

**PROVISIONAL SUMMARY RECORD OF THE ELEVENTH MEETING**

**WHO headquarters, Geneva  
Friday, 27 January 2017, scheduled at 14:30**

**Chairman: Dr R. BUSUTTIL (Malta)**

**CONTENTS**

	<b>Page</b>
<b>Health systems (continued)</b>	
<b>Evaluation and review of the global strategy and plan of action on public health, innovation and intellectual property .....</b>	<b>2</b>
<b>Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination .....</b>	<b>7</b>
<b>Member State mechanism on substandard/spurious/falsely-labelled/ falsified/counterfeit medical products.....</b>	<b>13</b>

## ELEVENTH MEETING

Friday, 27 January 2017, at 14:35

**Chairman:** Dr R. BUSUTTIL (Malta)

**HEALTH SYSTEMS:** Item 8 of the agenda (continued)

**Evaluation and review of the global strategy and plan of action on public health, innovation and intellectual property:** Item 8.4 of the agenda (documents EB140/20 and EB140/20 Add.1)

The CHAIRMAN invited the Board to take note of the report contained in document EB140/20 and to consider the draft resolution approving the terms of reference of the overall programme review contained in Annex 2 to the report. The financial and administrative implications of the draft resolution for the Secretariat were set out in document EB140/20 Add.1.

The representative of NEW ZEALAND said that, while the concept of the global strategy and plan of action on public health, innovation and intellectual property was sound, the report did not make a compelling case for continuation, or for a full and final evaluation. He would support those recommendations set out in Annex 1 to the report that concerned “business as usual” for WHO, including on health systems strengthening, promotion of public–private partnerships for research and development, use of flexibilities provided in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and regulatory strengthening. He would, however, hesitate to support many of the other recommendations, including for Member States to strengthen their monitoring and evaluation systems. He asked whether the continuation of the global strategy represented the best use of scarce resources; the Board might wish to consider stopping unnecessary further work and redirecting funding to higher priority programmes.

The representative of ALGERIA, speaking on behalf of the Member States of the African Region, said that the numerous challenges identified in the report, including insufficient investment in tackling priority health problems in lower-middle- and low-income countries, must be faced. The recommendations from the comprehensive evaluation outlined in Annex 1 to the report would require further study. He supported the terms of reference of the overall programme review set out in Annex 2. A review panel should be established at the earliest opportunity and its composition should respect gender balance and equitable geographical representation. It should take into account the expertise of key stakeholders, including WTO, WIPO and UNCTAD, as well as relevant recommendations contained in the report of the United Nations Secretary-General’s High-level Panel on Access to Medicines.

The representative of CANADA said that the amendment to the TRIPS agreement, which had recently entered into force, would help to improve access to affordable medicines for those in greatest need, and called for its swift implementation. She supported the establishment of a review panel with balanced representation, and sought clarification as to whether it would be mandated to consult stakeholders. Diverse membership and a broad consultative process would strengthen its work.

The representative of THAILAND expressed concern at the uneven implementation of the global strategy and plan of action among States. The South-East Asia Region was the only Region that had decided to conduct self-assessment, which was critical for raising awareness. Paragraph 1(a) of the

terms of reference of the overall programme review set out in Annex 2 to the report should be amended to read: “assess the continued relevance of the aim and objectives and the eight elements of the global strategy and plan of action;”. Paragraph 1(b) should be reworded along the following lines: “assess the implementation of the global strategy and plan of action and key barriers;”. Paragraph 1(c) should read: “review achievements, good practices and success factors as well as gaps, weaknesses and remaining challenges.”

The representative of VIET NAM said that the terms of reference of the overall programme review should mandate the review to: assess the feasibility of the global strategy in the context of the current global and national legal, financial and research and development environment; recommend a strategic approach to help WHO to perform its role in the implementation of the global strategy and the resources necessary for WHO to perform that role; determine mechanisms through which WHO could involve global, regional and national stakeholders to support the implementation of the global strategy at all levels; and recommend strategies to enhance the participation of WHO and global and regional stakeholders in Member States’ discussions of challenges in implementing the global strategy and plan of action.

The representative of CHINA, noting the indication in the report that the progress made was not necessarily a consequence of the global strategy and plan of action, expressed concern that Member States had not given sufficient attention to the implementation of the strategy and plan of action. Her Government stood ready to engage with WHO and other partners to get the most out of collaboration between developed and developing countries and between developing countries to spur technological innovation and boost pharmaceutical manufacturing capacity in developing countries. Intellectual property barriers must also be removed in order to improve low- and lower-middle-income countries’ access to medicines.

The representative of MEXICO said that greater focus should be given to health research and development in order to raise awareness and strengthen political will to allocate resources to relevant research centres. To promote implementation of the global strategy and plan of action, clear research and development priorities should be set and efforts made to improve access to knowledge, promote technology transfer and innovation in public health. He welcomed the terms of reference of the overall programme review in Annex 2 to the report and suggested that, once the key gaps and challenges to implementation of the global strategy and plan of action had been identified, a policy toolkit should be developed to monitor the implementation and impact of recommendations made.

