World Health Organization

SEVENTY-SECOND WORLD HEALTH ASSEMBLY **A72/A/PSR/13**
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COMMITTEE A

PROVISIONAL SUMMARY RECORD OF THE THIRTEENTH MEETING

Palais des Nations, Geneva
Tuesday, 28 May 2019, scheduled at 09:00

Chairman: Dr S.P.V. Lutucuta (Angola)

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COMMITTEE A

THIRTEENTH MEETING

Tuesday, 28 May 2019, at 09:55

Chairman: Dr S.P.V. Lutucuta (Angola)

1. SIXTH REPORT OF COMMITTEE A (document A72/79)

The RAPPORTEUR read out the draft sixth report of Committee A.

The report was adopted.[1]

2. STRATEGIC PRIORITY MATTERS: Item 11 of the agenda (continued)

Access to medicines and vaccines: Item 11.7 of the agenda (document A72/17) (continued from the twelfth meeting)

The CHAIRMAN recalled that a drafting group had been set up to discuss the draft resolution on improving the transparency of markets for medicines, vaccines, and other health products, the revised version of which was proposed by the delegations of Andorra, Brazil, Egypt, Eswatini, Greece, India, Italy, Kenya, Luxembourg, Malaysia, Malta, Portugal, the Russian Federation, Serbia, Slovenia, South Africa, Spain, Sri Lanka and Uganda, and read as follows:

> The Seventy-second World Health Assembly,
>
> PP1 Having considered the Report by the Director-General on Access to medicines and vaccines[2] 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;
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> PP2 Recognizing the critical role played by health products [FOOTNOTE:] and services innovation in bringing new treatments and value to patients and health care systems around the world;
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> FOOTNOTE: For the purposes of this resolution, health products include medicines, vaccines, medical devices, diagnostics, assistive products, cell- and gene-based therapies, and other health technologies.
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> PP3 Recognizing that improving access to health products 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 concerned about the high prices for some health products, and the inequitable access within and among Member States as well as the financial hardships associated with high prices which impede progress towards achieving Universal Health Coverage;

[1] See page […]

[2] Document A72/17.

PP5 Recognizing that the types of information publicly available on data across the value chain of health products, including prices effectively paid by different actors and costs, vary among Member States and that the availability of comparable price information may facilitate efforts towards affordable and equitable access to health products;

PP6 Seeking to enhance the publicly available information on the prices applied in different sectors, in different countries, the access to and use of this information, while recognizing different national and regional legal frameworks and contexts and acknowledging the importance of differential pricing;

PP7 Taking note of the productive discussions at the last Fair Pricing Forum in South Africa regarding the promotion of greater transparency around prices of health products, especially through sharing of information in order to stimulate the development of functional and competitive global markets;

PP8 Noting the importance of both public and private sector funding for research and development of health products, and seeking to improve the transparency of such funding across the value chain;

PP9 Seeking to progressively enhance the publicly available information on inputs across the value chain of health products and the public reporting of the relevant patents, their status and the availability of information on the patents landscape covering a particular health product as well as its marketing approval status;

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 comprehensive data on clinical trials is important for promoting the advancement in science and successful treatment of patients, while protecting personal patient information;

PP11 Agreeing that policies that influence the pricing of health products and that reduce barriers to access can be better formulated and evaluated when there is reliable, comparable, transparent and sufficiently detailed data [FOOTNOTE] across the value chain;

[FOOTNOTE: including but not limited to the availability, especially in small markets, units sold and patients reached in different markets and the medical benefits and added therapeutic value of these products;]

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

1.1 Take appropriate measures to publicly share information on the net prices [FOOTNOTE] of health products;

FOOTNOTE: For the purposes of this resolution, net price or effective price or net transaction price or manufacturer selling price is the amount received by manufacturers after subtraction of all rebates, discounts, and other incentives.

