Improving the transparency of markets for medicines, vaccines and other health-related 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, Malaysia, Portugal, Serbia, Slovenia, South Africa, Spain, Turkey, Uganda

Provisional Agenda Item 11.7

The Seventy-Second World Health Assembly

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 A72/xx), pursuant to resolution WHA70.12;

Concerned about the high prices for new medicines, vaccines, diagnostic tests, and the unequal access and financial hardships associated with high prices;

Noting with concern that the high prices of medicines impede progress for the many countries that have committed to the attainment of Universal Health Coverage (UHC);

Reaffirming the consensus reached at the last Fair Pricing Forum in South Africa to promote greater transparency around prices of medicines, vaccines and health technologies applied in different Member States, especially through sharing of information in order to stimulate the development of healthy and competitive global markets;

Noting the importance of public and private sector funding of research and development of medicines, vaccines and other health technologies, and seeking to improve the transparency of information concerning the allocation of investments and the costs for research and development directly associated with each specific product, including costs incurred for patient enrolment and costs associated with conducting the trials, such as data collection and management and analysis of results

Seeking to enhance the publicly available information on the costs of manufacturing of medicines, vaccines and health technologies, and the patent landscape of medical technologies;

Noting with concern that despite the latest Declaration of Helsinki outlining the ethical imperative to make publicly available the results of all clinical trials, including negative and inconclusive as well as positive results, the public access to complete and comprehensive data on clinical trials is still limited, and that this in fact reduces access to knowledge that is critical for advances in science, which has direct and negative consequences on the knowledge about the safety and efficacy of medicines that are prescribed to patients;

Agreeing that policies that influence the pricing of health technologies or the appropriate rewards for successful research outcomes 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), the medical benefits and added therapeutic value of products;

1. URGES Member States to:

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

2. Require that all human subject clinical trial results be reported publicly, including the costs incurred to undertake each trial and the direct funding, tax credits or other subsidies contributions received from governments;

3. Require as a condition of registration 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 R&D costs directly associated with each clinical trial used to support the registration 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 procedure;

4. Improve the transparency of the patent landscape of medical technologies, using approaches that do not create barriers to generic competition through sharing complete and up to date information;

2. REQUESTS the WHO Director-General to:

1. Support Member States in collecting, analysing and creating standards for information on prices, reimbursement costs, clinical trials outcome data and costs for relevant policy development and implementation towards Universal Health Coverage (UHC);

2. Create a web-based tool for national governments to share information on medicines prices, revenues, R&D costs, the public sector investments and subsidies for R&D, marketing costs, and other related information;

3. Create a forum for relevant experts to develop, with industry representatives, payers, patients, charities and health NGOs, suitable options for alternative incentive frameworks to patent 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;

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

5. 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.