World Health Organization

SEVENTIETH WORLD HEALTH ASSEMBLY **A70/A/PSR/8**
26 June 2017

COMMITTEE A

PROVISIONAL SUMMARY RECORD OF THE EIGHTH MEETING

Palais des Nations, Geneva
Friday, 26 May 2017, scheduled at 14:30

Chairman: Dr H. M. AL-KUWARI (Qatar)
later: Mr P. DAVIES (Fiji)
later: Dr H. M. AL-KUWARI (Qatar)

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EIGHTH MEETING

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Chairman: Dr H. M. AL-KUWARI (Qatar)
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HEALTH SYSTEMS: Item 13 of the agenda (continued)

Evaluation and review of the global strategy and plan of action on public health, innovation and intellectual property: Item 13.4 of the agenda (document A70/21) (continued from the seventh meeting, section 3)

The representative of MALAYSIA welcomed the evaluation and agreed with the recommendation on strengthening efforts to tap into traditional medicinal knowledge by boosting local research and development, enhancing educational and training efforts, and negotiating partnerships with high- and upper-middle-income countries. With regard to the transfer of technology, the Secretariat should make a platform available for sharing information on technology transfer between Member States. Although WHO had made efforts to enhance awareness of the use of flexibilities under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), it should also provide support for capacity-building on the technical and legal aspects of mitigating the effects of "TRIPS-plus" provisions in free trade agreements.

The representative of SOUTH AFRICA, speaking on behalf of the Member States of the African Region, said that although some of the objectives of the global strategy and plan of action on public health, innovation and intellectual property had been met, others had not, and the limited success reported in low-income countries was a particular cause for concern in the African Region. She supported the recommendation for an overall programme review in 2017. While the recommendations set out in the evaluation report were numerous, their implementation would contribute significantly to improving access to safe, affordable and quality medicines in Africa and to strengthening global research and development efforts. Investment in activities to implement the recommendations should be increased.

The representative of MEXICO said that intellectual property considerations, especially patents, should be included in the work of health policy-makers, which should be linked to the discussions on the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, in particular in the context of the use of traditional medicines. Implementation of the recommendations of the evaluation would lead to the adoption of public policies with measurable outputs, and must include the engagement of all relevant actors. The results of the evaluation should be shared with all stakeholders, including representatives of academic institutions, standard-setting authorities, and public and private entities involved in public health. The Government of Mexico had established an observatory for health investigation, and was making efforts to mainstream a culture of intellectual property considerations into the work of health institutions, through awareness-raising campaigns, analyses of data on patents and the dissemination of information on intellectual property. The Government was participating in a

consortium on transnational global research and innovation on health, and was sharing information with the aim of using laboratory findings to develop new medicines and treatments.

The representative of SAUDI ARABIA said that although efforts were being made to modernize hospitals and provide state-of-the-art health services, it was difficult for the Ministry of Health of Saudi Arabia to meet health service provision needs without additional support. Innovation was promoted in Saudi Arabia and encouraged through a national competition, which was organized and judged jointly by the Ministry of Health and representatives of the private sector.

The representative of INDONESIA said that research and development in new medicines was crucial to improve global health and attain the Sustainable Development Goals. Research on the medicinal value of biodiversity was key to meeting the need for new medicines. The Indonesian Government was therefore promoting research into traditional medicines and the use of local content in the pharmaceutical industry. WHO should support Member States in their application of the TRIPS Agreement, particularly with regard to compulsory licensing and parallel imports of medicines and vaccines. Intellectual property regulations should not jeopardize public access to medicines and vaccines. The Indonesian Government had conducted a self-assessment of its implementation of the global strategy and had found its progress to be on track. She encouraged the Secretariat to provide support to Member States in implementing the global strategy.

The representative of INDIA said that his Government had conducted a self-assessment and had begun working on the development of an information-sharing platform.

The representative of the PHILIPPINES said that the Government of the Philippines had enacted legislation on the accessibility of affordable, quality medicines, which embodied the flexibilities afforded by the TRIPS Agreement. That notwithstanding, drug prices in the Philippines were among the highest in Asia. The use of TRIPS flexibilities was therefore crucial for addressing current and emerging health challenges. The Government intended to expand social health insurance coverage with a view to reducing out-of-pocket expenses, which were often used to purchase essential medicines. He agreed with the recommendations set out in the evaluation report with regard to delinking the final cost of medicines from the cost of research and development; making drug price data transparent; increasing industry accountability; and strengthening government commitment to increase investments in health.

The representative of THAILAND noted with concern the uneven progress in implementation of the global strategy and plan of action across low-, middle- and high-income countries. She commended the work of the Regional Office for South-East Asia, which had supported Member States in the Region in conducting self-assessments, the results of which were not only useful to guide implementation, but also fostered country ownership of the global strategy and plan of action. She expressed concern that the budget for implementation of the global strategy and plan of action had to compete with other programme activities under WHO programme budget category 4.3 on access to medicines and health technologies and strengthening regulatory capacity. Given the importance of implementing the global strategy and plan of action for the attainment of target 3.b of the Sustainable Development Goals, the Secretariat should do its utmost to safeguard the budget and mobilize additional resources to that end.