1.2 Take the necessary steps, as appropriate, to support dissemination of and enhanced availability of and access to aggregated results data and, if already publicly-available or voluntarily-provided, costs from human subject clinical trials regardless of outcomes or whether the results will support an application for marketing approval, while ensuring patient confidentiality;

1.3 Work collaboratively to improve the reporting of information by suppliers on registered health products, such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives;

1.4 Facilitate improved public reporting of patent status information and marketing approval status of health products;

1.5 Improve national capacities, including through international cooperation, open and collaborative research for development and production of health products, especially in developing countries and low- and middle-income countries (LMICs), including for diseases that primarily affect them, as well as for product selection and cost-effective procurement, quality assurance, and supply chain management;

OP2 REQUESTS the WHO Director-General to:

2.1 Continue to support Member States, upon their request, in collecting and analysing information on economic data across the value chain for health products and data for relevant policy development and implementation towards achieving Universal Health Coverage (UHC);

2.2 Continue supporting Member States, especially LMICs, in developing and implementing their national policies relevant to the transparency of markets for health products, including national capacities for local production, rapid and timely adoption of generic and biosimilar products, cost-effective procurement, product selection, quality assurance and supply-chain management of health products;

2.3 Support research on and monitor the impact of price transparency on affordability and availability of health products, including the effect on differential pricing, especially in LMICs and small markets, and provide analysis and support to Member States in this regard as appropriate;

2.4 Analyse the availability of data on inputs throughout the value chain, including on clinical trial data and price information, with a view to assessing the feasibility and potential value of establishing a web-based tool to share information relevant to the transparency of markets for health products, including investments, incentives, and subsidies;

2.5 Continue WHO's efforts to biennially convene the Fair Pricing Forum with Member States and all relevant stakeholders to discuss affordability and transparency of prices and costs relating to health products;

2.6 Continue supporting the existing efforts for determining patent status of health products and promoting publicly available user-friendly patent status information databases for public health actors, in line with the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, and to work with other relevant international organizations and stakeholders to improve international cooperation, avoid duplication of work, and promote relevant initiatives;

2.7 Report to the Seventh-fourth World Health Assembly (through EB148) on progress made in implementing this resolution.

The representative of ITALY, speaking in his capacity as the Chairman of the drafting group, thanked all delegations that had contributed to the development of the draft resolution. Informal consultations had evolved into a formal drafting group that had forged a rich consensus. Divergent opinions had been expressed in an atmosphere of collaboration and trust, and a growing number of Member States had elected to sponsor the revised draft. The issue of access to medicines had stirred great interest, not only among policy-makers, policy regulators and government officials, but also among physicians, health professionals and experts from across the globe. Even patients and civil society groups had expressed a keen desire to participate in the dialogue.

The CHAIRMAN took it that the Committee wished to approve the revised draft resolution.

The revised draft resolution was approved.[1]

The representative of GERMANY said that her country, which had a proven record of engaging honestly in constructive multilateralism, was a committed member of the governing bodies and a strong supporter of WHO politically, financially and technically. It had established transparent procedures for drug assessment and made the prices of new drugs fully available to the public, in the knowledge that improving access to medicines was key to attaining the health-related Sustainable Development Goals, and that full, unbiased clinical evidence and balanced approaches to drug pricing were needed to deliver powerful and innovative treatments. That being said, the process that had culminated in the resolution's approval posed serious concerns. Despite the fact that market transparency was a highly complex issue that called for proper assessment of the potential implications for health care systems, the resolution had bypassed the Executive Board, in breach of established procedure. The process had not allowed for the necessary consultations or the involvement of all relevant experts. Moreover, the negotiations had been severely inhibited by the leaking of perceived positions with a view to intimidating some delegations. Given those severe and unprecedented governance concerns and the need to re-establish a spirit of trustful, respectful and good faith negotiations, her country dissociated itself from the resolution.

