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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	seventy-SECOND WORLD HEALTH ASSEMBLY A72/A/CONF./2 Agenda item 11.7 21 May 2019 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	Some countries from Monday are no longer listed as co-sponsors (Tunisia and Uganda) While not reflected, several new countries have joined as cosponsors.
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;	PP1 Having considered the Report by the Director-General on Access to medicines and vaccines[1] 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;	Footnote added

[1] Document A72/17.

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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;	PP2 Recognizing that improving access to medicines, vaccines, [diagnostics, medical devices, (Zimbabwe)] 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;	Zimbabwe adds diagnostics, medical devices
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;	PP3 Recognizing the critical role played by health products [FOOTNOTE: definition of health products (Zimbabwe)] and services innovation in bringing new treatments and value to patients and healthcare systems around the world; [move PP3 before PP2 (Zimbabwe)]	Some efforts to define health products (good luck with that, since some probably not invented yet).
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.	PP4 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 impede progress toward Universal Health Coverage.	Reference to cell and gene therapies, diagnostic tests, eliminated. Products and services changed to products and other technologies. (note: CAR T or some gene therapies are considered a service by some, a product by others).

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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	PP5 Recognizing that publicly-available data on prices [and costs, (retain: Brazil, India, Norway, Thailand) (DEL, US, Germany, Switzerland, 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)	US, Germany, Switzerland and Japan seek to eliminate references to costs. (These counties want to eliminate any reference to (R&D) costs out throughout the resolution). UK, Germany and Bulgaria reserve on whole paragraph.
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;	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)	Germany has a reservation on the paragraph. Some other relatively unimportant changes.
7. Commending the productive discussions at the last Fair Pricing Forum in South Africa regarding the promotion of greater transparency around prices of medicines,	PP7 Commending the productive discussions at the last Fair Pricing Forum in South Africa regarding the promotion of greater transparency around prices of	No change

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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;	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;	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)]	US, Germany, Japan, Switzerland, UK ask to delete reference to “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;” Brazil, Thailand, South Africa, Norway, India ask to retain the R&D costs data.
9. Seeking to progressively enhance the publicly available information on the costs throughout the value chain of medicines, vaccines, cell and gene therapies and	PP9 Seeking to progressively enhance [, on a voluntary basis, (Germany, UK)] the publicly available information on the [costs throughout the value chain of medicines,	Germany and UK want “on a voluntary basis. Germany wants “use of” patent landscapes”. Is this some enforcement agenda?

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diagnostic tests and other health products and services and the patent landscape of medical technologies, while welcoming recent initiatives to achieve this goal;	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]	Germany, Japan and Switzerland want to eliminate transparency of patent landscape of medical technologies. Brazil, Malta, Spain, Thailand, South Africa, Norway prefer Monday language
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;	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;	No change
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	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	US wants to eliminate reference to “appropriate rewards for successful research outcomes” which can be seen as a delinkage reference (market entry rewards)

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of public funding and subsidies), and the medical benefits and added therapeutic value of products;	(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)	
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.	[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)	This is about “units sold” Thailand, India, Kenya want to delete references to “efficacy of health systems” I think US, Germany and Bulgaria want to delete the whole paragraph - and Spain to remain with the original text.
1. URGES Member States, within the context of their own legal system and practice, to:	OP1 URGES Member States, within the context of their own [relevant (Spain)] [national (DEL, Australia)][FOOTNOTE: (NZ)] [legislation (DEL, Spain)] and [the broader (Finland, Poland, Russia)] [and [relevant (India)] regional (Spain)] legal frameworks [they operate in (Finland, Poland, Russia)], to:	Monday version closer to Article 1 of TRIPS. Proposed changes not too important, although move it into less traditional formulations.
Opt 1.1. Undertake measures to publicly share information on prices and	1.1 Undertake measures to publicly share information on prices and reimbursement	Strong support from US, Japan, Switzerland on sharing prices (three countries that