The representative of ECUADOR said that his Government had approved legislation on knowledge and innovation, which set out the regulations for intellectual property and was essential for knowledge management and ensuring that access to knowledge and innovation benefited the whole of society, including the owners of intellectual property rights. Governments should have robust, transparent mechanisms for reaping the benefits of patents and promoting innovation to meet public

health needs. The international community should collaborate with WHO in establishing a high-level group to develop a plan of action to facilitate technology transfer, in order to strengthen national policies on health products and increase sharing of knowledge and information on best practices between countries. Technical support must be provided to enable countries to strengthen capacities for the transfer and development of technology. All Member States should use TRIPS flexibilities, and international organizations should support low- and middle-income countries in applying TRIPS flexibilities through the application of article 31bis of the TRIPS Agreement.

The representative of PAKISTAN said that the global strategy and plan of action was the key to promoting new thinking on innovation and access to medicines, and securing an enhanced and sustainable basis for needs-driven essential health research and development on diseases that disproportionately affected developing countries. He welcomed the evaluation and commended the work of the Secretariat in supporting Member States in their implementation of the global strategy and plan of action.

The representative of SENEGAL said that lower-middle- and low-income countries should develop research policies and multisectoral action plans on innovation, and should strengthen public–private partnerships for research and development. Member States of the African Intellectual Property Organization should establish an interministerial committee to work on the development of generic medicines. The benefits of the TRIPS Agreement should be optimized, and partnership synergies should be enhanced.

The representative of VIET NAM said that the evaluation report had accurately observed the implementation status of the global strategy and plan of action in lower-middle-income countries, such as Viet Nam, where a lack of funding and support was a common problem. Several of the evaluation recommendations were being implemented in Viet Nam, including the promotion of upstream research; cooperation between the public and private sectors; strengthening efforts to tap the unrealized potential of traditional medicinal knowledge; mobilization of sustainable financial resources for health technology innovation; and cooperation between the Government and stakeholders to improve the enabling environment for technology transfer.

The representative of BANGLADESH said that there was a dearth of research on neglected tropical diseases and vaccine production in developing countries. Bangladesh was making efforts to enhance technology transfer and identify gaps in research and development with regard to medicines and vaccines, in particular on diseases that disproportionately affected developing countries. Technology transfer was key to enhancing research and development in countries with limited resources. In order to make use of TRIPS flexibilities, research was being conducted on generic formulations of vaccines and drugs; affordable oral cholera vaccines and rotavirus vaccines had thereby been made available on the domestic market. Developing countries had much to gain from implementing the global strategy and plan of action.

The representative of KNOWLEDGE ECOLOGY INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that the evaluation report was disappointing. It framed research and development market failures narrowly and failed to acknowledge that lack of access to medicines was also a market failure. The global strategy and plan of action seemed to have no relevance to patients or taxpayers in higher-income countries. North–South divides had contributed to blocking reforms that would only benefit developing countries. To play a meaningful role in reforming the global research and development financing system, benefits must be more inclusive. Lastly, the evaluation report failed to mention delinkage, which was the only reform that would eliminate conflicts between innovation and access.

The representative of the MEDICINES PATENT POOL, speaking at the invitation of the CHAIRMAN, said that the Medicines Patent Pool was an example of successful implementation of the global strategy and plan of action as a mechanism to promote transfer and access to health-related technologies. Transparency of patent status information was crucial. The Medicines Patent Pool had launched an online platform to enable stakeholders to understand the intellectual property status of priority HIV, hepatitis and tuberculosis medicines in low- and middle-income countries. Further expansion of that tool was being considered.

The representative of the WORLD FEDERATION OF PUBLIC HEALTH ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, encouraged all stakeholders to apply mechanisms to protect health, enhance prevention and promote health and well-being, and to harness knowledge and skills through strong community engagement. He called on governments to enable all sectors involved in public health to further develop public health functions and quality health systems as global public resources. All sectors should be held accountable for the health impacts of their policies and actions.

The representative of STICHTING HEALTH ACTION INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that the evaluation fell short in its recommendations and unfairly blamed low-income countries for weak awareness and leadership. That conclusion was unfounded, given the commitment shown by stakeholders in those countries despite considerable political resistance. He urged Member States to enhance efforts to restructure biomedical research and development systems in order to include mandatory contributions to future initiatives under the global strategy and plan of action and integrate the recommendations concerning delinkage.

The representative of MÉDECINS SANS FRONTIÈRES INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that the evaluation report merely restated the problem originally identified in the report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health, namely that there was insufficient investment in research and development for diseases that mainly affected lower-middle- and low-income countries. It also neglected key elements of the global strategy and made recommendations that were sometimes at odds with its conclusions. He expressed concern that the evaluation report did not mention the need for a possible essential health and biomedical research and development treaty, as set out in the annex to resolution WHA61.21 (2008). In addition, the recommendation that Member States should ensure that health research and development at the national and subnational levels was prioritized was too vague and unclear. Consequently, the evaluation report did not provide a sound basis for informing the overall programme review planned for 2017.

