PROVISIONAL SUMMARY RECORD OF THE TWELFTH MEETING

Palais des Nations, Geneva
Monday, 27 May 2019, scheduled at 14:30

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

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COMMITTEE A

TWELFTH MEETING

Monday, 27 May 2019, at 14:40

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

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 eleventh meeting, section 3)

The CHAIRMAN said that the drafting group established to discuss the draft resolution on improving the transparency of markets for medicines, vaccines, and other health products (document A72/A/CONF/2) was continuing its deliberations. She invited the Committee to resume its discussion of the Director-General’s report in document A72/17 and of the draft road map for access to medicines, vaccines and other health priorities, 2019–2023, set out in the Annex thereto.

The representative of MEXICO drew attention to the importance of facilitating access to health products and outlined national measures taken to that end, which were aligned with the two strategic areas set out in the draft road map. The WHO approach covered priority measures for health system strengthening, but specific requirements for achieving the elements described in the deliverables should be defined under each strategic area and WHO expectations made clear. Clear targets and how to achieve them should also be established, to help Member States address each strategic area, including its deliverables. Lastly, focal points should be appointed to facilitate communication with the Secretariat during the draft road map’s implementation.

The representative of SWITZERLAND commended the draft road map, notably the division of activities into two strategic areas and the inclusion of all health products, even those used for diagnosis. It was vital to promote transparent pricing of medicines; more transparent markets would improve States’ negotiating power, while maintaining a price differentiation that benefited countries with fewer resources. Worldwide transparency was in the interest of public health, and her Government supported efforts to strengthen international cooperation in that regard.

The representative of SOUTH AFRICA said that pricing of medicines was a major public health issue, as had been highlighted by the calls for greater price transparency at the most recent Fair Pricing Forum. The fact that the production costs of most medicines on the WHO Essential Medicines List represented a fraction of the high price charged by companies had prompted her Government to sponsor the draft resolution. Observing that biosimilar medicines were more affordable than biological medicines but also involved more complex science, she asked WHO to issue guidelines on how to evaluate them.

The representative of AZERBAIJAN commended the draft road map and ongoing efforts to improve access to health products. She drew attention to various national policies in that area and to the negative effect of high pricing on the State budget, adding that her Government had been working with UNDP and UNICEF to reduce costs and improve access to medicines.
The representative of AUSTRALIA said that equitable and reliable access to safe, effective and affordable health products was fundamental to achievement of universal health coverage and the Sustainable Development Goals. She welcomed the draft road map and the consultative approach used to develop it, and noted that the Secretariat would need adequate resources to ensure its successful implementation. Her Government would consider how the draft road map could be incorporated into both national and regional programmes.

The representative of COLOMBIA outlined several ways in which her Government was working to improve access to medicines and vaccines; the draft road map would give renewed impetus to those efforts. When it came to improving the quality, safety and efficacy of health products, prequalification and post-marketing surveillance would help ensure efficient health product registration processes.

The representative of the RUSSIAN FEDERATION highlighted the importance of developing unified regulations for health products, according to the risks associated with their use and based on international regulatory experience. She urged Member States to use data from the WHO Global Surveillance and Monitoring System to detect substandard and falsified health products at an early stage. The Organization’s work on the prequalification programme should be supported, as it would enable Member States to build national regulatory capacity. Indeed, WHO efforts to support regulatory system strengthening, including regular assessments of national bodies according to WHO frameworks, were key. Vaccine hesitancy, another issue to consider including in the draft road map, could be tackled by providing information on vaccine safety and efficacy. Her Government supported the draft road map and the development of the draft resolution.

The representative of the ISLAMIC REPUBLIC OF IRAN welcomed the consultative approach used to draft the road map and the comprehensive outputs identified. In order to achieve those outputs collectively, Member States would have to align their strategies and share experiences, incorporate the outputs into country support plans, and report regularly to the Health Assembly. As affordable health products were vital to the achievement of universal health coverage, WHO should facilitate the transfer of technology from vaccine-producing to other countries, and thereby making it difficult to guarantee the population’s right to health. Lastly, WHO should consider quality assurance measures for vaccine and medicine producers, which would make the market more competitive and therefore reduce prices.

