

Improving the [access to (Germany)]/ [transparency [in access (France)]/[of markets (DEL France)] for (DEL Germany)] medicines, vaccines and other health-related [products and (India)] 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 medicines, vaccines, and other health-related products is a multi-dimensional challenge that requires action at the entire product value chain and life cycle, from research and development to quality assurance, regulatory capacity, supply chain management and use (Germany, Sweden, Japan)]
[1ter: Recognizing the critical role played by health [products]/[technologies] innovation in bringing new treatments and value to patients and healthcare systems around the world. (USA)]
2. Concerned about the [high (USA, Brazil, DEL UK)] prices [and other access barriers (UK, DEL Brazil)], [for [some (Germany)] [new (DEL Uganda, Ecuador)] medicines, vaccines, diagnostic tests, [and other health-related products and technologies

(India)] and the [unequal (DEL India)]/[inequitable (India)] access within and among Member States and financial hardships associated with [high prices (DEL UK)]/[these barriers (UK)]; (DEL Brazil], which can impede progress toward Universal Health Coverage for all
[2ALT: Recognizing that publicly-available data on medicines prices are scarce and that the availability of price information is important for facilitating Member States' efforts towards the introduction of new medicines (Italy)]

3. [Deleted]

[3bis: Seeking to enhance the publicly available information on the actual prices applied by pharmaceutical manufacturers in different countries, [while at the same time (DEL Brazil)] recognizing [the [potential impact on (DEL Italy)]/[need to protect the principle of (Italy)] (DEL India)] differential pricing systems [and considering the need to protect [these systems (DEL Brazil)]/[them (Brazil)]; (DEL Italy, India)] (USA, reserve France)]

4. Commending the productive discussions at the last Fair Pricing Forum in South Africa regarding the promotion of greater transparency around prices of medicines, vaccines and health technologies, especially through sharing of information in order to stimulate the development of healthy and competitive global markets; (reserve UK, Germany)]

5. Noting the importance of public and private sector funding [of (DEL USA)]/[for (USA)] research and development of medicines, vaccines and other health technologies, [and seeking to improve the [level of information about them according to national legislation]/[transparency of information [on a voluntary basis (Denmark, Switzerland, DEL Brazil)]/[according to national legislation (Italy)] [concerning the allocation of investments and the costs for research and development [directly associated with each specific product

(DEL Germany)], 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, Switzerland, Germany)] (DEL USA)]

6. Seeking to enhance [the use of (UK)]/[transparency, on a voluntary basis, (Denmark, Poland, DEL Brazil, Spain, Ecuador, Greece)] [the publicly available information (DEL Denmark)] on the [costs [throughout the value chain (Ecuador, Greece)]/[of manufacturing (DEL Sweden, Germany, Netherlands)] of medicines, vaccines and health [technologies]/[products]], and (DEL USA)] the patent landscape of medical technologies (USA, Ecuador, DEL Sweden, Germany, Netherlands)]; [and welcoming recent initiatives to achieve this goal (USA)]
7. Noting [with concern that despite (DEL USA)] the latest Declaration of Helsinki[, which promotes making (USA)] [outlining the ethical imperative to make (DEL USA)] publicly available the results of [all (DEL Germany, Switzerland)]/[some (Germany, Switzerland)] clinical trials, including [negative and inconclusive (DEL Switzerland)] as well as positive results, [the (DEL USA)]/[and noting that (USA)] public access to [complete and comprehensive (DEL Switzerland)] data on clinical trials is [still limited (DEL USA)]/[important for promoting (USA)]], and that this [in fact reduces (DEL Denmark, Germany)]/[can reduce (Denmark, Germany)] (DEL USA)] access to knowledge that is critical for [the advancement (USA)]/[advances (DEL USA)] in science [and successful treatment of patients (USA)]], 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; (DEL USA)]
[7bis: Also noting the need for protection of confidential clinical trial data including personal patient information (USA)]

8. [Agreeing that policies that influence the pricing of health products or the appropriate rewards for successful research outcomes [should consider (USA)] [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), (Brazil, DEL USA)] 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)]

