World Health Organization

SEVENTIETH WORLD HEALTH ASSEMBLY **A70/A/PSR/9**
26 June 2017

COMMITTEE A

PROVISIONAL SUMMARY RECORD OF THE NINTH MEETING

Palais des Nations, Geneva
Saturday, 27 May 2017, scheduled at 09:00

Chairman: Dr H. M. AL-KUWARI (Qatar)

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COMMITTEE A

NINTH MEETING

Saturday, 27 May 2017, at 09:35

Chairman: Dr H. M. AL-KUWARI (Qatar)

1. FOURTH REPORT OF COMMITTEE A (document A70/73)

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

The report was adopted.[1]

2. HEALTH SYSTEMS: Item 13 of the agenda (continued)

Addressing the global shortage of, and access to, medicines and vaccines: Item 13.3 of the agenda (continued from the eighth meeting) (document A70/20)

The representative of the BAHAMAS said that WHO's programme on the prequalification of medicines and vaccines was welcome and requested continued support and technical assistance from PAHO, WHO and other partners for the training of pharmacists in her country.

The representative of the RUSSIAN FEDERATION said that addressing the global shortage of, and access to, medicines and vaccines should be a standing item on Health Assembly agendas. The methodology and information resources used by WHO to produce the report could be employed to effectively implement sectoral measures. He outlined the steps taken in his country to ensure access to essential medicines, and the work in progress to support local research and development. He expressed support for WHO, WIPO and WTO efforts to move to compulsory licensing for drugs in countries that did not have the technical capacity to produce those medicines themselves.

The representative of AUSTRALIA said that a holistic approach was needed that considered more than just intellectual property rights. Australia's commitment to ensuring access to medicines at home and abroad was reflected in its active engagement in and support for WHO's work across the range of areas outlined in the report, as well as other key contributions including funding to support product development partnerships. She expressed support for the Organization's ongoing efforts to improve access to medicines and address shortages, noted the importance of continued collaboration among international agencies, and stressed that such complex work should be well coordinated so as to avoid duplication of efforts.

The representative of AUSTRIA said that other issues relating to access to medicines that needed to be investigated included market withdrawal of products, delayed market entry of innovative

[1] See page […].

products, alternative business models, transparency of medicine prices and incentives for research and development. Public investment was crucial for needs-driven, evidence-based research and development of new health technologies. Strict criteria must be applied when considering the patentability and exclusivity of essential medicines. She expressed appreciation for WHO's initiatives to foster dialogue among countries regarding the exchange of information and cross-border collaboration on public procurement.

The representative of COLOMBIA said that WHO instruments and initiatives addressing shortages of medicines must be worded so as to help Member States take public policy decisions on access to medicines in areas such as the production and use of generic medicines, barriers preventing biosimilars from entering the market and greater transparency in research and development expenses. Those areas should be included in future decisions on shortages and access to medicines. It was crucial to strengthen regulatory authorities and set fair prices that reflected the true therapeutic value of a given technology. Also, price negotiation and centralized purchases at the regional level required further discussion, as those mechanisms were highly recommended by WHO as a means of ensuring access to medicines and vaccines. He expressed interest in participating in the Member State consultation on the issue in 2017 and in the Health Data Collaborative. Lastly, he insisted that the recommendations of the United Nations Secretary General's High-level Panel on Access to Medicines should be included in the technical inputs being developed in support of public health policy decision-making, and should therefore figure on the agenda.

The representative of BARBADOS expressed appreciation for the work being done by WHO to address the global shortage of medicines and vaccines, specifically the plan to develop a global medicine shortage notification system. A policy on timely notification should be developed for the seamless application of appropriate measures. All countries, irrespective of their size, should have access to the outcomes and strategic solutions emerging from assessment of the magnitude and nature of the problem. She also recommended that PAHO's role in helping Barbados obtain access to difficult-to-obtain medicines and vaccines be strengthened by appointing a dedicated pharmaceutical advisor to the Office for Barbados and Eastern Caribbean.

The representative of IRAQ outlined several effective steps taken by his country to ensure the provision of essential medicines and vaccines. He underscored the role of WHO and other international organizations in providing assistance and procuring essential medicines through the drug and vaccine companies with which they worked. Given the repercussions of shortages of essential medicines and vaccines on health security, it was important to pool all efforts at WHO, giving special consideration to countries with particular needs, to ensure uninterrupted supplies and promote national production.

The representative of the PLURINATIONAL STATE OF BOLIVIA described a number of measures taken by his country to tackle the challenges inherent in ensuring access to affordable, high-quality, essential medicines, but said that more needed to be done, given that limited access to technology and certain international trade agreements had made it difficult to move forward with public health initiatives. He commended the report of the High-level Panel and endorsed the proposals to include the item on the agenda of the 142nd session of the Executive Board and as a standing item on the agenda of the Health Assembly.