The representative of INDONESIA expressed concern that no common understanding had been reached on terminology: document A72/17 referred to “fair” prices, while document A72/12 used the term “affordable”, which could give rise to different interpretations. Clear definitions were crucial for implementation of the draft road map, as was clear guidance to allow context-appropriate use and avoid any unintended consequences. His Government believed that equitable access to essential health products could be optimized through global, cross-sectoral cooperation and a transparent, participatory mechanism; such cooperation should, however, respect Member States’ respective laws and regulations. He therefore supported the ongoing consultation among Member States on the draft resolution.

The representative of NIGER welcomed the draft road map and observed that improving access to health products was a multidimensional challenge that required comprehensive policies and strategies at both national and international level. His Government had taken various initiatives, notably to improve national regulatory systems and develop a strategic plan for health product procurement.

The representative of JAPAN said that international cooperation was needed to address the issue of fair access to medicines and vaccines. Incentives such as investment and intellectual property protection should be offered to companies and research institutions in order to promote research and
development, particularly in the case of neglected tropical diseases. It was also important to harmonize and build capacity among regulatory authorities, and he highlighted several examples of international collaboration in that area by his Government. Lastly, the draft road map should be implemented jointly with other stakeholders and organizations such as WIPO and WTO, to avoid duplication of work, especially regarding trade agreements and intellectual property rights. The Secretariat should therefore continue to consult with Member States on the actions proposed for 2020 and beyond.

The representative of ECUADOR welcomed the draft road map and expressed the hope that Member States would be able to take immediate and concrete action to improve access to medicines. The current debate on transparency of markets for health products could be the starting point for a discussion on the cost, research and development of medicines. She urged Member States to include the entire value chain in their discussion of the draft resolution and to establish reporting mechanisms that would allow access to that information. She urged the Secretariat to intensify its efforts to promote equitable access to health products, strengthening the management of purchases through pooled procurement mechanisms similar to those used in the Americas; build national capacities to make use of Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities; work for greater transparency and information on scientific evidence, data, and fair and affordable pricing; and promote research and development of health products meeting public health needs.

The representative of ANGOLA said that, in order to achieve universal health coverage, inefficient and vulnerable supply chains must be fixed and financial constraints eased. Tax relief, customs exemptions and the use of generic medicines and vaccines would improve access to, and the affordability of, safe, effective and quality medicines. Member States should be empowered to establish sustainable procurement mechanisms for medicines and vaccines, particularly those that helped eliminate disease transmission. WHO support for research and development was paramount, as it facilitated local production. It was also important to support the development of commercial and intellectual property policies aimed at improving public health, innovation geared towards affordable and accessible health products, and normative and regulatory instruments aimed at combating counterfeiting and low-quality pharmaceutical products.

The representative of THAILAND, expressing concern at the affordability of essential medicines, in particular new patented medicines and biologicals, said that the drafting group should bear in mind the need to separate research and development costs from manufacturing costs, so as to ensure fair pricing. Member States should represent the interests of the people, not of pharmaceutical companies. Given the high cost of medical diagnosis, cost-effective forms of laboratory testing should be developed. He asked the Director-General to take a leading role in addressing the matter, in close collaboration with relevant organizations.

The observer of PALESTINE, noting that greater access to affordable medicines and vaccines helped stop the spread of noncommunicable diseases and epidemics across borders, said that the draft road map would be key to achievement of the health-related Sustainable Development Goals. Millions of Palestinians remained unable to access the medicines, vaccines and health products they needed because of shortages and the long-standing blockade imposed on the Gaza Strip. He thanked the Government of India and UNICEF for ensuring access to high-quality medicines and vaccines, and WHO for bringing pressure to bear on the Government of Israel in that respect. It was to be hoped that the occupying power would definitively lift the ban on the import of medicines before the end of 2019.

