EXECUTIVE BOARD
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PROVISIONAL SUMMARY RECORD OF THE TWELFTH MEETING

WHO headquarters, Geneva
Wednesday, 30 January 2019, scheduled at 14:30

Chairman: Ms M.N. FARANI AZEVÊDO (Brazil)

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TWELFTH MEETING

Wednesday, 30 January 2019, at 14:30

Chairman: Ms M.N. FARANI AZEVÊDO (Brazil)

1. STRATEGIC PRIORITY MATTERS: Item 5 of the agenda (continued)

Eleventh revision of the International Classification of Diseases: Item 5.9 of the agenda (documents EB144/22 and EB144/22 Add.1) (continued)

The CHAIRMAN recalled that the Board was considering a draft resolution on the topic, proposed by the Secretariat.

The representative of ARGENTINA[1] proposed that, in the draft resolution, the words "the criteria defined for" be inserted at the start of subparagraph 3(2) and the words "in all official languages of the Organization" be inserted after the word "dissemination" in subparagraph 4(1) of the draft resolution.

The representative of NORWAY[1] underscored the need to pay careful heed to comments on the inclusion of the supplementary chapter on traditional medicine. While the Secretariat had made it clear that the chapter was for diagnostic purposes only and not an endorsement of any form of treatment, a clear distinction had to be maintained between it and all other chapters, in order to safeguard the standing of the International Classification of Diseases.

The representative of THAILAND[1] said that the time frame for full implementation of the eleventh revision of the International Classification of Diseases should be reconsidered, given the substantial amount of time and training required. The Secretariat should provide Member States with the software for transitioning to the new codes, facilitate use of the offline coding tool, develop training courses on the new codes, and help Member States build their own national coding capacities.

The representative of PANAMA[1] said that, in the future, certain diagnostic categories, such as metabolic syndrome and prehypertension, should be described in greater detail. Her Government was working with PAHO to ensure a smooth transition to the eleventh revision.

The representative of SWITZERLAND[1] said that the time frame for full implementation of the eleventh revision should be extended in view of the substantial financial and technical efforts it required. He asked the Secretariat how it intended to support Member State efforts to achieve full implementation and ensure funding for the planned revision cycle.

The representative of the DOMINICAN REPUBLIC[1] suggested that room should be made in the supplementary chapter on traditional medicine for the indigenous medicine practiced in the Americas and that the report should refer to the work of Member States that did not host WHO collaborating centres.

[1] Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

The representative of the RUSSIAN FEDERATION[1] asked for confirmation that a licence would be needed to implement the eleventh revision, given that neither the report nor the draft resolution made any reference to licences. The tenth revision would be in implementation for at least four more years and would therefore serve as the basis for monitoring fulfilment of the Thirteenth General Programme of Work, 2019–2023. He therefore urged the Secretariat to consider the option of not requiring a licence for the tenth revision, to allow it to be fully implemented by Member States. He expressed support for the draft resolution and said that his Government stood ready to assist in the preparation of the Russian-language version of the eleventh revision.

The representative of the UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND,[1] noting the varying time frames in which Member States would implement the eleventh revision, proposed that the draft resolution be amended to include a reference to a transitional period of five years. During that period, the Secretariat would support statistical reporting under both the tenth and eleventh revisions and provide electronic translation tools.

The representative of PERU[1] said that implementation of the eleventh revision represented a challenge for Member States that had not yet developed systems for reporting on the causes of mortality and morbidity. In order to build national capacities in that regard – an activity that should be spearheaded by WHO – he suggested that transition tables should be drawn up, a strategy devised for gradual migration to the eleventh revision, and regional training workshops held.

The representative of INDIA[1] welcomed the inclusion in the eleventh revision of the supplementary chapter on traditional medicine and suggested that it should be expanded to incorporate all major traditional medicine systems. Sufficient funding for implementation of the eleventh revision should be ensured and the Secretariat should provide regular updates to Member States on the progress made.