The representative of CANADA said that, while the Secretariat's report was a positive step in the process of comprehensively examining access to medicines and vaccines, engaging in constructive dialogue and then taking action on consensus-based priorities, it lacked information on how WHO coordinated its work internally and externally and did not analyse or prioritize – or put forward a methodology for analysing and prioritizing – critical elements to ensure vital aspects were tackled

collectively. It was hoped that work to define key terms and map out potential causes of shortages and the related contexts would soon be completed. While there was clear value in harmonizing terminology, differences in domestic regulatory frameworks could make it difficult to adopt common definitions for domestic application. She welcomed efforts to organize key events alongside other critical WHO meetings and endorsed the proposal to make access to medicines a standing item on the agenda of the Health Assembly.

On the domestic front, the Canadian Government was introducing a series of regulatory changes aimed at lowering the costs of medicines, stopping excessive pricing practices, making new medicines more swiftly available and protecting consumers. It was also supportive of initiatives to improve access to life-saving vaccines and medicines for the world's most vulnerable and hard-to-reach populations, which could be significantly enhanced by working with global partners such as the GAVI Alliance, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the STOP TB Partnership. Noting that it would not be possible to conclude the discussion of what was a very complex issue in one session, she expressed support for the proposal to include the item on the agenda of the 142nd session of the Executive Board in January 2018 and was of the view that it should be a standing item on the agenda. She also supported the proposal to hold consultations on the item prior to the 142nd session of the Executive Board.

The representative of ECUADOR said that his Government aimed to ensure that free, safe and effective essential medicines were readily available and accessible, but that many such medicines were hard to access for market-related reasons. The Government had little room to negotiate with suppliers, and individual interests were protected to the detriment of collective rights and the equal distribution of health care resources. Some medicines were not available in their generic form, which had a budgetary impact and made it difficult to attain domestic and global targets. The Government was working to eliminate patent-related barriers; indeed, it was fundamental to ensure that the right to health and life was weighed against intellectual property rights when considering access to medicines. In addition, steps should be taken to strengthen all systems aimed at promoting access to medicines, the use of flexibilities under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), joint procurement and negotiation, price-fixing mechanisms, national or regional State production, and research, and technical support provided to ensure that related policies were properly implemented.

To ensure access to life-saving medicines, Member States should continue to invest in and sustain their national health systems and eliminate conflicts of interest with the pharmaceutical industry. Furthermore, robust account should be taken of the recommendations of the High-level Panel. While shortages were a major aspect of the complex issue of access to medicines, so was the unequal distribution of resources across the globe. He therefore endorsed the proposal to make the issue a standing agenda item.

The representative of PAKISTAN commended the Organization's work to address the global shortage of medicines and vaccines. Access to quality, safe and effective medicines required a comprehensive health systems approach that addressed all stages of the medicines value chain, from needs-based research to manufacturing processes and systems. It was essential that medicines should be available and affordable to all.

The representative of JAPAN said that access to medicines and vaccines was key to achieving universal health coverage; weakening intellectual property rights would not serve that common goal. Research and development activities benefited not only industries but also people around the world, and the intellectual property system played a critical role in providing incentives. Because access to medicines and vaccines was a multifaceted challenge, the discussion could not focus on intellectual property protection alone. The High-level Panel's report was extremely limited in scope, did not adequately consider past discussions at United Nations and WHO meetings, and had not been drawn

up in a Member State-led process. The challenges of access to medicines and vaccines required a comprehensive approach and consideration of the multiple factors and joint activities presented in the WHO, WIPO and WTO study entitled Promoting access to medical technologies and innovation: Intersections between public health, intellectual property and trade. He endorsed the proposal to include the item on the agenda of the 142nd session of the Executive Board

The representative of ETHIOPIA, speaking on behalf of the Member States of the African Region, said that universal health coverage would be achieved only when access to safe, effective, quality and affordable essential medicines and vaccines was ensured. Effective national medicines policies, implemented in accordance with good governance principles, were important. He commended the United Nations Secretary-General for having convened the High-level Panel.

He welcomed the draft definitions relating to both the supply and demand sides of the issue. The African Region was seriously affected by national and regional shortages of medicines, vaccines and medical devices, including during public health emergencies; distribution and affordability were also problematic.

All stakeholders should make a joint effort to strengthen national production, information on demand and supply, and notification systems in relation to medicines, vaccines and medical devices, which should be subject to clear price regulation and cost transparency. Financial and material aid should not be limited to, or earmarked for, certain products or brands. WHO should step up efforts to help Member States develop quality-assurance systems for medicines, vaccines and medical devices, in the light of the challenges posed by substandard and falsely labelled medical products. The WHO prequalification process should take into account and encourage local manufacturing of quality medicines, vaccines and medical devices, and WHO should help Member States build their capacity to support the efforts of local manufacturers to engage in good manufacturing practices.

The representative of INDONESIA said that clear and functional definitions of stock outs and shortages were crucial to the development of an advanced notification system for medicines and vaccines at risk of shortage. The definitions needed to be accompanied by clear guidance to avoid misunderstandings and unintended repercussions. To that end, input from Member States was important. Supply-chain management remained a complex issue in Indonesia, which promoted the active involvement of all stakeholders in an effort to tackle the problem. His Government looked forward to sharing its experience and participating in the broader Member State consultation.