The representative of the UNITED STATES OF AMERICA, endorsing the comments of the representative of New Zealand, said that the overall programme review should seek to identify areas of consensus on lessons learned from implementation of the global strategy and plan of action. Paragraph 1 of the terms of reference of the overall programme review should be amended to read along the following lines: “As directed in resolution WHA68.18 (2015), the overall programme review, as distinct from the evaluation, will be a more policy-oriented, forward-looking exercise. The review panel should seek to identify areas of consensus, in line with the 10 principles of the global strategy and plan of action (contained in the Annex to resolution WHA61.21(2008)). Guided by the report of the comprehensive evaluation and, where appropriate, taking into account other evidence and involving relevant stakeholders, including public and private sector entities involved in biomedical research and development, the programme review will:”. At the beginning of paragraph 1(b), the word “assess” should be replaced with “consider the evaluation of”. He proposed the addition of a new paragraph 1(c)bis that read: “ensure that over the course of the evaluation, there is appropriate input and review by the three agencies specified in resolution WHA61.21(2008) as implementers of the global strategy and plan of action, namely WIPO, WTO and UNCTAD”. He also proposed a new paragraph 2 that read: “The final report of the overall programme review of the global strategy and

plan of action, focusing on its achievements, remaining challenges and recommendations on the way forward, will be presented to the Seventy-first World Health Assembly in 2018 through the 142nd session of the Executive Board.”.

The representative of FIJI said that paragraph 1(a) of the terms of reference of the overall programme review did not suggest any actions to be taken in response to an assessment of the continued relevance of the aim and objectives of the global strategy and plan of action. Paragraph 1(d) should be amended to read: “based on an assessment of the costs and benefits of the global strategy and plan of action, determine whether it should be continued to 2022 and, if it is continued, provide details of what may need to be improved and modified in the next stage of its implementation;”.

The representative of COLOMBIA said that a holistic approach should be adopted with respect to the evaluation and continued implementation of the global strategy and plan of action, and highlighted the relevance of the report of the High-Level Panel on Access to Medicines. Frank and open discussions should be held with a view to negotiating an international instrument on the financing and coordination of health research and development, giving due consideration to the recommendations pertaining to the global strategy, the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination and the report of the High-Level Panel on Access to Medicines.

The representative of the UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND said that the global strategy and plan of action provided a comprehensive and coherent approach for action. WHO was best placed to continue to coordinate efforts in formulating collaborative solutions to the complex issues tackled in the global strategy and plan of action. Taking note of the report and approving the terms of reference would allow the overall programme review to move forward.

The representative of INDIA<sup>1</sup> said that, given the low level of awareness of the global strategy and plan of action, and the lack of monitoring and reporting systems identified, more should be done to promote and support implementation. The terms of reference of the overall programme review should provide for consideration of the recommendations of the High-Level Panel on Access to Medicines, and suggest ways in which the global strategy and plan of action could facilitate their implementation. They should also provide for the monitoring and analysis of public health implications of international agreements, including trade agreements, in line with the provisions of resolution WHA 56.27 (2003). The terms of reference should focus on effective implementation, and should not be used to reopen elements of the global strategy and plan of action. India had some concerns with regard to paragraph 1(a) of the terms of reference and stood ready to work with others in reaching a consensus on the revised terms of reference.

The representative of SWITZERLAND<sup>1</sup> said that more Member States should have participated in the valuable external evaluation. He commended the evaluation team’s decision to categorize countries on the basis of income, which facilitated the identification of countries’ specific challenges and ensured that those most in need would receive support. The review panel should adopt the same approach, and he hoped that its proposals would enjoy a consensus.

The representative of PANAMA<sup>1</sup> supported extending the deadline of the overall programme review to 2018. Panama’s National Health Research Agenda aimed to enhance the country’s

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

innovation capacity and intellectual property regimes and bolster the transfer of technology with a view to promoting innovation in public health. However, in common with other middle- and low-income countries, Panama was aware of its limitations in terms of knowledge and technical and financial capacity. WHO and other international organizations should promote implementation of the global strategy in countries where limited progress had been made. A balance must be struck between intellectual property rights and public health needs, and the flexibilities provided in the TRIPS agreement should be used to protect public health.

The representative of INDONESIA<sup>1</sup> said that her country needed to foster research and development so as to meet public health needs and strengthen synergies between institutions and ministries; challenges to be faced including promoting sustainable funding mechanisms and capacity-building. Indonesia recognized the importance of managing intellectual property to contribute to innovation and public health and would be pleased to report progress in implementing the global strategy results using WHO national assessment tools. She supported the proposal to extend the deadline of the overall programme review to 2018 and also supported the draft resolution.

The representative of SOUTH AFRICA<sup>1</sup> said that the global strategy on public health, innovation and intellectual property was particularly important for low- and middle-income countries, and questions concerning its continued relevance were surprising. She supported the proposal to extend the deadline of the overall programme review to 2018. Lack of awareness of the global strategy among Member States impeded its implementation, and further efforts should be made to encourage participation of Member States. The work of the High-Level Panel on Access to Medicines should be taken into consideration in the overall programme review.