The representative of BELGIUM[1] expressed support for the proposed five-year transition period, given that implementation of the eleventh revision would be a multi-year process. He stressed that the International Classification of Diseases should remain a classification system for diseases, and that the inclusion in the eleventh revision of the supplementary chapter on traditional medicine should in no way imply an explicit or implicit endorsement of traditional practices as evidence-based medicine.

The representative of the INTERNATIONAL SOCIETY FOR BIOMEDICAL RESEARCH ON ALCOHOLISM, speaking at the invitation of the CHAIRMAN, welcomed the inclusion of gaming disorder as a new diagnostic entity, since it would facilitate research and development on preventive measures and treatment options.

The representatives of the WORLD FEDERATION FOR MENTAL HEALTH and of IOGT INTERNATIONAL, speaking at the invitation of the CHAIRMAN, also welcomed the inclusion of gaming disorder.

The ASSISTANT DIRECTOR-GENERAL (Health Metrics and Measurement) said that the decision to include gaming disorder had been backed by professional organizations and clinical experts from a large number of Member States. The diagnostic criteria focused on the seriousness of the condition and the symptoms could not be attributed to other causes. The Secretariat had further tested the clinical and public usefulness of gaming disorder as a diagnostic category through a systematic scoping review using the most recent research and evidence. That process had confirmed that gaming

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disorder was indeed a public health concern requiring standardized data and guidelines at the international level. The Secretariat had initiated a dialogue with representatives of the video gaming and other related industries on the public health implications of gaming.

Concerning the inclusion of the supplementary chapter on traditional medicine, she emphasized that it was not a replacement for the other 24 chapters, but rather an additional, optional diagnostic tool that would enable the collection of data and information on traditional medicine diagnoses.

Responding to comments concerning implementation, she said that transition tables were available for each individual code, and paragraphs 46 to 50 of the report set out provisions that took into account the requests of individual Member States. Regional introductory training had already begun, and all regional workshops would be completed before the Seventy-second World Health Assembly. Some Member States were already preparing for implementation and receiving country-specific support. Based on current practice, the eleventh revision would come into effect in January 2022, and a postponed implementation time line would prevent certain Member States from getting started early. There would be no implications for Member States that fell behind with implementation.

Lastly, she confirmed that the eleventh revision could be used in primary health care, as indicated in the report.

The CHAIRMAN took it that the Board wished to suspend consideration of the draft resolution to allow for informal consultations.

It was so agreed.

(For continuation of the discussion, see the summary record of the sixteenth meeting, section 3.)

2. OTHER TECHNICAL MATTERS: Item 6 of the agenda

Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits: Item 6.1 of the agenda (documents EB144/23 and EB144/23 Add.1)

The CHAIRMAN drew the attention of the Board to the report contained in document EB144/23 and the draft decision contained therein. The financial and administrative implications of the draft decision for the Secretariat were set out in document EB144/23 Add.1.

The representative of ROMANIA, speaking on behalf of the European Union and its Member States, said that the candidate countries of Montenegro, Serbia and Albania, the country of the stabilization and association process and potential candidate Bosnia and Herzegovina, as well as Ukraine and Georgia aligned themselves with her statement. Referring to the draft decision, she said that the phrase "contained in document EB144/23" should be inserted after "report" in both of the preambular paragraphs. In subparagraph 1(a), the words "identify and" should be added after "other partners to". Subparagraph 1(b) should be amended to read: "to closely monitor instances where influenza virus sharing is affected, including due to the implementation of the Nagoya Protocol and/or for other reasons, and to present findings thereon to the next meeting of the PIP Advisory Group". Subparagraph 1(c) should be amended to read: "to assess the usefulness of the prototype search engine developed to identify products that have made use of genetic sequence data of influenza viruses with pandemic potential". Subparagraph 1(d) should be amended to read: "to explore possible next steps in raising awareness of the PIP Framework among databases and initiatives, data providers and data users, and to present such possible steps to the next meeting of the PIP Advisory Group". She proposed the insertion of a new penultimate operative paragraph, to read: "to work collaboratively across WHO to raise awareness

among Member States of the implications for public health of implementation of the Nagoya Protocol, particularly given the cross-cutting nature of relevant issues".

