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

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 A72/xx) (INSERT EB REF)], pursuant to resolution WHA70.12;
   [1bis: Recognizing that improving access to health products is a multi-dimensional challenge that requires action at the entire product [lifecycle (DEL Brazil)]/[value chain (Brazil)], from research and development to quality assurance, regulatory capacity, supply chain management and use (Germany)]

2. Concerned about the [high (DEL UK)] prices [and other access barriers (UK)], [for [some (Germany)] new medicines, vaccines, diagnostic tests, and the unequal access [among the member states (Hungary)] and financial hardships associated with [high prices (DEL UK)]/[these barriers (UK)]; (DEL Brazil], [which [can (UK)] impede progress toward Universal Health Coverage (Brazil)]

3. [Noting with concern that [among [many (DEL Spain)] other factors (Germany)] the high prices of medicines [can (Germany)] impede progress for the many countries that have committed to the attainment of Universal Health Coverage (UHC); (DEL Brazil friendly proposition)]

Proposal to merge PP2&3 (Sweden)

4. [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; (DEL or REFRAME UK, Denmark, Sweden)]
   ALT4:

5. 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 [on a voluntary basis (Denmark, DEL Brazil)] [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 (DEL Denmark)]
   (Comment by Austria: to coerce companies into disclosing the use of private funds for research and development can lead to resistance and not to the aim of cooperation with pharma industry. Therefore, Austria can only support this paragraph in relation to public funds.

6. Seeking to enhance [the use of (UK)]/[transparency, on a voluntary basis, (Denmark, Poland, DEL Brazil, Spain)] [the publicly available information (DEL Denmark)] on the costs [of manufacturing (DEL Sweden, Germany, Netherlands)] of medicines, vaccines and health technologies[, and the patent landscape of medical technologies (DEL Sweden, Germany, Netherlands)];

7. Noting with concern that despite the latest Declaration of Helsinki outlining the ethical imperative to make publicly

available the results of [all (DEL Germany)]/[some (Germany)] 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 (DEL Denmark, Germany)/[can reduce (Denmark, Germany)] access to knowledge that is critical for advances in science, which [has direct and negative (DEL Denmark, Germany)]/[can have (Denmark, Germany)] consequences on the knowledge about the safety and efficacy of medicines that are prescribed to patients;

8. [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; (DEL Germany)]

   [ALT 8: Noting that costs of R&D inputs, including information on the role of public funding and subsidies, the medical benefits and added therapeutic value of products influence the price of health technologies (Germany)]

   [NEW 9: Reaffirming the health systems approach and Universal Health Coverage are needed in order to improve access to medicines, vaccines and other health-related technologies sustainably and effectively (Germany)]

   [NEW 10: Concerned that in some settings needed medicines, vaccines, and other health products do not reach patients for a [huge variety (DEL Sweden, Spain)/[variety (Sweden, Spain)] of reasons including health system and health financing-related reasons and issues on the [so-called “last mile” (DEL or REFRAME Brazil, Sweden)] that prevent medicines, vaccines, and other health products from being available where needed including in hospitals and pharmacies. (Germany, Sweden)]

Proposal from Spain to combine PP10 and PP1bis

1. URGES Member States [on a voluntary basis and according to national context (Denmark, UK, Sweden)] to:

1. [Consider measures to facilitate information sharing (Australia, UK)] [Undertake measures to [provide or improve access to medicines and vaccines, including, but not limited to, and as appropriate to national context, by strengthening the health system and its sustainable and adequate financing, by Universal Health Coverage, social protection schemes, strengthening production and regulatory capacity, supply chain management, quality assurance of medicines, vaccines, and health products, appropriate use of health products, voluntary joint procurement, incentives for R&D, addressing shortages and promoting transparency and (Germany, Sweden)] [publicly (DEL Denmark)] share information (DEL Australia)] [as appropriate (Hungary)] on prices [[and reimbursement (DEL Germany) cost of medicines, vaccines, cell and gene-based therapies and other health technologies (DEL Denmark)];

2. [Require that all (DEL Australia)]/[Encourage where appropriate that (Australia, Denmark, Sweden)] 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 (DEL Germany)];

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; (DEL USA, Australia, Denmark)]

3ALT: Work collaboratively to consider measures to improve the reporting by suppliers of information on registered health technologies, including medicines, vaccines, cell and gene-based therapies (Australia, Poland?)

3ALT: Require as a condition of registration for medicines, vaccines cell and gene-based therapies and other relevant technologies [information on quality, efficacy and safety (Germany)];

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; (DEL Germany)]

   4ALT: Consider, as appropriate, how to increase awareness of domestic arrangements on patenting of medical technologies (Australia)

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);

   1ALT: Support Member States in improving access to medicines, vaccines, and health products and implementation towards Universal Health Coverage (Germany)

2. [Produce a feasibility study (Austria, UK)]/[Propose a model/concept for the possible creation of (Spain)]/[Create (DEL Spain)] a web-based tool for national governments to share information [where appropriate (Australia, Denmark)] on medicines prices, revenues, R&D costs, the public sector investments and subsidies for R&D, marketing costs, and other related information [on a voluntary basis (Germany)];

3. [Create a forum for relevant experts to develop, [with industry representatives, payers, patients, charities and health NGOs (REPLACE WITH FENSA Brazil)], suitable options for [alternative (DEL Germany)] incentive frameworks [to patent monopolies (DEL Germany)] 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; (DEL USA)]

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

Proposal to capture ongoing WIPO/WTO work (UK)

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.