The REPRESENTATIVE OF THE DIRECTOR-GENERAL (Evaluation and Organizational Learning) thanked speakers for their valuable comments and suggestions, which would help to advance implementation of the global strategy and plan of action. Specific comments and suggestions would be shared with the overall programme review panel.

The Committee noted the report.

Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination: Item 13.5 of the agenda (document A70/22)

The representative of BAHRAIN said that the list of specific health conditions in paragraph 4(a) of Annex 1 to the report should include a reference to chronic noncommunicable diseases, tobacco use, obesity and unhealthy lifestyles. Those issues were of particular importance in the Arabian Gulf countries. He also suggested that, with a view to facilitating the work of the Global Observatory on

Health Research and Development, reference should be made in paragraph 6 of Annex 1, to drug licensing and the registration and follow-up of clinical trials.

The representative of INDIA strongly supported the proposal to create a voluntary pooled fund for health research and development, including for his country's projects. More resources would be required to advance research and development.

The representative of the RUSSIAN FEDERATION noted with satisfaction the establishment of the Global Observatory on Health Research and Development and agreed with its workplan. Particular attention should be paid to research on antimicrobial resistance and diseases of epidemic potential. She also agreed with the scope of the Expert Committee on Health Research and Development and hoped that its remit would include medical products and technologies.

Mr Davies took the Chair.

The representative of SWITZERLAND said that it was time to take stock of progress achieved since the adoption of resolution WHA66.22 (2013). He welcomed the further development of the Global Observatory on Health Research and Development and the establishment of the Expert Committee on Health Research and Development. The proposed operational plan to create a voluntary pooled fund was welcome, and would allow resources to be allocated to priority areas of research and development. However, funding for the demonstration projects remained insufficient, and the Swiss fund for matching contributions from low- and middle-income countries had not been fully utilized. The Swiss Government stood ready to match future contributions. To date, interest in setting up the voluntary pooled fund had been limited. It was time to move beyond the strategic workplan endorsed in resolution WHA66.22 (2013) and explore complementary voluntary ways to strengthen coordination and financing of global health research and development. Inclusive partnerships, including with low- and middle-income countries, would be needed in that regard.

The representative of INDONESIA supported the proposed creation of a voluntary pooled fund, but advised that the mechanism for pooling funds must ensure transparency, accountability and information sharing among all stakeholders. The Secretariat should facilitate collaborative research among Member States under a single topic, such as Type III diseases, but using funds from individual countries, in order to boost the development of products with shared patents.

The representative of ANGOLA, speaking on behalf of the Member States of the African Region, welcomed the proposals contained in the report and supported the proposed workplan and budget for the Global Observatory on Health Research and Development and the creation of a voluntary pooled fund. All six of the demonstration projects would provide important contributions to health research. Medicines and vaccines developed using the voluntary pooled fund must be accessible, affordable, effective and good quality, and the costs of investment in research and development should be delinked from the volume and price of the resulting health products. It was clear that additional resources were required. A stronger case for research and development needed to be made to development partners, Member States and all relevant stakeholders, including ministries of science and technology, and agriculture, and innovative approaches must be explored. The research and development initiative provided an opportunity to develop new products to achieve the goals of the 2030 Agenda for Sustainable Development. The Member States of the Region looked forward to stronger regional efforts in terms of coordination and priority-setting for research and development.

The representative of IRAQ said that research and development was strongly linked to the development of national health plans, given the need for scientific data to draft and successfully

implement those plans. WHO must therefore provide support for implementation of the proposals contained in the report and ensure that sufficient financing was made available for research and development projects.

The representative of THAILAND observed that the shortfall in the overall budget posed challenges to the successful implementation of demonstration projects and the functioning of the Global Observatory on Health Research and Development. He expressed concern that the annual minimum funding of US$ 100 million for the voluntary pooled fund over a 10-year period was therefore too ambitious. Moreover, Member States' contributions to the fund were likely to be limited, owing to the global financial crisis and austerity measures. Private-sector support might be more realistic, but potential conflicts of interest would have to be carefully monitored under the Framework of Engagement with Non-State Actors. The operational plan for the voluntary pooled fund must focus on both fundraising and effective spending and its priorities should be aligned with financial capacity and political reality.

The representative of COLOMBIA emphasized the importance of a holistic, integrated and coordinated approach to WHO research and development initiatives. Successful implementation of the Global Observatory on Health Research and Development, the voluntary pooled fund and the demonstration projects was essential and would prove that alternative models for promoting research and development for accessible, suitable medicines were possible. The Global Observatory should make more information available, in particular on chronic diseases, which would help in priority–setting and decision-making. A meeting should be organized to enable Member States to assess progress, continue discussions on the action plan contained in resolution WHA66.22 (2013) and the points agreed in resolution WHA69.23 (2016), and address the recommendations of the United Nations Secretary-General's High-level Panel on Access to Medicines.

The representative of GERMANY said that her Government's recent contributions to the Global Observatory on Health Research and Development and the demonstration projects were evidence of the importance it attached to combating poverty-related and neglected tropical diseases. She agreed with the comments made by the representative of Thailand that activities should be prioritized within the context of available funding and that the development and financial capacity of the voluntary pooled fund should be based on the experience of past years.