The representative of BRAZIL<sup>1</sup> requested clarification on the selection procedure of the evaluation team and cost of outsourcing the preparation of the comprehensive evaluation. The report had a number of shortcomings and did not reflect the importance of the global strategy. Countries had been classified according to World Bank country income groups, which was not in line with Health Assembly resolutions. Other failings included: unclear methodology; a lack of expertise on intellectual property management among the evaluators; the absence of reference to the High-Level Panel on Access to Medicines; a disregard for the importance of public sector funding for research and development; no explanation provided for the lack of awareness of the global strategy; and insufficient assessment of the Secretariat's efforts to promote its implementation. Countries must receive support from the Secretariat to promote the use of flexibilities provided in the TRIPS agreement and the principles of the Consultative Expert Working Group on Research and Development: Financing and Coordination. The overall programme review should not be guided by the report of the comprehensive evaluation in view of the latter's shortcomings. Paragraph 1(a) of the terms of reference of the overall programme review should be amended to provide for an assessment of the implementation of the global strategy and plan of action by all actors, including the Secretariat, and the need for updates. Convergence between the global strategy and the work of the High-Level Panel on Access to Medicines should also be assessed.

The representative of the MEDICINES PATENT POOL, speaking at the invitation of the CHAIRMAN, said that her organization exemplified successful implementation of the global strategy and plan of action as a mechanism to promote transfer of and access to health-related technologies. The Medicines Patent Pool had initiated a feasibility study on expanding that mechanism to other patented essential medicines. New incentive mechanisms could promote the development of new

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tuberculosis regimens, an area requiring further policy experimentation. She looked forward to the implementation of additional mechanisms to fill gaps in innovation and access.

The representative of MEDICUS MUNDI INTERNATIONAL – INTERNATIONAL ORGANISATION FOR COOPERATION IN HEALTH CARE, speaking at the invitation of the CHAIRMAN, called for publication of the final evaluation report, and expressed concern about the limited awareness of the global strategy and plan of action. The executive summary did not refer to the work of the Secretariat or consider such key issues as high prices of medicines. It also failed to mention the pressure placed on certain developing countries to prevent the use of flexibilities provided in the TRIPS agreement, and did not pay due consideration to the findings of the High-Level Panel on Access to Medicines. Member States should demand a transparent and meaningful overall programme review, with clear terms of reference.

The REPRESENTATIVE OF THE DIRECTOR-GENERAL (Evaluation and Organizational Learning) thanked representatives for their comments and expressed his appreciation to the 68 Member States that had contributed to the evaluation. The procedure for selection of the evaluation team was clearly set out in documents EB138/38 and EB138/38 Add.1. Given the difficulties in defining the terms “developing countries” and “developed countries”, the evaluation team had proposed that reference should be made to the World Bank country income groups, a proposal that had been supported by the ad-hoc evaluation management group. The approach had been outlined in document EB138/38 Add.1, and Member States had been informed of it during a briefing after the 138th session of the Board in January 2016, and had raised no objections. As to the limited references to the High-Level Panel on Access to Medicines, he said that the evaluation had covered the period 2008–2015, whereas the High-Level Panel had been launched only in November 2015. In order to submit the report by December 2016, most of the evaluation work had been completed earlier that year. The evaluation team nevertheless considered the work of the High-Level Panel to be crucial. The full version of the report had been provided to all national focal points and missions in Geneva on 16 December 2016, and published on the WHO website on 20 December 2016. Efforts had been made to reach as many concerned parties as possible.

The ASSISTANT DIRECTOR-GENERAL (Health Systems and Innovation), expressing her appreciation for the comments made, said that the 18 members of the overall programme review panel had been selected from a pool of persons nominated by Member States on the basis of their technical expertise and experience at the international level; the need for gender balance and equal geographical representation had been recognized. The composition of the panel had been approved by the Officers of the Board. The panel would be convened shortly to commence the programme review. Matters raised regarding the implementation of the global strategy and plan of action would be considered once the terms of reference of the overall programme review had been approved.

**The Board noted the report.**

The CHAIRMAN suggested that consideration of the draft resolution and the terms of reference of the overall programme review could be postponed in order to allow the Member States concerned to hold informal consultations with a view to preparing an amended version of the text.

**It was so agreed.**

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

**Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination:** Item 8.5 of the agenda (documents EB140/21 and EB140/22)

The representative of THAILAND said that, despite considerable efforts, funding for the implementation of the strategic workplan endorsed in resolution WHA66.22 (2013) remained insufficient. Further reprioritization was required and raising awareness of the success of demonstration projects could help to attract donors. In the interests of transparency, the composition of the Expert Committee on Health Research and Development and the timeline for the selection process should be clarified. She endorsed the operational plan for the voluntary pooled fund and the terms of reference of the Global Observatory on Health Research and Development, and of the Expert Committee.

The representative of CANADA expressed support for the further formalization of the terms of reference of the Global Observatory. The application of open access principles to the Global Observatory would maximize its reach. Her Government supported, in principle, the establishment of a voluntary pooled fund as a means of addressing research and development priorities and was reviewing draft options for funding and the operational plan. A focused event prior to or following the forthcoming financing dialogue would be preferable to holding a specific high-level event before the Seventieth session of the World Health Assembly with the purpose of promoting increased investment in research and development

The representative of the RUSSIAN FEDERATION expressed support for the establishment and actions of the Global Observatory. Particular attention should be given to research on antimicrobial medicines for diseases with epidemic potential. She supported the terms of reference of the Expert Committee, and trusted that the Committee would make specific proposals on medical products and technology.

The representative of the DEMOCRATIC REPUBLIC OF THE CONGO, speaking on behalf of the Member States of the African Region, said that there should be a clear separation of responsibilities between the different entities. Particular emphasis should be placed on remedying the funding gaps for the six demonstration projects selected and for the Global Observatory. The Member States of the African Region were encouraged to participate in the mobilization of resources for the demonstration projects, particularly as the creation of an African observatory for research was being planned.