The representative of THAILAND, observing that her country always defended global rather than national interests, pointed out that under the Universal Declaration of Human Rights, all human beings were born free and equal in dignity and rights; it followed that everyone had the right to access affordable medicines. The Health Assembly had been mandated by resolution WHA62.16 (2009) to delink research and development costs from the price of medicines. The voluntary nature of paragraph 1.2 of the resolution would keep the cost of clinical trials undisclosed rather than transparent. Therefore, while her Government joined the consensus on the rest of the resolution, it dissociated itself from paragraph 1.2 and reserved the right to implement policies related to mandatory cost declaration in Thailand.

The representative of the UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND said that his country was strongly committed to improving access to medicines in order to achieve the best health outcomes for people globally, the Sustainable Development Goals and universal health coverage. The issues around improving access to medicines were complex and multi-dimensional. His delegation had been keen to ensure that new approaches to transparency posed no threat in lower-income countries in which preferential and differential pricing was working well and had participated in the negotiations in good faith. However, given the complexities and the need to adopt an evidence-based approach, Member States should have had more time to consider the potentially far-reaching implications of the resolution and consult stakeholders appropriately. The decision to bring the draft resolution straight to the current Health Assembly without giving the Executive Board the opportunity to review it, in addition to the manner in which the negotiations had been conducted, did not reflect the spirit of collaboration and consensus-building expected of the Organization. His Government therefore had no option but to dissociate itself from the resolution.

[1] Transmitted to the Health Assembly in the Committee's seventh report and adopted as resolution WHA72.17.

The representative of the UNITED STATES OF AMERICA enthusiastically welcomed the resolution's focus on improving price transparency for health technologies and encouraged governments around the world to promote competition by publishing the prices of medicines and other health products. He was fully in favour of transparency of patent information and clinical trial results, and of timely reporting, bearing in mind the need to protect confidentiality. He was pleased to join the consensus in support of the resolution.

The representative of HUNGARY expressed disappointment at the direction the discussions had taken. Her Government was committed to greater price transparency, but its concerns at measures urged by the resolution had not been allayed by the assertion that they should be in accordance with national and regional legal frameworks and contexts. It also shared the governance concerns voiced by previous speakers and had therefore ultimately decided to dissociate itself from the resolution.

The representative of BRAZIL fully agreed that no delegate should ever be intimidated into adopting a position that differed from his or her national position. However, the open-ended, transparent, inclusive and exhaustive process followed had given all Member States the opportunity to make their views clear to everyone, including civil society representatives. Moreover, there had been at least two rounds of informal consultations before the start of the Health Assembly.

The adoption of a resolution by the Health Assembly without prior review was not without precedent. During the current session, the Health Assembly had adopted a consensus-based decision on the public health implications of implementation of the Nagoya Protocol, even though no draft decision on that item had been presented to the Executive Board and the decision would also have wide-ranging implications and had required extensive consultations with civil society and other stakeholders.

The resolution just approved was a meaningful, balanced and comprehensive response by WHO to a pressing global problem. As well as doing justice to the Committee's deliberations, it inspired faith that WHO remained able to fulfil its promise to help Member States achieve universal health coverage by 2030.

The representative of JAPAN said that, while her Government valued price transparency and therefore considered that the resolution was in line with Japan's health system, improving transparency was a complex issue and the draft's submission directly to the Health Assembly had left no time for discussion at the Executive Board. Moreover, the negotiations had been conducted in a manner that constituted a continuous breach of trust. It was to be hoped that better management of such negotiations, which should be conducted in compliance with the relevant rules, would be ensured at future Executive Board sessions and Health Assemblies.

Member States had different methods of ensuring transparency, some of which might fall outside the narrow definition of "net price" provided in the resolution. She emphasized that all action arising from the resolution would be executed in accordance with national and regional legal frameworks and contexts, and no Member State would be forced to provide unavailable data or agree to an action.

The representative of COSTA RICA, noting that high out-of-pocket health spending could push many people below the poverty line, thereby deepening inequality, acknowledged that research, development and innovation in medicines, vaccines and other health products played an invaluable part in improving the health of populations. However, those advances should be placed within the reach of all societies, not only those with the economic means to access them. His Government supported the resolution, which would allow governments to have a greater say on the price of medicines and health products.