The representative of the UNITED STATES OF AMERICA expressed disappointment that the demonstration projects had received so little funding and that non-traditional donors had not been successfully encouraged to contribute to health research and development. If a feasible path for achieving the goals of the voluntary pooled fund was not established in the near future, WHO might have to consider ending the initiative, which risked diverting attention and resources away from more viable work.

The representative of the BOLIVARIAN REPUBLIC OF VENEZUELA supported the initiative to establish national and regional observatories and the proposal to create a voluntary pooled fund. His Government would introduce the workplan at the national level, in accordance with the regulatory framework in force.

The representative of SOUTH AFRICA said that progress in implementing the initiatives related to innovation and affordable access to medicines had been slow due to limited funding. The only way to ensure the timely development and availability of new and better quality medicines, vaccines and diagnostic tools was for Member States and other stakeholders to increase investment in health research and development. She therefore supported the workplan and the proposal to create a voluntary pooled fund. Interested countries should meet to discuss how to strengthen the proposed

voluntary pooled fund, as innovative ways to finance that work were clearly needed. For example, South Africa was part of the new 3P Project that aimed to "push" for up-front financing, "pull" in research and development via financial incentives, and "pool" data and intellectual property. She urged the Secretariat to prioritize full implementation of the global strategy and plan of action on public health, innovation and intellectual property, and called on Member States to support that process.

The representative of BANGLADESH said that the Global Observatory on Health Research and Development had produced visible results. Research scientists were already making use of the data made available by the Global Observatory. He called for more effective programmes for research and training in tropical and noncommunicable diseases and nutrition, and financial and technical support for low- and middle-income countries. He welcomed the creation of the Asia Pacific Observatory on Health Systems and Policies, which should focus on the Region's specific needs and provide advice to country offices. He agreed with the findings of the report and called for greater progress to be made.

The representative of MALDIVES welcomed the contributions made by Member States to minimize the financial gap for the implementation of the demonstration projects; however, a more tangible and sustainable financial mechanism was needed to further minimize the funding gap. Moreover, financing options for the proposed voluntary pooled fund should be further explored, and resources mobilized for the establishment of the Global Observatory on Health Research and Development. It was vital to create and strengthen the research capacities of smaller developing countries to enable them to participate fully in the implementation of the strategic workplan for the Global Observatory. Proper management of voluntary donations was essential to mitigate the effect of conflicts of interest in the project selection process.

The representative of ARGENTINA said that it was imperative to find new and innovative options to ensure the availability of sustainable financing for research and development. With regard to paragraph 9 of Annex 2 to document A70/22, she said that the proposed use of priority review vouchers had not been amended to reflect the analysis of the Consultative Expert Working Group on Research and Development. Moreover, the proposed use of social impact bonds would not achieve the delinking of price and costs. It was therefore important to define basic requirements for a sustainable voluntary pooled fund; the new funding mechanism should take into account the role of Member States in mobilizing resources for and implementing the fund, particularly in terms of prioritization of diseases and projects. In addition, more information was needed on the proposed intellectual property management model, together with a detailed analysis of how that model would encompass the principles of the Consultative Expert Working Group on Research and Development and the objectives of the global strategy and plan of action on public health, innovation and intellectual property. The recommendation of the Consultative Expert Working Group to establish a binding agreement based on Article 19 of the WHO Constitution should be considered.

Turning to the terms of reference of the Global Observatory on Health Research and Development contained in Annex I to the report, she proposed that, in paragraph 4(a), the word "Compile" should be inserted at the beginning of the sentence, and the words "specific health conditions" should be replaced by "Type II and Type III diseases and on the specific research and development needs of developing countries in relation to Type I diseases, as well as, where appropriate, for other products with insufficient investment in research and development".

The representative of KNOWLEDGE ECOLOGY INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that, although worthwhile, the proposal to organize a specific high-level event ignored the goal of building a new framework for funding research and development that was needs-driven and consistent with the objective of access to medicine for all. In order to truly achieve access to medicines for all, delinkage should be on the agenda each time public sector funding

of research and development and any related reforms were discussed. Moreover, implementation of the Global Observatory on Health Research and Development should be more ambitious; for example, the Global Observatory should collect and make available data on research and development investment flows, the costs associated with specific clinical trials, and the role of governments in funding drug development.

Dr Al-Kuwari resumed the Chair.

The representative of STICHTING HEALTH ACTION INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that the basic failures in research and development would never be solved through fragmented and underfunded initiatives. Scaling back on the medical research and development framework would have severe consequences in future. The core principles of the Consultative Expert Working Group on Research and Development should be applied to all WHO-led initiatives on research and development, which should be conducted in coordination with other United Nations bodies. He encouraged WHO to convene an open-ended meeting on the follow-up of the report, which should include the first negotiations on a global research and development framework, as requested in resolution WHA69.23 (2016). Member States should consider introducing mandatory financial contributions in order to ensure sustainable development.

