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Advance unedited document as it appeared on screen on 23 May 2019 at  
18:38

**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, Egypt, Greece, Malaysia, Portugal, Serbia, Slovenia, South  
Africa, Spain, Turkey**

The Seventy Second World Health Assembly,

**PP1** Having considered the Report by the Director-General on Access to medicines and vaccines<sup>1</sup> 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; (include medical devices: Zimbabwe)

**PP2** Recognizing the critical role played by health products [FOOTNOTE: definition of health products (Zimbabwe, Uruguay)] and services innovation in bringing new treatments and value to patients and healthcare systems around the world;

**PP3** Recognizing that improving access to medicines, vaccines, [diagnostics, medical devices, (Zimbabwe, Uruguay)]/[and other health products (India)[FOOTNOTE: devices, etc.(Chair, India)]]/[health-related products (DEL, India)] and other technologies is a multi-dimensional challenge that requires action at, 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;

**PP4** [Seriously (Iran)] Concerned about the high prices for some medicines, vaccines and other health-related products and other technologies, and the inequitable access within and among Member States as well as the financial hardships associated with high prices which [can (DEL Iran, Ecuador)] impede[s (Iran)] progress toward Universal Health Coverage.

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<sup>1</sup> Document A72/17.

[PP Recognizing the challenges posed by different national [economic (Kenya) (DEL, Uruguay, Brazil)] circumstances and health systems [of Member States (DEL Uruguay)], including pharmaceutical and reimbursement policies, in the pursuit of transparency, and the need to preserve incentives for differential pricing [based on a country's level of economic development (US) (DEL, Kenya)](reserve on para: Spain) (move para after PP6: Brazil)

[PP Seeking to have transparency of the placing on the market of medicines, vaccines and other health-related products and other technologies such as where marketing authorization holders supply these products in line with a county's needs and demands, and where marketing authorization holders do not place products on the market in spite of needs and demands.] (Malta)

**PP5** Recognizing that publicly-available data on [actual/effectively paid (Switzerland)] prices [and costs, (retain: Brazil, India, Norway, Thailand, Greece, Ecuador) (DEL, US, Germany, Japan)] vary among Member States and that the availability of [comparable (reserve: NZ)] price information may facilitate efforts towards affordable and equitable access to medicines, vaccines and other health-related products and other technologies (reserve on para: UK, Germany, Bulgaria)

**PP6** Seeking to enhance the [access and use of (South Africa, UK)] publicly available information on the prices applied in different sectors, in different countries, [while (Bulgaria)] [incentivizing its use (Brazil, Norway, Switzerland)] recognizing [that (Bulgaria)] differences in health systems and [the need to preserve incentives for (US)] differential pricing [systems (DEL, Bulgaria)] [are justified (Bulgaria)]; [FOOTNOTE: includes rebates and discounts, etc. (Spain, Norway, Brazil)] (reserve on para: Germany)

**PP7** 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;

**PP8** 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]/[taking into consideration (Greece)] 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; (DEL, US, Germany, Japan, Switzerland, UK) (Retain: Brazil, Thailand, South Africa, Norway, India)]

**PP9** Seeking to progressively enhance [, on a voluntary basis, (Germany, UK)] 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 (DEL US)] [use of (Germany)] patent landscape of medical technologies (DEL Germany, Japan, Switzerland)], while welcoming recent initiatives to achieve this goal; [retain PP9 as proposed: Brazil, Malta, Spain, Thailand, South Africa, Norway]

**PP10** 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;

**PP11** Agreeing that policies that influence the pricing of health products and services [or the appropriate rewards for successful research outcomes (DEL US)] 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 (DEL US, Germany, UK, Japan)] medical benefits and added therapeutic value of products; (Retain PP11 as original: India, South Africa, Kenya, Malta, Brazil, Spain, Thailand)

[**PP12** 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 (DEL Thailand, India, Kenya)] [to assess (Thailand, India, Kenya)] the impact of the variety of barriers to access health related products and services.] (US) (DEL Germany, Bulgaria) (retain original: Spain)

**OP1** URGES Member States in accordance with national and regional legal frameworks and contexts to:

**1.1** Take appropriate measures to publicly share information on the net prices [FOOTNOTE] of medicines, vaccines, and other health-related products and other technologies (reserve on para: Australia, UK, NZ, Japan)

**FOOTNOTE:** Net price or effective price or net transaction price is the list price minus all rebates, discounts and other incentives. All terms reflect the manufacturer's selling price, which is the amount received by manufacturers. [park: OOP, consumer, retail prices] (reserve para: Finland, NZ, Australia, UK, US, Japan)