The representative of AUSTRALIA, echoing the concerns of earlier speakers, said that Member States should have had the opportunity to discuss the resolution well ahead of the Health Assembly, at the Executive Board. That being said, she appreciated the comprehensive approach it embodied, in line with the direction set by the road map for access to medicines, vaccines and other health products, 2019–2023, and the constructive spirit of the discussions among Member States. She endorsed the resolution, in particular the request that the Director-General should support research on and monitor the impact of price transparency on the affordability and availability of health products, and looked forward to further efforts being made to improve transparency collectively and individually, in line with different national contexts.

The representative of CANADA said that his Government had joined the consensus on the resolution, it being important to improve the transparency of markets for health products in order to enhance access to medicines and vaccines, but that a process involving greater engagement from all Member States, with ample time for discussion and analysis, might have led to an enhanced outcome on such an important and multidimensional topic.

The representative of INDONESIA noted the reservations expressed by some delegates, but said that the resolution was nonetheless timely and constituted a benchmark in global efforts to ensure equitable access to medicines and health products. It also sent an important message: that WHO would act responsibly in ensuring such access, which could be optimized through global and cross-sectoral cooperation and an effective, transparent and participatory mechanism that respected domestic legislation and regulations. His Government wished to be added to the list of sponsors of the resolution.

The representative of SWEDEN said that, although his Government had joined the consensus on the resolution, it nevertheless felt that a better outcome would have been obtained had there been more time to consider what was an important, complex and multisectoral issue. He fully endorsed the remarks of previous speakers on the process and governance of the negotiations.

The representative of NORWAY welcomed the resolution, which was the result of hard work and many compromises, and would, it was hoped, lead to lower prices for medicines. In that sense, it represented a milestone and a first step towards improving access.

The representative of SPAIN agreed with the points made by the representative of Brazil and objected to the statement of the delegation whose concerns had been fully reflected in the final version of the resolution but which had in the end dissociated itself from it. Although the resolution contained too many exceptions and would have benefitted from greater clarity regarding costs, particularly of research, development and clinical trials, it constituted a reasonable step towards addressing a problem that affected everyone. It was not in the public interest to abandon the endeavour for greater transparency, and the pharmaceutical industry had to understand that there was no turning back. The issue of access to medicines and health products could only be addressed through regional and international action.

The representative of BOTSWANA, speaking on behalf of the Member States of the African Region, pointed out that the informal consultations on the resolution had been open to all Member States and had seen active participation on their part. The consultation process had involved lengthy negotiations, and Member States' willingness to compromise in order to achieve the balanced text required for consensus was borne out by the fact that the African Region and the European Union had delivered a joint statement. The African Region fully supported the resolution, which was key for realizing universal health coverage and the broader Sustainable Development Goals.

The representative of BURUNDI endorsed the resolution on the grounds that the public interest should outweigh the interests of the pharmaceutical industry. He also endorsed the statement of the representative of Brazil, adding that the sovereign right of decision lay with the Health Assembly.

The representative of SWITZERLAND welcomed the resolution as an important step towards price transparency for medicines worldwide, but regretted that it had been approved after problematic and lengthy negotiations rather than unanimously.

The representative of ALGERIA welcomed the resolution's approval, which reflected the consensus reached on the sensitive issues it addressed and was in line with his Government's policy on price transparency.

The representative of NEW ZEALAND endorsed the resolution, noting that improved access to medicines, vaccines and other health products was crucial to the achievement by all countries of universal health coverage. The discussions of the issue had recognized the realities of different national contexts and health systems, but had been compressed to a point that should not set a precedent for the Organization: complicated issues had to be considered sufficiently in advance of the Health Assembly.

The representative of MALTA agreed that equitable access to quality and affordable medicines, vaccines and technologies was central to universal health coverage. The initiatives proposed in the resolution would ultimately improve such access and promote the sustainability of national health systems. While those initiatives were particularly relevant for small markets, like that of Malta, they could also be relevant in other countries. Sharing transparent information to support decision-making was a basic requirement.