The representative of GABON, speaking on behalf of the Member States of the African Region, welcomed the new guidelines for pandemic preparedness and implementation of 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, which presented both opportunities and challenges for public health. He stressed the need to share biological materials and strengthen the influenza surveillance and response capacity of national regulatory authorities, and expressed support for the draft decision.

The representative of JAPAN expressed concern about the inclusion of seasonal influenza and generic sequence data in the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Seasonal influenza vaccines might be difficult to manufacture in timely fashion, as seasonal influenza occurred annually and multiple samples were required for vaccine production. He agreed on the need to clarify, in cooperation with the Global Influenza Surveillance and Response System, the implications of the Nagoya Protocol for seasonal influenza virus sharing. Regarding genetic sequence data, he said that the current scope of the PIP Framework should be maintained so as to avoid adversely affecting research and development. He supported the draft decision.

The representative of INDONESIA said that the inclusion of seasonal influenza viruses in the PIP Framework required further discussion. The Global Influenza Surveillance and Response System was not sufficient to address the challenges and uncertainties inherent in the sharing of seasonal viruses, and it might be preferable to develop another mechanism or specific framework to that end. He supported the proposal to include genetic sequence data in the PIP Framework and to treat them on an equal footing with biological materials. Given the different views on the issue, he proposed that the Secretariat should convene an intersessional meeting of the Executive Board to discuss the draft decision with a view to its adoption at the Seventy-second World Health Assembly.

The representative of DJIBOUTI, speaking on behalf of the Member States of the Eastern Mediterranean Region, agreed that the draft decision should be forwarded to the Seventy-second World Health Assembly for adoption, but stressed that implementation of the Nagoya Protocol presented challenges as well as opportunities, in particular in terms of genetic sequence data and the sharing of seasonal influenza viruses with pandemic potential. The Secretariat should monitor the impact of those challenges, especially on low- and middle-income countries, with a view to resolving them in relation to the access criteria and process and to benefit-sharing mechanisms. The timely sharing of seasonal influenza viruses and related benefits should continue to be encouraged through the Global Influenza Surveillance and Response System and the PIP Framework.

The representative of BRAZIL commended efforts to reflect on the inclusion of seasonal influenza viruses and genetic sequence data in the PIP Framework, but emphasized the importance of ensuring that the Framework continued to function. Noting the problems posed by seasonal influenza virus sharing and Nagoya Protocol implementation, he urged the Secretariat to find ways to ensure that the Framework and the Protocol were complementary. More time was needed to discuss the draft decision and proposed amendments, and intersessional work should therefore take place on the issue.

The representative of MEXICO said that maintaining and improving the PIP Framework should be a WHO priority. The Secretariat should strengthen communication with the secretariat of the Convention on Biological Diversity and subsequently provide feedback to Member States on meetings or workshops on implementation of the Nagoya Protocol. He asked for the Secretariat's views on the

implication of exchanging samples and vaccines in the light of the study into criteria to identify a specialized international access and benefit-sharing instrument, and the scoping study on digital sequence information presented in November 2018 at the third meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Nagoya Protocol on Access and Benefit-sharing. He agreed that more time was needed to consider the proposed amendments to the draft decision.

The representative of the UNITED STATES OF AMERICA said that he did not support re-opening the PIP Framework for negotiation, changing the scope to include seasonal influenza viruses or redefining PIP biological materials. The Director-General should assert his leadership on public health to heighten awareness of the deleterious public health impact of certain domestic measures to implement the Nagoya Protocol. Given that the public health implications of the Protocol extended well beyond influenza, WHO should take a cross-cutting, whole-of-organization approach in discussions of emerging barriers to seasonal influenza virus sharing.

He shared the concerns raised by the PIP Framework Advisory Group about companies that benefited from the results of product evaluation using materials received by another entity but considered that the proposed modification to footnote 1 of the Standard Material Transfer Agreement 2 – Annex 2 to the PIP Framework, – was overly broad and could have undesired consequences. He also considered that there had been insufficient time to examine the amendments to the draft decision proposed by the Member States of the European Union.