The representative of the UNITED STATES OF AMERICA said that the primary criterion for the selection of members of the Expert Committee on Health Research and Development should be extensive and successful experience in managing research and development. The Secretariat should also ensure the absence of potential conflicts of interest, and individuals from institutions with projects that were being funded or considered for funding should not be eligible to serve on the Committee. It was deeply disappointing that the demonstration projects had received so little funding and that there had been little success in encouraging non-traditional donors to contribute to health research and development. While he appreciated the Secretariat's further fundraising efforts, he said that if no feasible path was found to attract new contributions the relevant projects might have to be terminated as they could divert attention and resources away from more viable work. Until further financing was secured, the Expert Committee should limit any additional research and development approvals to shorter-term development projects.

The representative of CHINA welcomed the clear terms of reference of the Global Observatory. However, a feedback mechanism should be established to correct any possible errors resulting from

the overlapping of and discrepancies among the different areas for which data was collected. The Director-General should give careful consideration to the dates for and the duration of the Expert Committee's work and ensure that it provided effective and practical technical advice.

The representative of MEXICO said that it was important to promote policy coherence, including in the work of the Expert Committee on Health Research and Development and the Scientific Working Group. Regarding the sustainable funding mechanism, she emphasized the need for transparent operations with clear objectives that enhanced collaboration and knowledge-sharing among countries. She would welcome the creation of a pooled fund that could accept voluntary funding from non-State actors.

The representative of COLOMBIA said that work should continue in implementing the Global Observatory, the demonstration projects and the voluntary pooled fund. The Global Observatory should promote open knowledge through platforms that were not subject to intellectual property rights, which could be optimized collectively in the research and development process. It should also incorporate more information on all initiatives for the development of high-cost medicines, including those for cancer treatment. Transparency and adherence to principles such as geographical distribution and gender balance should be ensured in the selection of Expert Committee members. The negotiation of an international agreement for the coordination and financing of research and development was the best way of implementing the Expert Committee's recommendations. He would welcome the holding of another open-ended meeting of Member States to assess progress and continue discussion on the Expert Committee's recommendations.

The representative of PERU<sup>1</sup> said that a system to register health research projects had been set up in Peru 2016, and had been recognized by WHO and PAHO as an essential step towards the implementation of clinical research registries in the Region of the Americas. He supported the proposed creation of a voluntary pooled fund.

The representative of GERMANY<sup>1</sup> announced that, in addition to its earlier commitments to the Global Observatory on Health Research and Development, his Government had made available to WHO at the end of 2016 €2 million in support of the demonstration projects.

The representative of INDIA<sup>1</sup> said that he would have welcomed information on possible action to overcome the funding gaps identified. The report did not elaborate on how the Global Observatory, Expert Committee and voluntary pooled fund would adhere to the principles of affordability, effectiveness, efficiency, equity and delinkage, and how sustainable funding would be provided. It should be updated to refer to the request, in resolution WHA69.23(2016), for the Director-General to request the Seventieth World Health Assembly to consider convening another open-ended meeting of Member States to address the remaining issues in the report of the Consultative Expert Working Group on Research and Development, which was specifically related to the outstanding issue of commencing negotiations for a binding research and development instrument.

The representative of SWITZERLAND,<sup>1</sup> welcoming the terms of reference of the Global Observatory and the Expert Committee, said that little time remained to mobilize additional resources for the financing and implementation of the demonstration projects and the Global Observatory. His Government had therefore agreed to extend the term of its remaining matching fund of approximately US\$ 1.3 million until the end of 2017. It had established that fund to match contributions by low- and

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medium-income countries by 50% for up to US\$2 million, from which US\$ 700 000 had already been released. To obtain the necessary financing, it was vital to inform Member States and donors of the quality of projects and the Global Observatory and the progress achieved. In the near future, a decision would have to be made as to whether to proceed with or abandon the voluntary pooled fund. However, such a fund was essential to fill the research and development gaps that primarily affected low- and middle-income countries.

The representative of BRAZIL<sup>1</sup> said that the composition of the Expert Committee should reflect the geographical diversity and expertise of WHO's membership. WHO's efforts to promote policy coherence were welcome. The voluntary pooled fund should optimize some of the principles and recommendations formulated by the Consultative Expert Working Group to ensure the affordability of products. The terms of reference for the Global Observatory should refer to the Global Observatory as a tool to identify gaps in research and development and facilitate coordination, and not limit its scope to generating reports; subparagraph 4(c) should be amended accordingly. The collaborative structure comprising the Global Observatory, the Expert Committee and the voluntary fund needed to evolve to monitor, coordinate and address gaps in research and development for medical products. Challenges remained regarding the sustainability of the pooled fund, which alone required up to US\$ 7.6 million to operate, and he supported the planned high-level event to promote investment in research and development. WHO should not shy away from discussions on alternative models for vital public health innovations, and should give serious consideration to the drafting of a research and development instrument.

