malaysia, Portugal, Serbia, Slovenia, South Africa, Spain, Tunisia, Turkey, Uganda

Provisional Agenda Item 11.7

VERSION 20 May 2019

The Seventy-Second World Health Assembly

1. Having considered the Report by the Director-General on Access to medicines and vaccines (document A72/17) and its annex “Draft Road Map for access to medicines, vaccines, and other health products” and the Report by the Director-General on Medicines vaccines and health products, Cancer medicines (document EB144/18), pursuant to resolution WHA70.12;
2. Recognizing that improving access to health-related products and other technologies is a multi-dimensional challenge that requires action at, and adequate knowledge of, their entire value chain and life cycle, from research and development to quality assurance, regulatory capacity, supply chain management and use;
3. Recognizing the critical role played by health products and services innovation in bringing new treatments and value to patients and healthcare systems around the world;
4. Concerned about the high prices for some medicines, vaccines, cell and gene therapies, diagnostic tests and other health-related products and services, and the inequitable access within and among Member States as well as the financial hardships associated with high prices which can impede progress toward Universal Health Coverage.
5. Recognizing that publicly-available data on prices and costs are scarce and that the availability of price and cost information is important for facilitating Member States’ efforts towards the introduction of and affordable access to new medicines, vaccines, cell and gene therapies, diagnostic tests and other health-related products and services
6. Seeking to enhance the publicly available information on the actual prices applied in different sectors, in different countries, recognizing differences in health systems and differential pricing systems;
7. Commending the productive discussions at the last Fair Pricing Forum in South Africa regarding the promotion of greater transparency around prices of medicines, vaccines, cell and gene therapies, diagnostic tests and other health technologies, especially through sharing of information in order to stimulate the development of healthy and competitive global markets;
8. Noting the importance of both public and private sector funding for research and development of medicines, vaccines, cell and gene therapies, diagnostic tests, and other

health technologies, and seeking to improve the level of information about them, in accordance with national legislations, concerning the allocation of investments and the costs for research and development, including costs incurred for conducting the clinical trials involving human subjects in order to obtain marketing approval, reimbursement or coverage for products or services;

9. Seeking to progressively enhance the publicly available information on the costs throughout the value chain of medicines, vaccines, cell and gene therapies and diagnostic tests and other health products and services and the patent landscape of medical technologies, while welcoming recent initiatives to achieve this goal;

10. Noting the latest Declaration of Helsinki, 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 complete and comprehensive data on clinical trials is important for promoting the advancement in science and successful treatment of patients, provided the need for protection of personal patient information;

11. Agreeing that policies that influence the pricing of health products and services or the appropriate rewards for successful research outcomes should consider and can be better evaluated when there is reliable, transparent and sufficiently detailed data on the costs of R&D inputs (including information on the role of public funding and subsidies), and the medical benefits and added therapeutic value of products;

12. Seeking to have better evidence of the units sold and reaching patients in different markets in order to evaluate the efficacy of health systems and the impact of the variety of barriers to access health related products and services.

1. URGES Member States, within the context of their own legal system and practice, to:

Opt 1.1. Undertake measures to publicly share information on prices and reimbursement cost of medicines, vaccines, cell and gene-based therapies and other health technologies;

Opt 1.2. Require the dissemination of results and costs from human subject clinical trials regardless of outcome or whether the results will support an application for marketing approval, while also taking appropriate steps to promote patient confidentiality;

Opt 1.3. Require the following information be made public for medicines, vaccines cell and gene-based therapies and other relevant technologies;

- a) Annual Reports on sales revenues, prices and units sold,
- b) Annual Reports on marketing costs incurred for each registered product or procedure,
- c) The costs directly associated with each clinical trial used to support the marketing authorization of a product or procedure, separately, and
- d) All grants, tax credits or any other public sector subsidies and incentives relating to the initial regulatory approval and annually on the subsequent development of a product or service;

Opt 1.4. Improve the transparency of the patent landscape of medical technologies, including but not limited to biologic drugs, vaccines and cell and gene therapies and diagnostic tests.

Opt 1.5. Report to the WHA 73 on the use of generic and/or biosimilar products and health services, and the policies and information that governments have used to enable early market entry, substitution and uptake of such products and services, including in particular those recommended by WHO in its guidelines.

Opt 1.6. Collaborate on the production of and open dissemination of research and know-how regarding the developing, manufacturing and supply of medicines, vaccines, cell and gene therapies and diagnostic tests, and help build national capacities of especially the LMIC countries and for diseases that primarily affect them, supported by WHO.

2. REQUESTS the WHO Director-General to:

Opt 2.1. Support Member States by providing tools and, upon their request, guidance, in collecting and analysing information on prices, costs and clinical trials outcome data for relevant policy development and implementation towards Universal Health Coverage (UHC);

Opt 2.2 Support Member States, especially the LMIC countries, in partnership with relevant stakeholders, to promote access to research and the know-how to manufacture and otherwise provide generic medicines, medicines, vaccines, cell and gene therapies, diagnostic tests and other products and services.

Opt 2.3 Collect and analyse clinical trial data with regard to medicines and the procurement prices of medicines and vaccines from national and international agencies.

Opt 2.4 Propose a model/concept for the possible creation of a web-based tool for national governments to share information, where appropriate, on medicines prices, revenues, units sold, patent landscapes, R&D costs, the public sector investments and subsidies for R&D, marketing costs, and other related information, on a voluntary basis.

Opt 2.5. Create a forum for relevant experts and stakeholders, consistent with FENSA, to develop, suitable options for alternative incentive frameworks to patent or regulatory monopolies for new medicines and vaccines that could better serve the need of Member States to attain Universal Health Coverage and the need to adequately reward innovation, utilizing information from expanded transparency of markets health-related innovations.

Opt 2.6 Create a biennial forum on the transparency of markets for medicines, vaccines and diagnostics, to evaluate progress toward the progressive expansion of transparency,

Opt 2.7 Continue its efforts to periodically convene a Fair Pricing Forum with all relevant stakeholders to discuss affordability and transparency of prices and costs relating to health-related products and services.

Opt 2.8 Formalize the biennial Fair Pricing Forum which creates a critical opportunity to discuss transparency of markets for medicines, vaccines, cell and gene therapies and diagnostics, and to evaluate progress toward the progressive expansion of transparency.

Opt 2.9 Provide a report to the 146th session of the Executive Board on the measures that are needed for the WHO Global Observatory on Health R&D to enhance the reporting on pre-clinical investments in R&D by both the public and the private sectors.

Opt 2.10 Submit a report to the EB 146 and EB 147 on progress in implementing this resolution.