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reimbursement cost of medicines, vaccines, cell and gene-based therapies and other health technologies;	cost of medicines, vaccines, cell and gene-based therapies and other health technologies; (retain; Spain, Switzerland, US, Thailand, Norway, Malta, Japan) (make consistent with PPs) ALT 1.1 (Germany, Australia, UK, Canada, NZ) Consider measures to facilitate [public (Kenya)] information sharing on prices and costs of medicines, vaccines, cell and gene-based therapies and other health technologies (make consistent with PPs)	oppose transparency of any cost data), as well as from countries like Thailand, Norway, Malta) Germany, Australia, UK, Canada, NZ, propose to downgrade the earlier “undertake measures to publicly share information” to “consider measures to facilitate information sharing” and eliminate “public” Kenya asks to put “public” back in Alt.1.1.
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;	1.2 [Require]/[Encourage and support (NZ, Australia, Canada)] the dissemination of results [and costs (DEL US, Switzerland, UK, Germany, Japan) (retain: Spain)] from human subject clinical trials [regardless of outcome or whether the results will support an application for marketing approval, (DEL Switzerland)] while [ensuring (Switzerland, India)] [also taking appropriate steps to promote (DEL Switzerland, India)] patient confidentiality; (retain original 1.2: Norway, South Africa, India)	US, Switzerland, UK, Germany and Japan want to eliminate reference to the dissemination of costs - Spain wants to maintain it. NZ, Australia and Canada want to downgrade the requirement for dissemination - only “encourage and support” Switzerland wants to limit dissemination of trial results only to those supporting marketing approval - not all trials, regardless of outcomes, by all entities doing trials.
Opt 1.3. Require the following information be made public for medicines, vaccines cell and	[1.3 [Require]/[Encourage [suppliers (Tunisia, Indonesia)]/[manufacturers], [on a	Perhaps the most important paragraph.

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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;	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	Germany, Switzerland, UK and Japan ask to delete the original paragraph. If not deleted, US, Japan and Germany, NZ, Belgium, US, Australia propose measures that would make disclosures voluntary, not public at all, or not even sought.

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	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)	
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.	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,	Switzerland, Germany, Australia, NZ, Japan, Canada propose alternative that eliminates “improve the transparency of ..”

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	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 publicly 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 [national 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,	Brazil, Indonesia propose language on administrative status of patent applications and patent quality. Switzerland, Germany, Australia, NZ, Japan, Canada propose language to “increase awareness of international, regional and domestic arrangements on patenting of medical technologies”, and on “existing publicly accessible databases.” Not sure what “arrangements on patenting” they are referring to. The Patent Prosecution Highway?

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	and improve the quality of patents;] (Brazil, Indonesia-para 1.4 GSPA)	
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.	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)	US, Canada, propose to eliminate or weaken.
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.	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)	US proposes to delete paragraph that would give WHO a mandate to collaborate on the production and dissemination of research and know-how on manufacturing, services like CAR T.
2. REQUESTS the WHO Director-General to:	OP2 REQUESTS the WHO Director-General to:	

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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);	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);	US proposes to delete “providing tools” or “guidance” and “costs,” and takes a reservation on “clinical trial outcomes.”
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.	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)	This is for WHO “to promote access to research and the know-how to manufacture and otherwise provide generic medicines” US proposes to delete the whole paragraph.
Opt 2.3 Collect and analyse clinical trial data with regard to medicines and the procurement prices of medicines and	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	Switzerland, Germany and Japan want to delete the whole paragraph.

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vaccines from national and international agencies.	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)	US, Switzerland, want to delete reference to "costs" South Africa wans trial costs included. & India want WHO to collect & analyse also costs of clinical trials - US and Switzerland object to it
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.	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.	Several countries want to demote this from a model/concept to a "study on feasibility" 8 brackets in this paragraph alone. US wants to del "R&D Costs", EVEN THOUGH this is "on a voluntary basis."

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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.	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)	The US and Japan want to delete proposal for forum to "develop, suitable options for alternative incentive frameworks to patent or regulatory monopolies for new medicines and vaccines" Brazil wants to eliminate reference to "forum" Australia, UK and Germany have a reservation.
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,	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)	Australia, Germany reserve. Several countries want to merge with the Fair pricing forum. KEI prefers the a separate forum that only deals with transparency issues. Combing with "fair price" discussion is not always efficient.
Opt 2.7 Continue its efforts to periodically convene a Fair Pricing Forum with all relevant stakeholders to discuss affordability	2.7 Continue its efforts to periodically convene [a]/[the (Australia)] Fair Pricing Forum with all relevant stakeholders to discuss affordability and transparency of	Minor editorial fix

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and transparency of prices and costs relating to health-related products and services.	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.	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.	No change
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.	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)]	Germany wants to delete paragraph asking WHO Global Observatory on Health R&D to "enhance . . reporting on pre-clinical investments in R&D by both the public and the private sectors."