The ASSISTANT-DIRECTOR GENERAL (Health Systems and Innovation), expressing her appreciation for the comments made, said that the Global Observatory portal was now live, and included data from a wide range of sources on research and development input processes. It also provided preliminary comprehensive analyses for selected diseases, the first of which were tuberculosis, malaria and leishmaniasis, which would provide useful input for the Expert Committee's discussions. Work had begun on developing better classification and standards for reporting on health research and development. Turning to the demonstration projects, she noted with appreciation the financial contributions made thus far, including the recent commitment by the Government of Germany, but acknowledged that major funding gaps remained. She requested donors to prioritize the African Network for Drugs and Diagnostics Innovation, which would have to cease its activities if it failed to secure financing in a timely manner. The Secretariat would take into account the suggestions on fundraising, and noted the comments on the need to produce final conclusions on the projects. Paragraph 6 of Annex 2 to document EB140/21 provided information on affordability of products.

**The Board noted the report contained in document EB140/21 and the terms of reference of the Executive Committee on Health Research and Development set out in document EB140/22.**

### **Report of the United Nations Secretary-General's High-level Panel on Access to Medicines**

The CHAIRMAN, recalling the agreement reached by the Board at its first meeting to discuss the findings of the report of the United Nations Secretary-General's High-level Panel on Access to Medicines under agenda item 8, invited representatives to comment on that document.

The representative of MALTA, speaking on behalf of the European Union and its Member States, said that the current innovation model had delivered consistent progress in global public health.

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

However, she recognized the challenges posed by the high cost of medicines to the sustainability of health systems and agreed with the acknowledgment in the High-Level Panel's report that there were many reasons why people did not receive the health care they needed. She would have preferred a more comprehensive and balanced approach. Objectives such as ensuring incentives for continued innovation, promoting and financing the research of new and improved medicines for all, and guaranteeing the accessibility were not contradictory and should be pursued jointly. The health ministers of the European Union had agreed to examine obstacles to the deployment of existing methods and consider new solutions to address market failure. An evidence-based analysis of the impact of incentives in European Union legal instruments would also be prepared. WHO should continue its trilateral cooperation with WIPO and the WTO on the complex issue of access to medicines.

The representative of the NETHERLANDS said that the challenges described in the High-Level Panel's report applied to all countries. Pressure on public health spending was mounting due to the proliferation of high-cost medicines and rising drug prices. Solutions included new business models, such as the Medicines Patent Pool. His Government supported efforts to strengthen market-shaping initiatives, improve legislation and safeguard flexibilities under the TRIPS agreement. The Netherlands had a "fair price, fair medicine" initiative, which brought together coalitions of stakeholders in the development of new medicines to optimize the transparency of their research and development agendas, keep profit levels acceptable to all, and set prices and payment modalities in advance. More discussion was needed on how public funds were used in the development of new medicines, and steps must be taken to prevent "TRIPS Plus" provisions in free trade agreements and safeguard against the abuse of intellectual property rights. In May 2017, the Netherlands, jointly with WHO, would host a forum on the fair pricing of medicines.

The representative of the UNITED STATES OF AMERICA said that while his Government was committed to identifying practical ways to increase access to safe, effective and affordable medicines, it was strongly opposed to any further consideration of the report of the High-Level Panel, the mandate of which had been narrow and flawed. The report did not consider many critical facets of promoting innovation and access to medicines. The High-Level Panel had been unable to reach consensus on its key recommendations, some of which would have negative, unintended consequences for research and development. Furthermore, the High-Level Panel's work had not been driven by Member States, or mandated by the United Nations General Assembly. When taking note of the report, the United Nations General Assembly had declined to call on other United Nations entities to take the High-Level Panel's recommendations forward. It was unprecedented for the Executive Board to consider reports that singled out the policies of individual Member States for criticism. His delegation therefore could not accept proposals to welcome or endorse the report, or to consider the recommendations contained therein any further.

The representative of COLOMBIA said that actions at the global level to secure equitable access to medicines and ensure consistency between the various initiatives in that regard should be enhanced. The recommendations of the High-Level Panel presented viable alternatives for Member States to promote equitable access to medicines, in particular through maintaining flexibility under the TRIPS agreement. WHO should take up those recommendations and ensure their comprehensive implementation.

The representative of THAILAND said that much of the content of the report of the High-Level Panel was satisfactory and the Secretariat should therefore consult with Member States to establish which of the recommendations were considered acceptable and develop a five-year action plan for their implementation.

The representative of ALGERIA said that access to affordable medicines was a global problem, which was placing considerable pressure on governments and authorities, medical professionals, and patients whose right to health was under threat. The High-Level Panel's recommendations constituted an important step towards an equitable solution to the issue of access to safe, effective and affordable medicines for all.

The representative of INDIA<sup>1</sup> said that the report of the High-Level Panel was directly relevant under the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, and to the work of the Consultative Expert Working Group on Research and Development: Financing and Coordination. Some of the High-Panel's recommendations were already being addressed in those contexts, and others merited immediate attention. Without comprehensive measures to ensure equitable and affordable access to medicines and vaccines, attainment of the Sustainable Development Goals and achievement of universal health coverage would be impossible. The Executive Board should recommend that the Seventieth World Health Assembly convene an open-ended meeting of Member States to discuss the High-Level Panel's recommendations and other relevant recommendations emanating from the Consultative Expert Working Group. A web-based consultation with Member States should be organized prior to the Seventieth World Health Assembly to discuss the report and its recommendations.