The representative of the MEDICINES PATENT POOL FOUNDATION, speaking at the invitation of the CHAIRMAN, said that in order for licensing – a key deliverable of the draft road map – to facilitate access to safe, effective and affordable medicines, it must be closely aligned with public
health principles and integrated into a broader public health approach. She welcomed the deliverable whereby support would be provided for the expansion of the Medicines Patent Pool.

The representative of the INTERNATIONAL FEDERATION OF MEDICAL STUDENTS’ ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, called on Member States to work together to create minimum transparency standards and commit, along with the international academic community, to transparent research. WHO should use its technical expertise to help collect and share clinical research data, and work more closely with academia to negotiate licensing agreements with the private sector on publicly funded technology. It should also enable the sharing of best practices on the use of TRIPS flexibilities and provide technical support where necessary.

The representative of the INTERNATIONAL ASSOCIATION FOR HOSPICE AND PALLIATIVE CARE INC., speaking at the invitation of the CHAIRMAN, said that more had to be done to ensure universal access to essential palliative care medicines on the WHO Model List of Essential Medicines. Her Association and its partners stood ready to help Member States train health professionals to implement the draft road map and improve access to generic oral morphine.

The representative of the WORLD HEART FEDERATION, speaking at the invitation of the CHAIRMAN, said that, although many Member States had enacted national plans to tackle rheumatic heart disease following the adoption of resolution WHA71.14 (2018), they needed to improve access to benzathine penicillin G for that purpose, particularly in low-resource settings.

The representative of the EUROPEAN SOCIETY FOR MEDICAL ONCOLOGY, speaking at the invitation of the CHAIRMAN, encouraged Member States incorporating cancer medicines into universal health coverage packages to consider those on the WHO Model List of Essential Medicines or with high scores on her organization’s Magnitude of Clinical Benefit Scale. The draft road map, which she welcomed, should include efforts to expand access from primary to secondary and tertiary health care, which would cover cancer treatment, and to increase the availability of oral morphine for palliative care.

The representative of the GLOBAL HEALTH COUNCIL, INC., speaking at the invitation of the CHAIRMAN, welcomed the draft road map and said that Member States should develop affordable and more readily available paediatric medicines and encourage research and development on conditions exclusively affecting children, adolescents and young people. Applications for additions or changes to the WHO Model List of Essential Medicines should also be evaluated for the Model List of Essential Medicines for Children. She commended WHO efforts to address regulatory barriers to access to medicines and to increase access to diagnostics in low-resource settings.

The representative of THE WORLD MEDICAL ASSOCIATION, INC., speaking at the invitation of the CHAIRMAN, said that WHO should work on research and development, manufacturing and distribution models that addressed public health priorities such as antimicrobial resistance, medicine shortages and equitable access, and support governments using TRIPS flexibilities to access essential medicines. Member States should strengthen their regulatory systems to heighten transparency in medicine pricing and ensure they had the funding needed to meet the milestones listed in the draft road map.

The representative of the DRUGS FOR NEGLECTED DISEASES INITIATIVE, speaking at the invitation of the CHAIRMAN, said that transparency was important to advance scientific knowledge and demonstrate value for money, and was a matter of public accountability for any institution claiming
to support the Sustainable Development Goals. Discussions of costing must take into account different business models, portfolios and technologies.

The representative of the INTERNATIONAL PHARMACEUTICAL STUDENTS’ FEDERATION, speaking at the invitation of the CHAIRMAN, said that, as pharmacists played a key role at every link in the medical supply chain, a high standard of pharmaceutical education was needed to ensure that the future health workforce would be well equipped to tackle the lack of access to medicines. She called on WHO to include pharmacists in its work on equitable access to medicines and their appropriate use.