The representative of the INTERNATIONAL UNION AGAINST TUBERCULOSIS AND LUNG DISEASE, speaking at the invitation of the CHAIRMAN, said that although there was a desperate need for new vaccines, diagnostics and treatments for tuberculosis, investment in research and development in that area had fallen substantially. The Union was involved in the 3P Project, which rewarded and funded drug and regimen developers throughout the pipeline and facilitated collaboration via the sharing of intellectual property and data, resulting in affordable medicines that were delinked from the cost of investment in research and development. She encouraged WHO to ensure that the principles of the Consultative Expert Working Group on Research and Development were maintained and that new research and development models, such as the 3P Project, were supported.

The representative of MEDICUS MUNDI INTERNATIONAL – INTERNATIONAL ORGANISATION FOR COOPERATION IN HEALTH CARE, speaking at the invitation of the CHAIRMAN, said that despite recommendations in many forums, a research and development convention had not yet been negotiated; he encouraged WHO to convene an open-ended meeting to initiate discussions in that regard. All WHO-led research and development initiatives, including those on antimicrobial resistance, such as the proposed global development and stewardship framework, should adhere to the principles of affordability, effectiveness, efficiency, equity and delinkage. WHO should also advocate adherence to those principles in external research and development initiatives.

The representative of the GLOBAL HEALTH COUNCIL, INC., speaking at the invitation of the CHAIRMAN, encouraged the rapid operationalization and full funding of the Global Observatory on Health Research and Development. Recognizing the need for new and innovative sources of funding for both the Global Observatory and the proposed voluntary pooled fund, he cautioned that such funding should not come at the expense of existing successful programmes. He expressed concern that some of the funding for the demonstration projects had been provided with conditions attached; such an approach ran contrary to the principle of an independent pooled funding mechanism. Transparency was therefore essential to ensure that the Global Observatory and the voluntary pooled fund were based on sound science and public health.

The representative of MÉDECINS SANS FRONTIÈRES INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that reform of the way in which research and development was

prioritized, financed and conducted was essential. She encouraged Member States to align research and development incentives with public health needs through a global framework so as to ensure that efforts were coordinated effectively. In its current state, the Global Observatory on Health Research and Development did not provide the comprehensive data needed to prioritize and coordinate decisions on research and development, especially since the indicators selected did not include any of the core principles identified by the Consultative Expert Working Group on Research and Development. More information was needed on how the Global Observatory would provide sufficient data to inform Member States' priority-setting and investment decisions.

The ASSISTANT DIRECTOR-GENERAL (Health Systems and Innovation) welcomed speakers' interest in an item that remained critically underfunded and thanked those Member States that had provided support, including financial resources, for the Secretariat's work on the strategic workplan of the Consultative Expert Working Group on Research and Development. She encouraged the use of the Global Observatory on Health Research and Development, which was an interesting resource for analysis of the research and development landscape. The Global Observatory would continue to be expanded and updated as resources and information became available and WHO would proceed with the establishment of the proposed Expert Committee on Health and Research Development. With regard to the demonstration projects, she noted that no new resources had been pledged beyond the US$ 11 million raised over the previous three years; it would therefore be necessary to inform the proponents of the six projects that they would not receive further financial support before their unfinished projects were officially closed later in the year. Turning to the proposed voluntary pooled fund, she said that the Secretariat would inform the Board of the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases that the Health Assembly did not wish to pursue that proposal any further.

The Committee noted the report.

Addressing the global shortage of, and access to, medicines and vaccines: Item 13.3 of the agenda (document A70/20) (continued from the seventh meeting, section 3)

The representative of INDIA, supported by the representative of the UNITED STATES OF AMERICA, recalled that the discussion of the item had been suspended at the previous meeting to enable informal discussions to take place. In the light of those discussions, he proposed that the subject should be included on the agenda of the 142nd session of the Executive Board, to be held in January 2018.

The representative of COLOMBIA welcomed that proposal and said that Member States should hold consultations on the item prior to the 142nd session of the Executive Board.

The representative of BANGLADESH, speaking on behalf of the Member States of the South-East Asia Region and expressing support for the proposal made by the representative of India, said that ensuring access to effective, quality and affordable essential medicines and vaccines was vital for the achievement of the Sustainable Development Goals. Although data on stock outs were limited, such events did occur and he therefore welcomed the technical definitions drafted by the Secretariat on shortages at the supply and demand side and would welcome further consultations on those definitions. Several countries in the Region had the capacity and expertise to produce sufficient medicines to prevent shortages within the Region and to minimize the global risk of shortages, but only if information on shortages of specific medicines was collected in a timely manner. Support from the Secretariat to strengthen countries' regulatory capacities would be essential in that regard. Nevertheless, some Member States in the Region had limited or no production facilities and required

extra support to improve access to quality medicines and vaccines through bilateral or multilateral agreements or regional support from WHO. Public funding for research and development was needed and it was essential to delink prices from research and development costs. Good governance, transparency and accountability throughout the supply chain were also of particular importance. Lastly, he called for action in response to the recommendations of the United Nations Secretary-General's High-level Panel on Access to Medicines.