The representative of ICELAND,<sup>1</sup> speaking also on behalf of NORWAY, said that a more nuanced and balanced approach was required to address the highly complex and contentious issue of access to medicines. Further discussions should be held in the context of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

The representative of BRAZIL<sup>1</sup> said that the High-Level Panel's recommendations were relevant to several WHO platforms, including the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, the Consultative Expert Working Group and the blueprint for research and development preparedness and rapid research response, and to the Sustainable Development Goals alignment process, in particular health target 3.b on the TRIPS agreement and public health. An opportunity should be sought in the context of WHO to discuss some of the issues and recommendations contained in the report.

The representative of SWITZERLAND<sup>1</sup> said that the limited mandate of the High-Level Panel was regrettable; a more holistic approach would have been preferable. The recommendations were, however, interesting and some had already been taken up in other international forums. The recommendations did not, however, fully acknowledge the central role of intellectual property rights in the promotion of research and development. Weakening those rights would risk compromising biomedical innovation. Existing initiatives, which encouraged research and development while improving access to treatment for low- and middle-income populations, should be analysed. Rather than focusing on the recommendations of a report of limited scope, the Executive Board should concentrate on WHO's work on research and development and access to medicines.

The representative of JAPAN<sup>1</sup> said that financial incentives for the development of new drugs promoted research and development to the benefit of all. Appropriate protection of intellectual property rights was therefore essential. Unfortunately, the scope of the report of the High-Level Panel was limited; access to medicines was affected by health systems governance, quality and quantity of human resources, access to medical facilities and medicine supply systems in countries, and could

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

therefore only be addressed effectively through a comprehensive approach. The report did not take account of previous international discussions on research and development for medicines or on support for capacity-building for regulatory systems in developing countries. He expressed his Government's commitment to foster innovation in health care, in collaboration with international partners, to achieve universal health coverage.

The representative of the ISLAMIC REPUBLIC OF IRAN<sup>1</sup> said that the growing body of international trade and intellectual property law was limiting the scope of research and development, in particular the production of generic drugs, and restricting access to medicines and thus the enjoyment of the fundamental right to health. The High-Level Panel's recommendations must therefore be followed up. The Executive Board and the World Health Assembly should have an opportunity to consider the recommendations, in particular with regard to global agreements on the coordination, financing and development of health technologies, including drafting a binding instrument that delinked the cost of research and development from end prices. An open-ended working group should be set up to consider those recommendations.

The representative of SOUTH AFRICA said that the report of the High-Level Panel offered a means to advance the search for more accessible, affordable medicines. A selective approach could be used when taking up its recommendations.

The representative of the BOLIVARIAN REPUBLIC OF VENEZUELA<sup>1</sup> said that the report of the High-level Panel highlighted several important issues, including the high cost of health technologies, lack of transparency and lack of access to medicines. The production of generic drugs had proven an effective way to reduce prices and increase access. He encouraged Member States to discuss the findings and recommendations of the report as a means of enhancing efforts to improve access to medicines.

The representative of the GLOBAL HEALTH COUNCIL, speaking at the invitation of the CHAIRMAN, said she was optimistic about progress made on operationalizing the Global Observatory on Health Research and Development and encouraged Member States to ensure that it was fully funded. The Council supported ongoing efforts to develop new sources of funding and was encouraged by the commitment to ensuring the transparent operation of the voluntary pooled fund for health research and development, free from undue influence. Global health stakeholders from diverse sectors should be consulted as the process to improve access to medicines moved forward.

The representative of MÉDECINS SANS FRONTIÈRES INTERNATIONAL, speaking at the invitation of the CHAIRMAN, welcomed the work on establishing the Global Observatory and urged Member States to commit to providing the necessary additional funds for its operationalization. She welcomed efforts to develop terms of reference of the proposed Expert Committee on Health Research and Development, and asked the Committee to provide guidance on how the principles established under the Consultative Expert Working Group could be implemented in research and development initiatives both within and outside WHO. The Committee should also oversee policy coherence across WHO's research and development work. The allocation of funding from the proposed pooled fund would require careful consideration. It was critical to advance the recommendations of the High-Level Panel at the country level.

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

The representative of MEDICINES FOR MALARIA VENTURE, speaking at the invitation of the CHAIRMAN, said that the Global Observatory, which should be fully funded by Member States, should address data gaps, but care should be taken to avoid duplicating existing, successful efforts. She supported the establishment of a voluntary pooled fund, but cautioned that the fund should not encourage the reallocation of existing resources or duplicate other funding mechanisms. In addition, the fund should be transparently governed by an independent, non-political body, and should be implemented and developed via a multisectoral approach

The representative of OXFAM, speaking at the invitation of the CHAIRMAN, was pleased to note that the pressing issue of lack of innovation and access to affordable medicines was finally receiving the attention it merited at the global level. She urged the Secretariat and Member States to use the report of the High-Level Panel as a means to revitalize the Organization's stalled progress on innovation and access to medicines. WHO should provide leadership to ensure that public health decisions were not decided by commercial interests.

The representative of MEDICUS MUNDI INTERNATIONAL – INTERNATIONAL ORGANISATION FOR COOPERATION IN HEALTH CARE, speaking at the invitation of the CHAIRMAN, welcomed the progress made in the areas of work of the Global Observatory; however, the significant funding gap indicated that the voluntary pooled fund was inadequate. She urged the Executive Board to convene an open-ended meeting in 2017, as requested in resolution WHA69.23 (2016) to continue discussions on the remaining issues, including the negotiation of a research and development agreement. In view of their importance, the recommendations of the High-Level Panel should be discussed, endorsed and implemented by WHO.