The representative of PUBLIC SERVICES INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that transparency was required to put people over profit and align public health needs with economic and social development objectives. He supported the draft road map’s emphasis on fair and affordable pricing, its consideration of public health implications when providing technical support to Member States, and the importance it accorded to the health workforce. The Secretariat should provide concrete support to Member States, whom he urged to support the draft road map and the draft resolution.

The representative of MÉDECINS SANS FRONTIÈRES INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that the draft resolution could help save lives by correcting the power imbalance between those who needed medicines and pharmaceutical companies focused on maximizing profits. Noting that governments were not legally required to sign confidentiality agreements with pharmaceutical companies, she called on Member States to require companies to be transparent about their pricing, production costs and the proportion of their research and development budgets underwritten by taxpayers and nongovernmental organizations, and to approve the draft resolution.

The representative of the UNION FOR INTERNATIONAL CANCER CONTROL, speaking at the invitation of the CHAIRMAN, urged Member States to make use of the WHO Model List of Essential Medicines; develop effective regulatory systems, procurement strategies and fair pricing policies; make use of TRIPS flexibilities; strengthen their health worker training and supply chain management capacity; support policy options in the WHO technical report on cancer medicines pricing; and call for increased access to clinical trial outcomes. She urged the Secretariat to update its 2009 guidelines on the evaluation of similar biotherapeutic products, as called for in resolution WHA67.21 (2014), as the 2018 questions and answers document was not sufficient.

The representative of MEDICUS MUNDI INTERNATIONAL – NETWORK HEALTH FOR ALL, speaking at the invitation of the CHAIRMAN, said that Member States should support the draft road map, even though its use of the term “fair price” might legitimize high prices. The draft should also contain stronger support for TRIPS flexibilities. Governments and the Secretariat must work towards full transparency regarding price information, research and development costs and clinical trial outcomes. She echoed the call to update WHO’s guidelines on the evaluation of similar biotherapeutic products.

The representative of the INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS AND ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, acknowledged concerns about affordability, but said that some proposals related to transparency and intellectual property expressed in the draft road map and at the Health Assembly would discourage holistic and sustainable solutions to improve access. WHO should support the private sector’s efforts to address unmet medical needs.
The representative of STICHTING HEALTH ACTION INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that WHO acted as a steward of biomedical knowledge governance by providing technical support on the use of TRIPS flexibilities, promoting full disclosure of clinical trial data and supporting access to the true costs of research and development. Together with Member States, the Secretariat must remain at the forefront of efforts to reduce pervasive information asymmetries.

The representative of KNOWLEDGE ECOLOGY INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that the final version of the draft resolution should address every topic raised in the original draft. Governments and the public needed reliable information about clinical trial costs. If pharmaceutical companies failed to account for their research and development costs, their arguments for high prices would be undermined for a number of products.

The ASSISTANT DIRECTOR-GENERAL (Prequalification and Technology Assessment) summed up the Member States’ comments, which would be taken into account when implementing the draft road map, along with input received from them and the Executive Board over the past year. The draft road map would provide the Secretariat with a more systematic approach to supporting countries, and the Secretariat would report back on implementation, including cooperation with organizations such as WIPO and WTO. In response to concerns about budgeting, she assured Member States that the Secretariat would go through the normal operational processes to deliver on its commitments under the Programme budget 2020–2021 based on their recommendations.

The Committee noted the draft road map.

At the invitation of the CHAIRMAN, the SECRETARY read out a statement on behalf of the drafting group responsible for amending the draft resolution. The drafting group had made substantial progress since it had been convened on 23 May but required additional time to reach a consensus.

The CHAIRMAN suggested that the drafting group should be given additional time for discussion as requested, and that the Committee’s discussion of the subitem should be suspended until the next morning.

It was so agreed.

(For continuation of the discussion and approval of a draft resolution, see the summary records of the thirteenth meeting, section 2.)

The meeting rose at 15:45.