Assuming acceptance of those proposed amendments, he suggested that subparagraph 1(b) should be amended to read: "to closely monitor instances where influenza virus sharing is affected, including due to the countries' domestic measures implementing the Nagoya Protocol and/or for other reasons, and to present findings thereon to the next meeting of the Advisory Group, and to share these findings with the WHO's broader effort referenced below regarding the public health implications of the Nagoya Protocol". In subparagraph 1(d), the phrase "in consultation with Member States" should be added after "to explore". Subparagraph 2 should be amended to read: "to work quickly with Member States and relevant stakeholders to explore and evaluate approaches to address concerns regarding the issues raised in paragraph 23 of EB144/23".

The representative of BAHRAIN said that her Government remained committed to tackling pandemic influenza by sharing information on influenza-like illnesses, acute respiratory infections and viral investigation. It continued to work closely with the Global Influenza Surveillance and Response System to develop vaccines against influenza viruses. She supported the proposed amendment to the language of footnote 1 in Standard Material Transfer Agreement 2.

The representative of GERMANY said that, although the timely sharing of viral material and sequence data was crucial for effective crisis response, genetic sequence data and seasonal influenza viruses should not at present be included in the PIP Framework, the current scope of which should be maintained. He supported the draft decision as amended by the Member States of the European Union.

The representative of CHILE said that PIP Framework recommendations should be widely disseminated and worldwide compliance periodically monitored by the Advisory Group. She described her country's efforts since 2014 to build PIP capacity throughout the Region of the Americas.

The representative of AUSTRALIA said that further work relating to seasonal influenza viruses and genetic sequence data should not compromise the current functioning of the PIP Framework and the Global Influenza Surveillance and Response System. The Secretariat should continue to engage with the secretariat of the Convention on Biological Diversity, with a view to addressing uncertainties relating to Nagoya Protocol implementation. She expressed support for the draft decision in principle, but said that more time was needed to consider the proposed amendments to it.

The representative of CHINA described the mechanisms used in his country to participate actively in the PIP Framework and suggested that the Secretariat should step up its support for developing countries, including his, to improve laboratory and surveillance capacities in relation to the viruses covered by the Framework. Although he agreed with the Advisory Group's recommendation that the current scope of the PIP Framework be retained, some of the discussions that had taken place during the consultations in October 2018 had exceeded the Advisory Group's remit. There should also be further discussion of the opportunities and challenges arising from implementation of the Nagoya Protocol.

The representative of THAILAND,[1] concerned that the PIP Framework did not include seasonal influenza, asked the Secretariat to accelerate its work with the secretariat of the Convention on Biological Diversity so as to find the best way forward in that regard. He supported the amendments proposed by the Member States of the European Union, but reserved his position on the amendments proposed by the United States of America.

The representative of the DOMINICAN REPUBLIC[1] supported the move to analyse and present data on the sharing of seasonal influenza viruses in cases affected by application of the Nagoya Protocol. She agreed in principle with, and would give due consideration to, the amendments proposed by the Member States of the European Union.

The representative of NORWAY[1] said that WHO should work urgently with the Global Influenza Surveillance and Response System and other partners to address uncertainties related to the sharing of influenza viruses that had emerged as countries implemented the Nagoya Protocol. It was also important to address implications for the use of shared viruses and genetic data for vaccines production. He asked what the reasoning was behind the amendment to footnote 1 in Standard Material Transfer Agreement 2, and expressed support for the amendments to the draft decision submitted by the Member States of the European Union.

The representative of the ISLAMIC REPUBLIC OF IRAN[1] said that expanding the scope of the PIP Framework to include sharing of seasonal influenza viruses and genetic sequence data required further discussion; hasty decisions could have unforeseen repercussions on the functionality and acceptability of the Framework and its role in strengthening global influenza preparedness and response, in particular through the Global Influenza Surveillance and Response System. Most activities carried out under the high-level Partnership Contribution Implementation Plan 2018–2023 had focused on laboratory and surveillance capacity-building; in future, equal attention should be paid to all six areas, in particular influenza pandemic preparedness planning and burden-of-disease studies. WHO should continue to channel technical support towards building capacities to deliver a comprehensive response in the event of a severe pandemic.