The ASSISTANT DIRECTOR-GENERAL (Health Systems and Innovation), referring to the report of the High-Level Panel, welcomed the inclusion of the two recommendations proposed by WHO, through its membership of the Expert Advisory Group. She welcomed the recommendation that all relevant international agencies should cooperate to support governments to apply patentability criteria that were sensitive to public health concerns and looked forward to continued collaboration with WHO's partner agencies to that end. WHO had already taken action in relation to the High-Level Panel's recommendation to establish a global pricing database in order to increase transparency, including through the establishment of the WHO Global Reporting Mechanism for HIV, tuberculosis, malaria and hepatitis C treatments, and a comprehensive web platform that provided information on vaccine products, prices and procurement data. Within the framework of a new project on fair pricing, WHO would assess the production costs of essential medicines to allow procurement agencies to better evaluate performance and increase transparency. The project would also provide Member States with clear information on the prices of generic medicines. The Secretariat was committed to providing access to medicines for all, as an essential element of efforts to achieve universal health coverage.

**The Board noted the report.**

**Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products:** Item 8.6 of the agenda (documents EB140/23 and EB140/23 Add.1)

The CHAIRMAN invited the Board to note the report contained in document EB140/23 and consider the draft decision contained in document EB140/23 Add.1.

The representative of the CONGO, speaking on behalf of the Member States of the African Region, noted that although progress had been made, the countries of the Region still suffered from the consequences of the shortage and high cost of medicines. Insufficient production of generic

medicines exposed the countries of the Region to the harmful effects of falsified health products. The African Union Commission, with the support of WHO and subregional organizations, had established the African Medicines Agency; however, its efficacy and continued implementation would depend on the provision of support from subregional organizations. He expressed support for the proposed new working definitions of substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products. He noted the need for several editorial amendments to the French version of the draft decision, in particular regarding subparagraphs 2(a) and 2(b), which he could submit to the Secretariat.

The representative of MALTA, speaking on behalf of the European Union and its Member States, expressed support for the draft decision.

The representative of the RUSSIAN FEDERATION said that his Government's participation in the Member State mechanism had enabled the Russian Federation to develop an effective national strategy for detecting substandard and falsified medical products, including screening laboratories and a serialization system. He welcomed the guidance on developing a national plan to counter such products. The future success of the Member State mechanism would depend on the quality of information exchanged, for which guidelines and deadlines were needed. The information available online on the Member State mechanism should be enhanced in order to ensure the accessibility of information on materials and training sessions. The future work of the Member State mechanism should include a greater focus on specific types of substandard and falsified medical products and their supply on the Internet.

The representative of PAKISTAN said that his Government was committed to addressing the problem of SSFFC medical products by improving coordination among provinces, strengthening the national drug regulatory authority and introducing legislation. He highlighted the key role of laboratories in detecting SSFFC medical products, noting that the use of simple and less expensive technologies was in the interest of end-users. He encouraged regional and global collaboration, with the engagement of all stakeholders, to establish surveillance systems, regulatory frameworks and implementation alliances.

The representative of NEPAL said that, like other developing countries, Nepal faced huge challenges in tackling substandard and falsified medical products. She requested the Secretariat to provide support at the country level to: strengthen national capacity; develop the required tools and mechanisms; increase information sharing among national regulatory authorities; and promote the development of regional and global laboratory collaboration. She expressed support for the proposal to amend the term "substandard/spurious/falsely-labelled/falsified/counterfeit medical products" to "substandard and falsified medical products".

The representative of the UNITED STATES OF AMERICA said that his Government would continue to support the Member State mechanism on substandard and falsified medical products. Noting the importance of the global surveillance and monitoring system, he was pleased to note that WHO was supporting its continued development and maintenance to ensure the provision of sustainable resources for its use. His Government looked forward to working with Member States on the prevention, detection and response to substandard and falsified medical products, including through participation in the Steering Committee.

The representative of THAILAND expressed support for the proposed new term "substandard and falsified medical products", which addressed the issue of drug quality from a public health perspective and prevented conflation with intellectual property and trade-related issues. She called for the establishment of a list of relevant stakeholders and an analysis of the root causes of substandard, falsified and unregistered or unlicensed medical products in order to develop effective solutions to

prevent, detect and respond to such products. In addition to strengthening actions to address the issue from the supply perspective, concrete plans and interventions should be developed to raise consumer awareness and empower end-users to detect and report substandard and falsified medical products.

The representative of the DEMOCRATIC REPUBLIC OF THE CONGO supported measures to strengthen regulatory authorities and establish quality control and analysis laboratories at border points and within countries in order to tackle the problem of SSFFC medical products.

The representative of CHINA commended the work of the Member State mechanism in promoting the joint prevention and control of SSFFC medical products by global drug regulators. He welcomed the guidance provided in the report of the Member State mechanism and the introduction of new practices in some Member States, which should help national and regional drug regulators to adopt more effective measures. Recognizing the need for strengthened interregional and international cooperation, he called on WHO to continue playing a constructive role in strengthening research and information sharing. WHO should support developing countries to establish early warning, monitoring and traceability systems, carry out inspections, determine the origin of imported products, reduce prices, and improve consumers' access to high-quality medicines.