The representative of FRANCE recalled that, during the 140th session of the Executive Board, Member States had requested that the item should be included on the agenda of the current Health Assembly. She therefore did not understand why there was a suggestion to defer the item to the 142nd session of the Executive Board. Any discussions on the postponement should take place within a transparent framework with appropriate consultation of all Member States. If the matter was to be discussed, a document should be issued in that regard.

The representative of SOUTH AFRICA, supported by the representative of ETHIOPIA, said that there continued to be many people in the world that still did not have access to safe, quality medicines, due to difficulties related to selection, pricing, prescribing and their rational use. Regulatory and procurement systems remained weak in many countries, and age appropriate medicines for children were needed. United Nations agencies needed to work together to achieve coherence in their efforts, and careful thought and dialogue through an effective consultation mechanism were vital. Access to medicines could be made a standing item on the agenda of the Governing Bodies to make it clear that the issue would be discussed at the Seventy-first World Health Assembly. Moreover, the Director-General elect should be given time to study the report.

The representative of VIET NAM affirmed her Government's commitment to improving equitable access to safe, effective, quality and affordable essential medicines and noted that Member States needed to develop specific plans and policies on access to medicines. The challenges faced in her country included difficulty procuring pharmaceutical starting materials and problems supplying medicines with modest demand and medicines for treating rare diseases. She agreed with the draft technical definition of shortages and stock outs of medicines and vaccines set out in the report. Development of a database on the global supply of medicines for treating rare diseases should be prioritized.

The representative of SENEGAL said that Member States needed to implement programmes to ensure access to safe, effective, quality and affordable essential medicines for all. A comprehensive health systems approach was needed and quality, safety and effectiveness should be monitored throughout the pharmaceutical value chain. He drew attention to two significant disruptions in vaccine supply in 2016 and 2017, concerning the yellow fever vaccine in central Africa and the inactivated poliovirus vaccine.

The representative of the NETHERLANDS said that access to medicines affected developing and developed countries alike and her Government wished to have a comprehensive and transparent discussion on all aspects of the issue. Alongside the work of WHO, commitments from Member States, industry and civil society were all important. At the first WHO Fair Pricing Forum, which had taken place in the Netherlands, participants had emphasized the need for greater transparency on pricing inputs, highlighted reservations about value-based pricing, and noted the need for governments to work together for fair medicine prices. Her Government had recent experience of joining with others to negotiate a price with the pharmaceutical industry. Although no agreement with the industry had been reached, the joint rejection of the industry's offer due to its high price sent out an important signal. Governments should take up positions on fair pricing and continue working with the Secretariat towards that goal. She called upon Member States to engage in new business models and

market-shaping initiatives to move towards real solutions. She urged WHO to take a firm position on improving the legislative environment and preserving TRIPS flexibilities with regard to public health.

The representative of LEBANON noted that shortages of essential medicines would hinder progress towards achieving target 3.8 of the Sustainable Development Goals. Describing the efforts made in Lebanon to supply essential medicines to all, regardless of nationality, she expressed support for a comprehensive health systems approach and the new initiative on fair pricing. She supported work to design a framework for more detailed considerations of the technical definitions of shortages and stock outs, since functional definitions varied according to context. The Secretariat's work on health data management as part of the Health Data Collaborative was commendable.

The representative of EGYPT echoed the conclusions of the report of the United Nations Secretary-General's High-level Panel on Access to Medicines, which had been adopted by consensus. The Secretariat should consult Member States on ways to follow up on those recommendations, including by making access to medicines a standing item on the agenda of the Governing Bodies. He welcomed the entry into operation of the Global Observatory on Health Research and Development and the joint work of WHO and the Drugs for Neglected Diseases initiative, and valued Secretariat support for Member States on issues related to the quality and safety of medicines. The links between accessibility and affordability, and the emergence of substandard and falsified medicines required further research; the WHO global surveillance and monitoring system should collate and examine data on those links. He encouraged Member States to make full use of TRIPS flexibilities and requested that the Secretariat should continue providing guidance on that matter. Systematic efforts by Member States were required and action should be led by WHO. He expressed support for further consultations on the technical definitions.

The representative of SOLOMON ISLANDS, detailing efforts made in his country, said that, while his Government was committed to ensuring access to quality and affordable medicines and vaccines, the issue remained one of the major obstacles to universal health coverage in small island developing States. His country's low population and the long distances between medicine manufacturers, suppliers and end users resulted in high medicine costs. He therefore reiterated calls for help for smaller countries through initiatives such as pooled procurement of commonly used medicines and vaccines. He urged the Secretariat to maintain access to medicines and vaccines as a top priority and to make technical support available to all Member States, with special consideration for small island developing States.

The representative of PANAMA said that WHO had a crucial role to play in intervening when there was a shortage of essential medicines and verifying whether medicines and vaccines were truly accessible. While her Government was making efforts to ensure access to medicines and vaccines, mechanisms to deal with shortages and stock outs were poor. Small and developing States should receive support through strategic funds and joint purchasing to overcome the challenges of having a small pharmaceutical sector. She welcomed the report and said that her Government stood ready to help the Secretariat, in cooperation with other Member States, to implement the measures it contained.