Proposal to combine PP9 with PP2

[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)]

Proposal from Spain to combine PP10 and PP1bis, or preamble (Canada, Sweden, Brazil, USA, reserve Germany)

1. URGES Member States [[on a voluntary basis and (France, DEL India, Brazil, Uganda, Ecuador, Greece)] according to national [legislation and (Sweden)] context (Denmark, UK, Sweden, France, Japan, Germany, Canada)] 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)] [publicly (DEL Denmark)] share information (DEL Australia)] [as appropriate (Hungary)] on prices [[and reimbursement (Greece, DEL Germany, Japan) cost of medicines, vaccines, cell and gene-based therapies and other health technologies (DEL Denmark)];

(Proposal from USA, Switzerland, Brazil to revert to original text)
Undertake measures to publicly share information on prices and reimbursement cost of medicines, vaccines, cell and gene-based therapies and other health products;

[1ALT: Undertake measures to enhance transparency of markets for drugs and vaccines [and cell and gene-based therapies (Brazil)] which could include sharing information on prices and reimbursement costs of health products (Canada, reserve USA) [recognizing that pricing arrangements are context-specific (UK)]]

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

2ALT: Require the dissemination of results [and costs (Brazil)] 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 (USA)

3. [Require as a condition of [registration (DEL Italy)]/[reimbursement (Italy)] 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, Canada, Brazil)]

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?, Brazil, Canada)

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, Switzerland, France, DEL Brazil)];

Proposal by Spain to retain economic information in alternative text

4. [Improve the transparency of the patent landscape of medical technologies, using approaches that [do not create barriers to

generic (DEL USA, Brazil?)]/[promote (USA, Brazil?)]
competition [including through generics (Brazil)] 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)

4ALT: Consider as appropriate how to increase awareness of
international, regional and domestic arrangements on
patenting of medical technologies, and in particular awareness
of existing publicly accessible databases of patent status
information concerning health technologies (Switzerland)

NEW5: Promote the use of generic medicines through policies and
strategies that enable early market entry of generics, generic
substitution and maximization of uptake of generics including
those recommended by WHO in its guidelines on
pharmaceutical pricing policies (India)

NEW6: Collaborate for joint research and development and
manufacturing of medicines, vaccines, and health related
products and help build national capacities of especially the
LMIC countries and for diseases that primarily affect them,
supported by WHO (India, Uganda)

2. REQUESTS the WHO Director-General to:

1. [Continue to (UK)] Support Member States [by providing tools
and guidance to encourage more transparent and better
policies and actions to ensure fairer pricing and reduction of
out-of-pocket payments (Canada, proposal by Uganda to
include both paragraphs)]/[[, upon their request, (USA, Brazil)]
in collecting, analysing and creating standards for information
on prices, reimbursement costs, [and (USA, Switzerland)]
clinical trials outcome data [and costs (Brazil, DEL USA,
Switzerland)] 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)
- 1bis: Support Member States, especially the LMIC countries, in partnership with relevant stakeholders, to promote the use of generic medicines, collaborative research and development and local manufacturing of medicines, vaccines, and health products (India, Uganda)
- 1ter: Collect and analyze clinical trial data with regard to medicines and the procurement prices of medicines and vaccines from national and international agencies (India)
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 (DEL USA)] [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, Canada, Japan)]
4. [Create a biennial forum on the transparency of markets for medicines, vaccines and diagnostics, to evaluate progress toward the progressive expansion of transparency. (DEL Germany)]
- 4ALT: Continue its efforts to periodically convene a Fair Pricing Forum with all relevant stakeholders to discuss affordability

and transparency of pharmaceutical prices (USA, reserve Germany)

4ALT: Formalize the biennial Fair Pricing Forum which creates a critical opportunity to discuss transparency of markets for medicines, vaccines, diagnostics, and to evaluate progress toward the progressive expansion of transparency (Canada)

Proposal to capture ongoing WIPO/WTO work (UK, Canada, France, Japan)

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.

Proposal by India, Uganda for a concluding OP capturing periodic reporting on progress made in implementing this resolution

(Comment by Austria PP5: 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.