The representative of the UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND welcomed the proposed new term, "substandard and falsified medical products", which would provide clarity at the international level. She encouraged more Member States to participate in the development of a global communications strategy, funded by the United Kingdom, under Activity E (risk communication). In that regard, she sought assurance from the Secretariat that concerns regarding future funding for the strategy would be addressed. She would welcome collaboration in the potential international application of the national strategy to combat counterfeit and falsified medical products.

The representative of INDIA<sup>1</sup> expressed support for the outcomes of the fifth meeting of the Member State mechanism, including the working definitions, which should be widely disseminated among Member States, organizations of the United Nations system and other relevant organizations. In the light of the new definitions, the Member State mechanism should be renamed "the Member State mechanism on substandard and falsified medicines". He requested an update on the proposed study on the link between lack of access to quality, safe, effective and affordable products and the emergence of substandard and falsified products. With respect to regulatory system strengthening, he endorsed the proposals to keep all channels of support open and to publish a guidance manual for the use of the global benchmarking tool. He urged the Member State mechanism to address the issue of the transit of medicines. He looked forward to the proposed review of the Member State mechanism and supported the extension of its mandate.

The representative of SPAIN<sup>1</sup> welcomed the agreement reached on the definition of terms. In its upcoming role as Chair of the Steering Committee of the Member State mechanism, Spain would seek to strengthen the progress made, resolve pending issues and encourage Member States to implement the agreements already reached. Given the severity of the problem of SSFFC medical products at the global level and the damaging impact on public health, enhanced global collaboration was required to promote the Member State mechanism and strengthen quality assurance for medical products at every stage of the supply chain.

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The representative of TOGO<sup>1</sup> said that his Government was committed to participating in efforts to achieve the objectives outlined in the report. In order to take effective action against SSFFC medical products, his Government had incorporated in its national strategic plan objectives to improve the quality of health products and strengthen the fight against illegal pharmaceutical activity. Togo had conducted an evaluation of the medical product supply chain in 2016 with a view to creating an integrated system for the provision of health products.

The representative of PANAMA<sup>1</sup> said that her Government was committed to strengthening national capacity to tackle the issue of SSFFC medical products, and requested continued technical support from WHO and other organizations in that regard. In Panama, falsified and counterfeit medical products had previously been prosecuted under intellectual property legislation, but would soon be treated as public health offences. She emphasized the urgent need to introduce specific criminal legislation against falsified medical products to guarantee the quality of end products. Expressing support for the objectives outlined in the report, she added that the number of specialized workers needed to be increased at the country level.

The representative of INDONESIA<sup>1</sup> expressed support for the working definitions, which would provide clarity to all stakeholders and represented a milestone in the global fight to end the production and distribution of SSFFC medical products. As a member of the Steering Committee of the Member State mechanism, her country stood ready to participate in the review process concerning the implementation of strategies and actions outlined in the workplan. Her Government remained committed to preventing the production and distribution of SSFFC medical products.

The representative of BRAZIL,<sup>1</sup> welcoming the new working definitions, expressed the hope that the Board, at its current session, and the Seventieth World Health Assembly would endorse those definitions, especially the term “substandard and falsified medical products”. Advocating for further work on SSFFC medical products, he said that Brazil would be an active participant in the review of the Member State mechanism.

The representative of the INTERNATIONAL PHARMACEUTICAL FEDERATION, speaking at the invitation of the CHAIRMAN, welcomed the progress made by the Member State mechanism but called for consistency, integration and coordination of solutions at both the local and international levels. The Federation had developed a range of tools on the issue of SSFFC medical products, including a handbook and an interactive video. She called on Member States to include health care professionals in policy decisions in order to ensure that such decisions were appropriate to real life, and looked forward to participating in the review of the Member State mechanism.

The representative of the INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS AND ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, said that falsified medical products could only be eliminated through collective action and the sharing of expertise. She welcomed the proposed term “falsified”, which was aligned with the Federation’s view that efforts to tackle falsified versions of genuine approved medicines must not be confused with patent infringement disputes. She stressed the importance of WHO’s global coordination role on the issue.

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The representative of MEDICUS MUNDI INTERNATIONAL – INTERNATIONAL ORGANISATION FOR COOPERATION IN HEALTH CARE, speaking at the invitation of the CHAIRMAN, welcomed the consensus reached on the new working definitions, which would ensure that issues related to quality of medicines and intellectual property were no longer conflated. She called on the Secretariat to reassess the threat of quality-compromised medicines in the light of the new definitions and develop a public health oriented approach which addressed the root causes of the circulation of substandard and falsified medical products. She requested the Secretariat and Member States to communicate the new definitions to other international organizations.

The ASSISTANT DIRECTOR-GENERAL (Health Systems and Innovation) thanked Member States for their contribution to the work of the Member State mechanism. Responding to comments made, she said that the information available online would be reviewed and updated as a matter of priority, in line with the consensus reached by Member States. She thanked those Member States that were contributing to the WHO Global Reporting Mechanism and expressed the hope that it would continue to be expanded, as Member States had suggested. She assured the Board that WHO was working intensively on regulatory system strengthening as a key component of the response to substandard and falsified medical products.

**The Board noted the report and adopted the decision.<sup>1</sup>**

**The meeting rose at 17:30**

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<sup>1</sup> Decision EB140(6).