The representative of THAILAND said that reducing shortages and ensuring better access to medicines and health technologies required a strong early detection mechanism and prevention and mitigation strategies. Systems to monitor shortages and responses should engage all relevant stakeholders. Supply-side shortages were more common for products made by companies that had a market oligopoly or monopoly and for certain orphan drugs. Member States were encouraged to establish good governance in pharmaceutical management systems. The issue of affordability could be addressed in a number of ways, including price controls, bulk purchasing, strengthening of local manufacturing capacities and support for technology transfers. In her country's experience, strategic purchasing by insurance funds had significantly brought down the price of certain high-cost monopoly medicines and other medical products.

The representative of SURINAME, referring to two Caribbean regulatory systems for ensuring access to quality pharmaceuticals, said that her country had benefitted from PAHO and WHO support to that end. She congratulated WHO for its programme on the prequalification of medicines and vaccines. A firmer stand should be taken, however, against action that unnecessarily exposed health care systems and people to medicines that were too costly. Medicines that were developed with the assistance of public funds and data from primary health care systems across the world should be available for a fair price. Firm measures should be taken against pharmaceutical companies that had

obtained exclusive rights to medicines previously in the public domain and available at a reasonable price, as sudden price increases jeopardized health systems. The same effort put into research and development guidelines for medicines and vaccines for communicable and neglected diseases should be devoted to the development of innovative medicines, vaccines and other health technologies for chronic diseases.

The representative of MALAYSIA, referring to the shortages of combined inactivated poliovirus-acellular pertussis vaccine, said that the sudden introduction of at least one dose of inactivated poliovirus vaccine into national immunization programmes had caused a spike in demand. ln order to ensure sustainability in immunization programmes and access to medicines, the Secretariat should support the implementation of previous related Health Assembly resolutions, especially with regard to ensuring vaccine affordability for middle-income countries and setting up pooled procurement mechanisms to leverage economies of scale. She suggested pooling resources to prioritize the redistribution of medicines and vaccines to countries that needed them. She supported the recommendation to include the item on the agenda of the 142nd session of the Executive Board.

The representative of ARGENTINA said that her country had been working with the Southern Common Market (MERCOSUR) and PAHO on the issue of joint procurement. The Secretariat's report was technically correct, as each situation had to be identified as either a supply- or demand-side problem. However, some of the terms used, in particular "shortage" and "supply", needed to be clarified as there was some ambiguity in the draft definitions. Conceptual and homogenous definitions were needed in view of the numerous intermediaries involved in supply and demand. It should be possible to interpret the definition in the light of the value chain and a given situation. That would facilitate not only the conceptual interpretation of problems relating to the identification of causes but also the design of appropriate measures.

The representative of the UNITED REPUBLIC OF TANZANIA thanked the Secretariat for the progress made towards addressing the global shortage of medicines and vaccines, an issue that was also addressed in Sustainable Development Goal 3. Subsequent work should take into consideration the many factors influencing access to quality, safe and effective medicines: research, development and innovation, the capacity of national regulatory authorities, domestic pharmaceutical production, selection of medicines, pricing and reimbursement, efficient procurement, supply chain management, sensible prescribing and rational use. To that end, the planned broader Member State consultation should involve experts and stakeholders from developing countries. He expressed support for the inclusion of the item on the agenda of the 142nd session of the Executive Board.

The representative of the UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND said that the Secretariat's comprehensive report on access to medicines and vaccines clearly articulated the barriers to access and supported the proposals it set out. The issue of access had to be addressed comprehensively, promoting the use of intellectual property in a way that was oriented towards public health needs, while recognizing the crucial role intellectual property played in stimulating research and innovation. Her Government had reservations regarding the findings in the High-level Panel's report and the process used to reach them. She supported the proposal to include the item on the agenda of the 142nd session of the Executive Board.

The representative of BAHRAIN, speaking on behalf of the Member States of the Eastern Mediterranean Region, said that Member States should allocate sufficient funds to allow for compliance with good manufacturing practices and ensure the supply of quality products at risk of shortage. To that end, WHO should help Member States document best practices to improve access to medicines and establish regulatory mechanisms on essential medicines susceptible to shortage; review the WHO Model List of Essential Medicines to identify products or active pharmaceutical ingredients

at risk of shortage owing to the limited interest of manufacturers; help Member States address medicine and vaccine shortages and the underlying causes thereof by developing a global medicine shortage notification system; support Member State efforts to regulate health products through standardization and networking initiatives, regional or country-specific training programmes and information-sharing; and help Member States engage in policies, good practices and capacity-building to improve governance, efficiency and the quality of procurement and supply-chain management in both routine and emergency situations.