The representative of GREECE said that, in Europe, the economic crisis had exacerbated the problem of access to medicines. Particular issues included the financial burden of treating noncommunicable diseases, the scarcity of medicines to treat rare diseases and the withdrawal of medicines by manufacturers due to low prices. Access to medicines and vaccines was a global problem that required a global solution, including the initiatives introduced by WHO. A common language to define the problem, integrated communication between countries and data sharing for transparency were all lacking. His Government was participating in a joint initiative with other south

European countries to address access to health care and health system sustainability. Outlining the steps taken in his country on access to medicines, he said that any discussion of the topic was useful.

The representative of BRAZIL said that he supported the proposal to include the item on the agenda of the 142nd session of the Executive Board, and the suggestion that it should be made a standing item on the agenda of the Governing Bodies. While he would have preferred separate discussions on access to medicines, and medicines shortages and stock outs, because the two issues were not necessarily directly linked, he welcomed the opportunity to arrive at a common understanding on a critically important area of health. The affordability of access to health care would become ever more important at the technical and political levels as government budgets were affected by health care costs. If the item was included on the agenda of the 142nd session of the Executive Board, the Secretariat should prepare a report to form the basis of the discussion, with relevant technical information. The outcomes of discussions at the WHO Fair Pricing Forum and the conclusions of the report of the United Nations Secretary-General's High-level Panel on Access to Medicines should also be properly discussed at WHO.

The representative of ALGERIA welcomed the opportunity to address the issue of access to medicines, which was a far-reaching problem that merited a separate agenda item. The attention afforded the issue at the highest level, including in the recommendations made in the report of the United Nations Secretary-General's High-level Panel on Access to Medicines was commendable, since access to medicines, vaccines and other medical products was crucial, particularly in low- and middle-income countries, in order to control potential epidemics, combat antimicrobial resistance and achieve the Sustainable Development Goals. It should be borne in mind that the high cost of medicines, coupled with intellectual property barriers, encouraged the propagation of substandard and falsified medical products. In view of the need for more in-depth analysis of access to medicines and vaccines, he expressed support for the proposal made by India and seconded by the United States of America.

The representative of ANGOLA said that the development and implementation of national policies on medicines shortages and access to medicines was fundamental. Shortages and stock outs of medicines and vaccines could aggravate existing health issues, such as antimicrobial resistance and low-level implementation of vaccination programmes. Despite the availability of financial resources, yellow fever vaccines had not been available in a timely manner during an outbreak of the disease in her country in 2016. She welcomed work to develop a notification system for medicines and vaccines at risk of shortage.

The representative of SLOVAKIA said that the Secretariat's report had laid solid foundations for future work. A good supply of medicines was essential for functioning health systems. It was in the common interest to tackle shortages of medicines and vaccines, especially medicines to treat cancer and hepatitis C, and medicines for children, which were often protected by patents. He supported continued efforts at the global level to ensure fair pricing, develop a notification system for medicines and vaccines at risk of shortage and investigate the causes and scale of shortages of medicines and vaccines.

The representative of SWITZERLAND said that access to medicines and vaccines was affected by supply- and demand-side issues. Affordability could be improved through policies to ensure fair pricing and to boost the incomes of populations and provide them with insurance coverage. Governments bore primary responsibility for ensuring access to medical products and could take measures to remove barriers by establishing appropriate legal and policy frameworks to ensure timely marketing authorization for high-quality products, optimizing the laws, regulations and agreements applicable to the health sector, and allocating resources to health more efficiently. Access was a shared

global responsibility which required strategic partnerships that brought together public research entities, the pharmaceutical industry, nongovernmental organizations and multilateral agencies. His country's contribution to equitable global access involved a comprehensive approach that combined supply- and demand-side measures. A more comprehensive perspective on access and an inclusive partnership approach was needed to achieve health and well-being for all.

The representative of the BOLIVARIAN REPUBLIC OF VENEZUELA said that the Secretariat should provide additional resources to support Member States' efforts to ensure access to medicines and should examine how intellectual property regimes and the high prices of medicines exacerbated medicine and vaccine shortages. The Secretariat should also take action to ensure that manufacturers and suppliers participated in a notification system for medicines and vaccines at risk of shortage and demonstrated greater concern for patient welfare. States must enjoy greater authority to regulate medicines and implement mitigation strategies, including accelerated and collaborative registration procedures and globalized purchasing through agreements between States in cooperation with international agencies. The report of the United Nations Secretary-General's High-level Panel on Access to Medicines, which should be discussed by Member States, indicated that the cost of health technologies was a particular challenge for developing countries; the international health community must adopt measures to address that issue. The pharmaceutical industry had frequently sought to frustrate the interests of the Venezuelan people. His Government had adopted a declaration in support of the recommendation in the Secretary-General's report that the United Nations General Assembly should discuss the adoption of a strategic framework to accelerate work on access to medicines. He agreed with the proposal to include the item on the agenda of the 142nd session of the Executive Board.

The representative of NORWAY said that, although he supported patent-based research and development for medicines and other medical products, the market had failed to address certain public health needs. Supplementary mechanisms, such as product development partnerships, were needed to facilitate research and development on areas such as neglected tropical diseases and antibiotics. Public health authorities should set conditions to promote the accessibility and affordability of medicines developed through such partnerships. Barriers to access in the supply chain and national health systems should be addressed by national health authorities with technical support from WHO. The technical definitions and the notification system being developed by the Secretariat could help mitigate the negative effects of shortages of medicines.