**1.2** Take the necessary steps to disseminate and [ensure (retain: Spain, Tunisia, Uruguay)] [improve[d] (Chair, Switzerland)(DEL, Uruguay)] [full (Chair, Ecuador, Greece, Tunisia, Italy) (DEL, Uruguay)] availability [of (Spain, Tunisia)] and access to aggregate [information about (Australia, Kenya) (DEL, Ecuador, Uruguay)] [results [and costs (DEL, US, UK, Japan, Switzerland, Belgium) (reserve: Canada, NZ) (retain: Greece, Tunisia, Italy, India, Ecuador, Kenya, Turkey)] from] human subject clinical trials regardless of outcome or whether the results will support an application for marketing approval, while ensuring patient confidentiality; (reserve para: Finland, Australia, Canada, NZ)

**Co-Chair Proposal:** Take the necessary steps to [support dissemination (Australia)] disseminate and support full availability of and access to aggregate results [and costs] [, as appropriate, (Norway)] from human subject clinical trials regardless of outcomes or whether the results will support an application for marketing approval, while ensuring patient confidentiality (reserve: Canada (para and costs), Australia, NZ (para and costs), UK (costs), Finland (para), Japan (costs), Belgium (costs), Switzerland (costs), US (para and costs))

[**1.2 ALT** [Take [necessary (Uruguay)] steps to disseminate [and (Uruguay)]/[or (DEL, Uruguay)] support the full availability of aggregate results [and costs [,where available, (South Africa)]]/[as appropriate (Uruguay)] from human subject clinical trials regardless of outcome or whether the results will support an application for marketing approval, while ensuring patient confidentiality]] (NZ)

**TO COMPARE 1.2** [Take the necessary steps to [make available (Chair)] disseminate (Uruguay)]/[Require (Ecuador, Italy) (DEL, Switzerland)]/[Continue to (Finland)]/[Encourage and support (NZ, Australia, Canada, Switzerland, Tunisia)] the/[To disseminate (India)] dissemination of [aggregated (Chair, India, Uruguay)]/[summary (US, Kenya)] [results (DEL, South Africa)]/[costs (South Africa, Kenya, Brazil)]/[and costs (DEL US, Switzerland, UK, Germany, Japan) (retain: Spain, Ecuador, Greece, India, Uruguay)] from human subject clinical trials regardless of outcome or whether

the results will support an application for marketing approval, while [ensuring (Switzerland, India, Ecuador, Uruguay, Norway, Brazil)] [also taking appropriate steps to promote (DEL Switzerland, India, Uruguay)] patient confidentiality; (retain original 1.2: South Africa, India) (reserve para: Finland)

**[1.3** [Require]/[Encourage [suppliers (Tunisia, Indonesia)]/[manufacturers], [on a voluntary basis, (DEL, Spain)] [and working collaboratively to [consider]/[take] (Tunisia)] to make public (US, Japan, Germany) (DEL, Ecuador)] the following information [be made public (DEL, US)] for medicines, vaccines cell and gene-based therapies and other relevant technologies;

a) Annual Reports on sales revenues, prices [including the first point of sale price and the maximum retail price (India)] 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 [needs to be available (Tunisia)] 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;]

(DEL para, Germany, Switzerland, UK, Japan)

**[1.3 ALT** Work collaboratively to [towards improving (Australia)]/[consider]/[take (Ecuador, Malta, Tunisia, Norway, Indonesia, Spain, Thailand, Estonia)] measures to improve the reporting by suppliers [and consolidation by authorities (Brazil)] of information on registered health technologies, including medicines, vaccines, cell and gene based therapies [such as: (Brazil, Thailand, Estonia)] (Australia, NZ, Canada)

a) Annual Reports on sales revenues, prices [including the first point of sale price and the maximum retail price (India)] 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] (DEL, Switzerland, Belgium, NZ, Japan) (retain: Indonesia)

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;] (reserve NZ, Australia) (DEL Japan)

(reserve on para Germany)

**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. (retain: Norway, India, Ecuador, Zimbabwe, Kenya, US, Russia, Thailand, Colombia, Malta, Italy, Bulgaria)

**[1.4 ALT** Consider, as appropriate, how to increase awareness of international, regional and domestic arrangements on patenting of medical technologies, and in particular awareness of existing publically accessible databases of patent status information concerning medical technologies] (Switzerland, Germany, Australia, NZ, Japan, Canada)