The representative of INDIA said that his Government had initiated a series of measures to improve the quality of medical products, such as investment in the national regulatory structures, the competency of which had been confirmed by the WHO global benchmarking tool in February 2017. According to the report of the High-level Panel, shortages of medicines resulted from incoherencies in the policies of the various international agencies concerned, and could be addressed by utilizing TRIPS flexibilities and sharing the fruits of research and development. Cooperation between international organizations and Member States must be strengthened to that end.

The representative of the UNITED STATES OF AMERICA said that, while improving access to medicines remained a priority, preserving incentives for innovation was something to which all Member States should contribute. All action by WHO and its governing bodies must originate in a Member State process, which the High-level Panel was not. Because its mandate was fundamentally flawed, the Panel was an inappropriate starting point for such action; in addition, implementation of its recommendations could have negative unintended consequences. The panel of experts conducting the overall programme review of the global strategy and plan of action on public health, innovation and intellectual property was expected to complete its work by the end of 2017, and it was important that Member States prepare for discussion of the issue well in advance of the 142nd session of the Executive Board. His delegation would accept no proposal on the item other than to place it on the Executive Board agenda.

The representative of KAZAKHSTAN, acknowledging the major role played by WHO and other international organizations in combating the appearance of substandard and falsified medical products when medicines and vaccines were in short supply, especially in developing countries, said that vaccine-importing countries in particular required WHO assistance for the regulation of vaccine procurement in line with national immunization schedules. Mechanisms could be developed to eliminate the need for intermediaries, which often impeded national procurement and transportation procedures, and to ensure that countries did not acquire too few or too many vaccines. Vaccination refusal was another, emerging problem, the consequence of vaccine safety and quality issues and of misinformation. Proper advocacy and communication activities were needed to ensure that vaccination efforts reached the people for whom they were intended. He fully endorsed the proposal to address the issue at the 142nd session of the Executive Board.

The representative of the REPUBLIC OF KOREA said that the issue of access to medicines required a multidimensional approach that took account of the many factors involved: public health system resilience, health insurance, intellectual property policy, facilitating research and development. Her Government, for its part, had been working to build public–private partnerships to ensure a reliable supply of essential medicines and had established a vaccine development group that had recently helped develop a cholera vaccine. It would continue to share information on the supply of essential medicines and collaborate with WHO and Member States in that regard.

The representative of TUNISIA described the measures taken by her country to respond to shortages of medicines, and thanked WHO and the Tunisia Country Office for their support for the establishment of a special committee and an evaluation process for comparability studies on biosimilar

medicines. She expressed support for the proposal to address the issue at the 142nd session of the Executive Board.

The representative of YEMEN said that his Government's efforts to ensure access to essential medicines and vaccines had received support from neighbouring countries and the Gulf Cooperation Council, but were hamstrung by the ongoing conflict, which made distribution to health centres difficult. The already considerable cost of medicines on the local market was skyrocketing, especially when those medicines were in short supply, further restricting the population's access to them. His Government required further support from WHO and other specialized agencies and organizations to safeguard the health of the Yemeni population.

The representative of BOTSWANA highlighted the importance of ensuring access to medicines and vaccines in line with the Sustainable Development Goals, and agreed that the matter should be discussed at the 142nd session of the Executive Board. Botswana continued to face challenges related to access to medicines, and had launched initiatives to address them and promote the rational use of medicines. Much remained to be done, however, and she therefore fully appreciated the efforts of the Organization and the High-level Panel in that regard. She looked forward to the broader Member State consultation on implementation of the actions set out in the report, including the harmonization of terminology.

The representative of SOUTH AFRICA, referring to the Berlin Declaration of the G20 Health Ministers, urged WHO to work closely with the G20 and other stakeholders to ensure that previous resolutions on antimicrobial resistance were fully implemented by all Member States. South Africa continued to experience shortages of both old and new vaccines; WHO must therefore take urgent action to ensure that supplier-related shortages were addressed. She endorsed the proposal to discuss the issue at the 142nd session of the Executive Board.

The representative of MOROCCO said that access to medicines, vaccines and medical equipment was a basic human right and that the issue should be considered from that perspective. The item must be studied again in collaboration with other international organizations, especially WIPO; she therefore endorsed the proposal to discuss it at the 142nd session of the Executive Board.

The representative of NIGERIA said that vaccine availability had been a major issue during a recent outbreak of meningitis in his country, when it had become clear that the manufacturing and procurement regulations on certain medical commodities, especially vaccines, posed a challenge during emergencies. The Nigerian Government was therefore considering manufacturing some of those commodities locally, to safeguard the health of citizens. WHO assistance for countries with such plans should be explored at the 142nd session of the Executive Board.

The representative of SRI LANKA said that access to medicines was a fundamental right and outlined a number of measures taken by the national authorities in recognition of that fact.

The representative of BRAZIL endorsed the proposal to include the issue of access to medicines on the agenda of the 142nd session of the Executive Board and as a standing item on the Health Assembly agenda. The High-level Panel had been given a clear mandate and had followed due process; its membership was broad-based and its report contained many recommendations directly relating to items on the agendas of the Health Assembly and the Executive Board, and to the alignment of WHO with the health-related Sustainable Development Goals, including target 3.b. Document A70/20, on the other hand, did not fully cover the magnitude of the issue, and the Secretariat should

therefore increase the pace and depth of its analysis ahead of the 142nd session of the Executive Board.