The representative of CHILE said that the Secretariat should enhance efforts to address medicines shortages and stock outs, recognizing that the development and supply of medicines was not always aligned with public health needs. Governments should be encouraged to produce essential medicines with a view to addressing national or regional shortages. Support to help governments and organizations centralize the purchasing of essential medicines should be strengthened. The Secretariat should support regional negotiations to achieve fair prices. Further study of price-setting mechanisms was needed to ensure that prices were linked to development and production costs, rather than industry expectations. Discussion of the topic should be continued at the 142nd session of the Executive Board in January 2018.

The representative of the CONGO said that urgent action was required to tackle significant shortages of medicines and vaccines in his region of Africa, which experienced shortages of yellow fever vaccine, antibiotics, medicines for children and medicines to treat neglected tropical diseases and cancer. Access to medicines should be addressed through clear, coherent dialogue, and any working group established to consider the issue must have a clear mandate and terms of reference. Vested interests might seek to impede all efforts to enhance access to medicines. Item 13.6 of the agenda, Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical

products, should be discussed at the same time as the two topics under item 13.3 of the agenda. A special commission should make preparations to include the issue of the global shortage of, and access to, medicines and vaccines on the agenda of the 142nd session of the Executive Board and, subsequently, the agenda of the Seventy-first World Health Assembly.

The representative of NEPAL said that WHO could play a catalytic role in her country's efforts to address the high costs of medicines, which undermined access to health care. Although her Government was implementing resolution WHA67.22 (2014) on access to essential medicines, certain essential medicines were only available at high cost or were in short supply and there was limited national capacity to produce them. WHO should therefore facilitate collaboration among States within the South-East Asia Region with a view to procuring medicines from manufacturers at reasonable cost. The Secretariat should further support Member States to help them develop and implement treatment protocols to stem the inappropriate use of medicines, particularly antibiotics.

The representative of MEXICO expressed concern that inadequate supplies of, or access to, yellow fever, poliomyelitis and other vaccines could increase the risk of disease outbreaks in his country. WHO and other relevant international organizations must work closely with pharmaceutical producers and other stakeholders, on the sole basis of public health objectives, with a view to resolving shortages.

The representative of PORTUGAL supported the statement by the representative of India and supported by the representative of the United States of America. Inadequate access to medical products affected all parts of the world and threatened the sustainability of health care systems. OECD had underscored that governments needed to work closely with industry and regulators to ensure that the development and use of new health technologies delivered more affordable and cost effective treatments. WHO should explore how greater transparency could be pursued in determining the costs of research and development of new medicines and how those costs were reflected in consumer prices. Six European Union ministers of health had recently signed the Valletta Declaration for better access to medicines, in which they had agreed to strengthen their collaboration to that end. He agreed that the item should be included on the agenda of the 142nd session of the Executive Board.

The representative of COSTA RICA welcomed the shared commitment of the international community to promoting the sustainable manufacture and access to medicines, and its commitment to promoting access to clinical studies of medicines. All Member States should establish strategic alliances to ensure the availability of high-quality medicines.

The representative of GHANA said that it was critical to address ongoing gaps between the supply and demand of certain drugs, and the high cost of some critically important medicines and vaccines, including snake antivenoms, rabies vaccines and certain medicines to treat cancer. The international community must move beyond setting definitions to develop strategies to mitigate or avoid shortages or stock outs of essential medicines and vaccines. Benchmarks must be set and support given to States to help them manufacture effective, quality and affordable medicines, and conduct local research. The Secretariat should scale up efforts to prequalify locally manufactured medicines, and work on pricing, reinvestment and affordability regulations. He aligned himself with the statement by the representative of South Africa and called for an item on access to medicines and vaccines to be included on the agenda of the 142nd session of the Executive Board, with a view to its consideration at the Seventy-first World Health Assembly.

The representative of CHINA said that domestic pharmaceutical companies in his country were encouraged to submit their medicines for WHO prequalification and comply with WHO production management standards. The Chinese authorities also prioritized approval for the production of

medicines to treat rare diseases and diseases that affected children. To address the global shortage of, and access to, medicines and vaccines, all stakeholders should strengthen collaboration and establish well-coordinated response mechanisms that fostered synergies.

The representative of GERMANY said that her Government was implementing a range of projects to address access to medicines. A holistic approach should be adopted, with a focus on access to medicines as a function of resilient health systems, taking into consideration links with other sectors, such as trade or industrial development. A balance must be struck between the need to promote and finance research into new and better medicines, ensure that medicines were accessible and affordable for all, and secure the sustainability of health systems. Considerable progress in global public health had been achieved, including through incentives for private-sector innovation based on the protection of intellectual property, public and private financing, and public sector research. She looked forward to further discussion of the topic at the 142nd session of the Executive Board.

(For continuation of the discussion, see the summary record of the ninth meeting, section 2.)

The meeting rose at 17:40.

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