(Merge 1.4 and 1.4 ALT: Switzerland, Japan, Norway, Brazil, India, Canada) (Reserve on merging: Germany)

(Merge 1.4 and 1.4 ALT 2: Zimbabwe)

**[1.4 ALT 2** Facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly [nationa and (Zimbabwe)] global databases that contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents;] (Brazil, Indonesia-para 1.4 GSPA)

**1.5.** [Report to the WHA 73 (India)]/[Promote (India)] [on (DEL, India)] the use of generic and/or biosimilar products [and health services (DEL, Canada)], 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 [on pharmaceutical pricing policies (India)]. (DEL para, US) (move reporting requirement at end: Brazil, Tunisia)

**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 (DEL India)]/[LMICs] and for diseases that primarily affect them, supported by WHO. (DEL para, US) (Retain: India, Tunisia)

## **OP2** REQUESTS the WHO Director-General to:

**2.1** Support Member States [by providing tools and (DEL, US)], upon their request, [guidance (DEL, US)], in collecting and analysing information on prices, [costs (DEL, US)] [of medicines, vaccines and other health-related products [FOOTNOTE; health products definition (Zimbabwe)] (US)] and [clinical trials outcome (reserve, US)] data for relevant policy development and implementation towards Universal Health Coverage (UHC);

**2.2** Support Member States, especially the LMICs [countries (DEL)], in partnership with relevant stakeholders, to promote access to research and the know-how to manufacture and otherwise provide generic medicines, [biologics and biosimilar (Egypt, Zimbabwe)] medicines, vaccines, cell and gene therapies, diagnostic tests [medical devices (Tunisia, Zimbabwe)] [and other products and services (DEL, NZ)]. (DEL para, US) (Retain para: India, Tunisia, Egypt, Zimbabwe)

**2.3** Collect [,where available, (NZ)] and analyse [clinical trial data [including (India)] [costs (South Africa) (DEL, US, Switzerland)] with regard to medicines, [vaccines, cell and gene therapies (Zimbabwe, India)] (DEL Brazil, Malta)] [and the procurement prices of medicines and vaccines [and cell and gene therapies (Brazil, Malta)] from national and international agencies. (DEL, US, Bulgaria)] (DEL para: Switzerland, Germany, Japan) (Retain: India, Tunisia, Brazil, Zimbabwe, Malta, Ecuador) (Reserve para: Canada, Norway, UK, Australia)

**2.4** [Propose a model/concept for (DEL, Sweden, Germany, Australia, UK, Brazil, Canada)]/[Conduct a study on the feasibility [and potential value (Australia, UK, Canada), Brazil] [for (DEL, Australia)] (Sweden, Germany, Australia, UK, Brazil, Canada)] [the possible creation of (DEL, Sweden, Germany, Australia, UK, Brazil, Canada)] [of creating (Australia)] a web-based tool for national governments to [voluntarily (Germany) (DEL, Brazil)] share information, where appropriate, on medicines prices, revenues, units sold, patent landscapes, [R&D costs (DEL, US)], the public sector investments and subsidies for R&D, marketing costs, and other related information, on a voluntary basis.

**2.5** [Promote discussions with (Brazil)]/[Create a forum for relevant (DEL, Brazil)] 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 (DEL, Brazil)] adequately reward innovation, utilizing information from expanded transparency of markets health-related innovations. (DEL para, US, Japan) (reserve on para: Australia, Germany, UK)

**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, (reserve on para: Australia, Germany) (merge 2.6-2.8, Sweden, South Africa, US, Brazil, Egypt, UK (2.7 preference), Australia, Norway) (merge 2.6 & 2.7, Zimbabwe)

**2.7** Continue its efforts to periodically convene [a]/[the (Australia)] Fair Pricing Forum with all relevant stakeholders to discuss affordability and transparency of prices and costs relating to health-related products and services.

**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.

**2.9** [Provide (DEL, Germany)]/[To include in the report (Zimbabwe)] [a report (DEL, Norway)] to the 146th session of the Executive Board [on (DEL, Zimbabwe)] 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. (DEL para, Germany)

Merge 2.9 and 2.10 [To submit a report on progress on implementation this resolution including 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. (Zimbabwe)]

**2.10** Submit a report to the [WHA 74 through EB 148 (Brazil, Norway, Zimbabwe)]/[EB 148 (US)]/[EB 146 and EB 147] on progress in implementing this resolution.

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