The representative of AFGHANISTAN said that geographical factors and security problems had had a negative impact on access to essential medicines in Afghanistan. Smuggling of medicines had become commonplace and most essential medicines had to be imported from neighbouring countries. To tackle such issues, the Government had recently established a national medicine and health product regulatory authority and had adopted a national good governance framework for medicines and vaccines. It would welcome the support and expertise of WHO and Member States with strong regulatory systems, to strengthen implementation of those initiatives.

The observer of the INTERNATIONAL FEDERATION OF RED CROSS AND RED CRESCENT SOCIETIES said that the draft technical definitions of "shortage" and "stock out" should emphasize the need to identify them at all points in the supply chain. They should also provide specific guidance on reaching displaced and migrant populations and incorporate the latest guidance on the use of dose-sparing strategies. Shortages of medicines and vaccines were often related more to inequitable pricing structures and other economic factors than to poor stock management or global availability. Those factors should therefore be taken into account when addressing supply shortages.

The representative of the GLOBAL HEALTH COUNCIL, INC., speaking at the invitation of the CHAIRMAN, said that barriers to access should be approached using a comprehensive, long-term approach that effectively addressed the affordability, availability and acceptability of medicines and vaccines. He urged WHO to devise clearer technical definitions of "shortage" and "stock out", address the unmet need for research and development of medicines for children, and improve access to essential medical technologies for noncommunicable diseases.

The representative of the INTERNATIONAL ASSOCIATION FOR HOSPICE AND PALLIATIVE CARE, INC., speaking at the invitation of the CHAIRMAN, said that his organization remained concerned at the enormous scale of unnecessary suffering caused by the inaccessibility of indispensable opioid pain medicine. She therefore urged WHO to engage in more effective promotion of safe and balanced access to essential controlled medicines and to provide training for health care workers in palliative care and evidence-based pain control.

The representative of the INTERNATIONAL PHARMACEUTICAL FEDERATION, speaking at the invitation of the CHAIRMAN, urged WHO to identify products at higher risk of being in short supply, consider the impact of procurement strategies on shortages and find solutions that allowed for better access to information on supply shortages and stock outs.

The representative of the INTERNATIONAL PHARMACEUTICAL STUDENTS' FEDERATION, speaking at the invitation of the CHAIRMAN, said that the global response to the Ebola virus disease outbreak had demonstrated the value of public–private partnerships, which had resulted in the acceleration of vaccine development and clinical trials. He therefore urged WHO to promote the use of public–private partnerships as a means of increasing the global availability and accessibility of medicines and vaccines.

The representative of KNOWLEDGE ECOLOGY INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that WHO should draft a new resolution to address the transparency issues surrounding the availability and accessibility of medicines and vaccines. The resolution should include references to prices and manufacturing costs, including data on costs relating to research and development, and information on clinical trial outcomes and adverse effects. WHO

should also work to address incoherence between policies to promote innovation and to achieve universal access and ensure that the costs of research and development were de-linked from market prices.

The representative of MÉDECINS SANS FRONTIÈRES INTERNATIONAL, speaking at the invitation of the CHAIRMAN, expressed disappointment at the actions of certain Members States to delay urgently needed negotiations. Essential medical care was being rationed owing to high prices and unity was required, at least among countries ready to address the issue. WHO and health ministries should address the systemic policy incoherence that had led to the creation of the High-level Panel, including action on high drug prices and lack of patient-driven innovation. She welcomed the separate discussion on shortages, and urged the Organization to identify medicines at risk, estimate the scale of shortages and stock outs, and ensure the establishment of data collection mechanisms in that regard.

The representative of the MEDICINES PATENT POOL, speaking at the invitation of the CHAIRMAN, said that, through its voluntary licensing and patent pooling model, his organization's work supported the public health-oriented management of intellectual property rights with a view to accelerating access to affordable medicines in low- and middle-income countries. Its licences with the pharmaceutical industry were non-exclusive, to ensure competition, and consistent with the use of TRIPS flexibilities, enabling up to 130 low- and middle-income countries to access quality-assured generics. The organization currently had licences on 15 medicines for HIV, hepatitis C and tuberculosis, including nine formulations on the WHO Model List of Essential Medicines, and new patented medicines in other areas had been submitted for inclusion. An exploratory assessment of the potential expansion of the patent pooling model had been launched with the support of the Swiss Government, pursuant to recommendations by WHO and the Lancet Commission on Essential Medicines, during which his organization would consult with key stakeholders.