The representative of ANGOLA endorsed the resolution, which aimed to increase transparency with a view to providing access to medicines and vaccines for all, an essential step towards achieving the right to health and Sustainable Development Goal 3 (Ensure healthy lives and promote well-being for all at all ages). Affordable and accessible medicines, and the right to produce health products locally, were also integral to universal health coverage.

The representative of KENYA also said that access to medicines was a key component of universal health coverage and crucial to achievement of the Sustainable Development Goals. While she appreciated the efforts that went into making medical products and technologies available, access to medicines must prevail over other interests. She therefore endorsed the resolution, implementation of which would ensure the transparency needed to foster the affordability and availability of essential medical products and technologies.

The representative of SOUTH AFRICA, stressing that her Government attached great importance to access to medicines and to transparent pricing, welcomed the resolution's approval and trusted that Member States would commit to its implementation.

The representative of PORTUGAL fully subscribed to the remarks of the representatives of Spain and Brazil. The resolution could lead to genuine change in accessing medicines, and while stronger language would have been preferable on cost transparency, including regarding research and development, it represented a step towards the achievement of universal health coverage and realization of the right to health. In that regard, the WHO had a critical role to play and its leadership would be required to implement the resolution.

The representative of FRANCE endorsed the resolution, which reflected his Government's longstanding efforts to promote transparent and fair pricing of medical products, but expressed regret at the less than optimal circumstances in which the text had been discussed. The process had complicated the search for consensus and might undermine the resolution's implementation; that lesson should be borne in mind for the future. The resolution marked the first step towards a transparent pricing system for medicines, vaccines and other health products, and his Government remained open to further discussions of the matter.

The representative of BELGIUM also endorsed the resolution and agreed with previous speakers that transparency was an important element of access to and pricing of health products. Nonetheless, he expressed concern that the process leading to the resolution's approval had left little time to consult with specialists and other stakeholders, including WIPO and WTO.

The representative of ZIMBABWE endorsed the resolution.

The representative of the UNITED REPUBLIC OF TANZANIA expressed support for the process that had culminated in the resolution's approval, which he considered had been transparent and participative. The resolution itself represented a step towards access to affordable health products and would, it was hoped, deliver transparency on price. His Government therefore endorsed it.

The representative of ECUADOR said that a transparent market for medical products and other health technologies was vital to global public health and equitable and timely access to medical products, especially in developing and least developed countries. His Government supported the resolution, which should serve to catalyse additional action prompting the pharmaceutical industry to be more transparent about manufacturing and research and development costs, about the criteria used to set prices, and about how it determined which medicines should receive investment. It should also lead to broader discussion of transparency in clinical trials, price differentiation, regular reporting mechanisms and cancer medicine price-setting.

The representative of COLOMBIA expressed appreciation for the flexibility shown by other Member States in reaching a consensus on the resolution, which her Government fully endorsed, with a view to improving transparency of markets and thereby promoting equitable access to medicines, vaccines and other health products.

The representative of PERU, observing that full access to efficient, affordable and quality medicines, vaccines and medical technology was fundamental to the achievement of universal health coverage, expressed support for the resolution.

The representative of MEXICO said that the resolution, which was the outcome of a negotiating process conducted in keeping with the Organization's procedures, represented a big step in collaborative efforts to achieve Sustainable Development Goal 3 and universal health coverage.

The representative of the ISLAMIC REPUBLIC OF IRAN, observing that it was of the utmost importance to improve the transparency of markets for medicines, vaccines and other health products in order to achieve universal health coverage, endorsed the resolution, which was timely but would require international cooperation to implement. Its benefits should be extended to people everywhere, particularly those living in low- and middle-income countries.

3. SEVENTH REPORT OF COMMITTEE A (document A72/80)

The RAPPORTEUR read out the draft seventh report of Committee A.

The report was adopted.[1]

4. CLOSURE OF THE MEETING

After the customary exchange of courtesies, the CHAIRMAN declared the work of Committee A completed.

The meeting rose at 11:10.

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[1] See page […].