The representative of MEDICUS MUNDI INTERNATIONAL – INTERNATIONAL ORGANISATION FOR COOPERATION IN HEALTH CARE, speaking at the invitation of the CHAIRMAN, said that the current system of market-driven research and development clearly failed to address public health needs effectively. The report of the High-level Panel constituted a unique opportunity to revive discussion of intellectual property rights and access to medicines within WHO. It was therefore unfortunate that the Organization had so far failed to hold a comprehensive debate on the report and had not endorsed its recommendations. Her organization supported the proposal to discuss the issue as a standing agenda item at Health Assemblies.

The representative of the WORLD HEART FEDERATION, speaking at the invitation of the CHAIRMAN, said that people living with cardiovascular disease suffered acutely from poor access to medicines, and yet, collaboration and innovative solutions could secure reliable access to essential medicines. For example, shortages of individual cardiovascular medicines could be avoided by combining cost-effective, generic cardiovascular drugs into one single medicine, or "polypill", thereby simplifying supply chains and improving affordability, access to treatment and patient adherence. The inclusion of the polypill on the WHO Model List of Essential Medicines was currently pending; in the meantime, WHO should help Member States include generic cardiovascular drugs on national essential medicines lists, in existing formulations.

The representative of the INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS AND ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, said that timely dialogue was required between manufacturers and public health authorities to prevent shortages, anticipate changes in national health programmes, ensure more accurate demand forecasting, and reduce and harmonize regulatory approval times for post-approval changes and

in-country testing for lot release. Unfortunately, much of the discussion to date had focused on the report of the High-level Panel, which had been given an overly narrow mandate based on a false premise. The biopharmaceutical industry considered that neither the report nor its recommendations could serve as a sound basis for further consideration or action by the United Nations system.

The representative of STICHTING HEALTH ACTION INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that her organization was encouraged at the growing willingness of the United Nations and many Member States to confront issues of market exclusivity and monopoly pricing. Given the importance of both topics, WHO should provide a dedicated space for detailed discussion of the applicability of the recommendations made by the High-level Panel, which built directly on the progress made by the Consultative Expert Working Group on Research and Development: Financing and Coordination and by the global strategy and plan of action on public health, innovation and intellectual property, and were clearly aligned with those of the Organization's own experts. Many of the High-level Panel's recommendations were explicitly directed at both the Organization and its Member States and should be addressed collectively.

The ASSISTANT DIRECTOR-GENERAL (Health Systems and Innovation), responding to points made, expressed appreciation for the continued interest shown by Member States in discussing what was an important, complex matter and the hope that discussions would focus on practical strategies. The Secretariat had recently announced a pilot project for prequalification of biosimilar monoclonal antibodies for the treatment of cancer. It was hoped that the availability of high-quality alternatives to high-priced products would significantly increase access to such life-saving medicines. The Secretariat would continue its work on efficient and effective regulation, as strong regulatory systems were key to ensuring high-quality, locally produced essential medicines. With partners that included UNICEF and the GAVI Alliance, the Secretariat was tackling shortages of inactivated poliovirus vaccine, yellow fever vaccine and others by accelerating prequalification procedures and improving forecasting and demand intelligence.

She acknowledged the support of the Netherlands and the European Union in organizing the Fair Pricing Forum 2017. Greater price and cost transparency, both for research and development and for production, would be important to ensuring access to medicines in line with the Sustainable Development Goals. The Health Assembly had often discussed the need to de-link the price of medicines from the cost of research, and to achieve that goal both prices and costs should be known. So-called "value-based pricing" proposed to link prices to societal value, which would be unacceptable to public payers and patients in need.

Several Member States had raised points that should be addressed, such as the transition from donor financing, strategic local production, and a mechanism for effective pool procurement. She took particular note of the comments made by the representative of Portugal regarding a new agreement among some European Union countries on that matter that would be a valuable source of experience. With regard to the comment made by the representative of Canada concerning internal coordination, the Secretariat was planning to continue its work on access to medicines as a matter of priority, complemented by work on strengthening health systems and coordinated across the three levels of the Organization.

The Committee noted the report.

The DIRECTOR-GENERAL, underscoring the importance and complexity of the subject, recalled that two proposals had been made: that the matter should be included as a standing item on the agenda of future Health Assemblies, and that it should be discussed by the Executive Board at its session in January 2018. With a view to helping Member States reach agreement on how to proceed, the Secretariat had held informal consultations with some delegations that favoured the former approach but had indicated their willingness to be flexible, which was appreciated.

The representative of SOUTH AFRICA reiterated the proposal made by her delegation the previous day to the effect that the report of the High-level Panel should be discussed as a separate agenda item by the Executive Board.

The DIRECTOR-GENERAL clarified that the suggestion put forward was to include an item on addressing the global shortage of, and access to, medicines and vaccines on the agenda of the Executive Board for its January 2018 session.

The CHAIRMAN took it that the Committee agreed to that course of action.

It was so agreed.

Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products: Item 13.6 of the agenda (documents A70/23, A70/23 Add.1 and Add.2, and EB140/2017/REC/1, decision EB140(6))

The CHAIRMAN drew attention to the report by the Director-General on the item, contained in document A70/23, and to the report on the review of the mechanism, contained in document A70/23 Add.1. She invited the Committee to consider the draft decision contained in the report by the Director-General in the light of the recommendation made by the Executive Board in decision EB140(6), contained in document EB140/2017/REC/1. The financial and administrative implications for the Secretariat of the adoption of the draft decision were set out in document A70/23 Add.2.

The representative of INDIA welcomed the progress made by the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products and endorsed the outcome of its fifth meeting, including the definitions set out in Appendix 3 to the report thereof. The report should serve as the basis for the formulation of a further implementation strategy. Member States should work in harmony on issues concerning the regulation of substandard and falsified medical products. A study should be undertaken of the linkages between lack of access and the emergence of such products, further to work already conducted by the Secretariat in that area and as recommended by the Member State mechanism.

The representative of IRAQ highlighted a number of important measures in the fight against spurious medical products. Health audits should be carried out, including at borders and in all private sector institutions, and there should be collaboration between the public and private sectors. Comprehensive procurement policies were vital, and individual and institutional capacity-building needed. The Organization should support Member State activities to eliminate SSFFC medical products and to share information about unreliable or unaccredited companies, and all WHO regions should cooperate to establish a system to tackle the issue.

The representative of BARBADOS welcomed the new definition of counterfeit medicines and noted the need for sound national criminal legislation and regulatory frameworks, underpinned by proportionate sanctions, to address the SSFFC issue in a consistent and balanced manner. The existence of such products affected all regions and posed an unacceptable risk to public health. Welcoming the data-collection and knowledge-sharing activities of WHO in that area, she requested the Organization to provide support to Member States for the development of strategies to anticipate and prevent shortages and encourage transparent procurement practices; support in that regard had already been received at the regional and subregional levels in the Region of the Americas. WHO should also pursue its activities with Member States and relevant stakeholders in areas such as policy development, identification of good practices, data collection and analysis, and the issuing of alerts.

Regulatory strengthening and capacity-building support were also needed, together with assistance on communication with health care professionals and other stakeholders throughout the supply chain

The representative of CÔTE D'IVOIRE, speaking on behalf of the Member States of the African Region, said that SSFFC medical products posed a danger to public health and socioeconomic development and thus hampered progress towards the Sustainable Development Goals. In the African Region, such products had led to the re-emergence or spread of certain diseases; thousands of deaths each year were associated with antimalarial and anti-tuberculosis medicines. In addition, legal medicines distributors and States had seen a considerable reduction in revenue as a result of the introduction of substandard or falsified products. He gave a brief overview of global and regional instruments aimed at combating SSFFC medical products to which Member States of the Region had contributed, and expressed concern at the insufficient funding of the Member State mechanism, which should be given particular attention. Insufficient access to and shortages of affordable medicines provided fertile ground for the introduction of substandard or falsified medical products. WHO should therefore draw on the recommendations of the United Nations Secretary-General's High-level Panel on Access to Medicines to strengthen its efforts to end the deadly scourge from a public health and right-to-health perspective. The Member States of the African Region supported the replacement of the term "substandard, spurious, falsely-labelled, falsified and counterfeit medical products" by "substandard and falsified medical products".

The representative of NIGERIA said that measures taken in his country to improve the detection, prevention, tracking and tracing of SSFFC medical products included laboratory upgrades, deployment of detection and prevention technologies, and the promotion of local manufacturing of medicines and medical products. Nigeria was also implementing guidelines on good distribution practices for pharmaceutical products and a national policy on quality assurance for medicines and other health products, among other things. WHO and other development partners must help developing countries implement track and trace technologies. His delegation supported the use of the new term "substandard and falsified medical products".

The representative of the PHILIPPINES welcomed the Organization's work on terminology. Her country accepted the use of the simplified term "substandard and falsified medical products", which was clearer than "substandard, spurious, falsely labelled, falsified and counterfeit medical products". It would facilitate common understanding among Member States and improve public awareness, thereby promoting easier recall. Intellectual property rights should be excluded from the scope of the Member State mechanism, as interventions should focus on the quality, safety and efficacy of medical products.

The representative of the RUSSIAN FEDERATION, emphasizing the importance of international cooperation on the issue and expressing appreciation to China for its part in investigating recent crimes, welcomed the high-quality output of the Member State mechanism. Its recommendations were particularly valuable in the context of his country's efforts to ratify the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health. A pilot track and trace project had been launched in the Russian Federation earlier in 2017. The experience gained could be of use to other Member States. He expressed support for the change in terminology, as the term "substandard and falsified medical products" shifted the focus away from intellectual property issues towards the humanitarian perspective. Priority actions for the Member State mechanism should be to expand its Internet presence, prepare recommendations on the most significant types of offence and develop the global exchange of information. He supported the suggestions made in the report of the fifth meeting of the Member State mechanism, annexed to document A70/23.

The representative of VIET NAM welcomed the fact that the guidance on SSFFC medical products contained in the report of the fifth meeting of the Member State mechanism could be applied not only in countries with robust health regulatory systems, but also in poor countries. The agreement on working definitions of those medical products would help strengthen international and regional cooperation and enhance the effectiveness of efforts to combat them. However, the variation in definitions applied by different countries in practice hampered international cooperation efforts. Viet Nam was reviewing its pharmaceutical regulatory and quality management systems and promoting social mobilization in order to improve the quality control of medicines at the national level.

The representative of PAKISTAN said that SSFFC medical products constituted global and local health threats and required an effective, public health-based response. In countries with weak or non-existent regulatory systems and surveillance infrastructure, the problem was potentially more severe. Pakistan had therefore taken steps to modernize its medicines regulatory authority in line with international best practice.

The representative of the DOMINICAN REPUBLIC said that his country currently lacked the technological and regulatory capacity fully to implement the guidance contained in appendix 1 of the report of the Member State mechanism. The Ministry of Health nevertheless conducted ordinary and extraordinary inspections to detect SSFFC medical products and penalize offenders. The fight against those products could only be successful if complemented by ongoing awareness-raising and consumer education strategies.

The representative of the UNITED REPUBLIC OF TANZANIA commended the consensus reached on the definition of SSFFC medical products, and the replacement of the term by "substandard and falsified". The consensus on working definitions would facilitate the implementation of national action plans. His country had strengthened its national regulatory system to monitor the quality and safety of medical products and participated in the implementation of the East African Community Medicine Regulatory Harmonization Project.

The representative of THAILAND supported the use of the term "substandard and falsified" and its definition. Noting that some of the activities set forth in the report of the Member State mechanism had not been completed, she highlighted the need for a future workplan and sufficient additional resources to make the mechanism stronger and more successful. Effective communication, collaboration and information-sharing across all three levels of the Organization were also crucial to the mechanism's effectiveness. In order to combat SSFFC medical products successfully, building national capacities was critical.

The representative of JAPAN said that WHO should not engage in framework-building for intellectual property rights, as it did not have primary expertise in that area; it should instead focus on threats to public health, the economy and society. He stressed that the change in terminology did not mean tolerating the infringement of intellectual property rights, the protection of which should be taken into consideration in ongoing discussions on SSFFC medical products. Rather, it was intended to clarify discussion of SSFFC medical products in the WHO context; the use of "counterfeit" was important to protect intellectual property rights and therefore should not be discouraged in other contexts. It was crucial to improve access to medicines, secure the integrity of the supply chain and establish better regulatory systems for medical products.

The representative of NEPAL supported the use of the new term "substandard and falsified medical products". Like other developing countries, Nepal currently lacked the tools and capacities to detect such medicines. She called on WHO to support national efforts to strengthen regulatory

capacities, develop and share tools and mechanisms, improve information-sharing among regulatory authorities and develop regional and global collaboration between laboratories.

The representative of ANGOLA said that the definition of "substandard and falsified medical products" should include aspects related to their illegal sale. In Angola, most such products were sold on the informal market. Weak regulatory frameworks, difficult access to quality control laboratories and inadequate legislation were among the key challenges to be addressed.

The representative of the UNITED STATES OF AMERICA expressed his satisfaction with the progress made in turning the Member States mechanism into a viable, functioning venue. His delegation looked forward to the outcome of the study on the public health and socioeconomic impact of SSFFC medical products, and would work with others to promote its use to inform public health and public policy dialogue following publication.

The representative of KENYA supported the use of the term "substandard and falsified medical products". Kenya would prepare a national plan for preventing, detecting and responding to actions, activities and behaviours that resulted in SSFFC medical products, in line with the guidance contained in appendix 1 of the report of the Member State mechanism. The pharmaceutical industry and Member States must work more closely to introduce and implement authentication technologies for the prevention and detection of such products. His delegation endorsed the working definitions as contained in appendix 3 of the report, in particular the exclusion of the protection of intellectual property rights from the mechanism's mandate and the application of the criteria set out in the definitions to its deliberations and work.

The representative of INDONESIA said that collaboration among relevant stakeholders was crucial to prevent and combat SSFFC medical products. The guidance contained in appendix 1 of the report of the Member State mechanism, if properly implemented, could help countries strengthen national regulatory systems. An integrated digital supply chain monitoring system should be developed to facilitate tracking and tracing of SSFFC medical products. Her delegation supported the use of the new term "substandard and falsified medical products". Indonesia was following with interest the smartphone application pilot project, which had improved reporting of SSFFC medical products to regulatory authorities, and was pleased with regional cooperation efforts to improve reporting capacities.

The representative of SENEGAL, noting the serious consequences of SSFFC medical products, particularly for developing countries, said that tackling the issue required the harmonization of practices and definitions. In his country, efforts had included the establishment of a national committee and a publicity campaign on the dangers of using SSFFC medical products. He expressed support for the proposed draft decision and urged the Secretariat to help Member States with their national strategies to tackle substandard and falsified medical products.

(For continuation of the discussion, see the summary record of the tenth meeting, section 1.)

The meeting rose at 12:30.

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