The representative of PANAMA[1] echoed earlier requests for additional time to discuss the draft decision.

The representative of the RUSSIAN FEDERATION[1] said that the PIP Framework should not be expanded to include seasonal influenza virus. The Global Influenza Surveillance and Response System was effective, in particular in terms of sharing of seasonal influenza viruses, and should not be jeopardized by efforts to achieve the specific objectives of the PIP Framework. She had no objections to the proposed amendment to footnote 1 in Standard Material Transfer Agreement 2.

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The representative of INDIA[1] said that the sharing of influenza virus samples and gene sequence data through the PIP Framework should be on an equal footing with benefit-sharing under the Nagoya Protocol. The Framework's sustainability depended on its usefulness to Member States and all major stakeholders; concerns regarding genetic sequence data and benefit-sharing therefore required prompt attention. Facilitating access to vaccines and equitable benefit-sharing was a complex task that would require the sustained engagement of all concerned. He endorsed the draft decision, but requested further time for discussion of the amendments proposed by the Member States of the European Union and the United States of America.

The representative of the REPUBLIC OF KOREA[1] said that the reluctance of certain countries to share seasonal influenza virus strains owing to concerns relating to the Nagoya Protocol should be urgently addressed by the Secretariat. He supported the amendment to footnote 1 in Standard Material Transfer Agreement 2, which would encourage more equitable benefit-sharing.

The representative of SWITZERLAND[1] said that the PIP Framework was fully aligned with the objectives of the Convention on Biological Diversity and its Nagoya Protocol, but that all three instruments needed to complement each other. Even though information on the use of genetic sequence data might enhance understanding of the importance of those data in influenza pandemic preparedness and response, the objectives appeared to presume that genetic sequence data would be subject to benefit-sharing, a controversial issue in the context of the Convention on Biological Diversity and its Nagoya Protocol. She requested further information on the management of data collected through the prototype search engine, in particular in relation to the data type, access and ownership, and expressed reservations on the amendment to footnote 1 in Standard Material Transfer Agreement 2, which would require further in-depth analysis.

The representative of the INTERNATIONAL FEDERATION OF MEDICAL STUDENTS' ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, agreed that the current scope of the PIP Framework should be maintained and called on all Member States to implement the Nagoya Protocol and to amend footnote 1 in Standard Material Transfer Agreement 2, so as to minimize any threats to equitable data sharing and collective health security posed by private interests.

The representative of the INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS AND ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, noted the growing delays in virus-sharing as countries sought to implement the Nagoya Protocol, and therefore urged WHO to work with stakeholders to address those delays and to consider the impact of any future genetic data-sharing initiatives.

The representative of MEDICUS MUNDI INTERNATIONAL – INTERNATIONAL ORGANISATION FOR COOPERATION IN HEALTH CARE, speaking at the invitation of the CHAIRMAN, expressed concern that the draft decision did not explicitly include genetic sequence data as biological material within the scope of the PIP Framework, which undermined the equal footing principle and pandemic preparedness, and disagreed with the negative language it used to refer to the Nagoya Protocol. It was the responsibility of governments, not Global Influenza Surveillance and Response System laboratories or the Advisory Group, to address concerns about seasonal influenza virus sharing.

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The ASSISTANT DIRECTOR-GENERAL (WHO Health Emergencies Programme) said that any attempts to modify the PIP Framework in the face of new challenges should proceed with caution, and agreed on the need for further consultation and discussion. That being said, cooperation in virus and benefit sharing had to continue, since the Framework's objective was to provide health security through the rapid sharing of viruses and the associated benefits. The Secretariat believed that the PIP Framework should be separated from broader discussion of access and benefit sharing for a wider set of pathogens, which would require diverse approaches. The Nagoya Protocol envisaged future benefits and promoted collective security, but it should also support effective collective protection from acute threats to global health security. The Director-General was setting up a task force to tackle the complex issues involved and was working with internal and external experts to prepare concept documents for discussion with Member States.

He expressed appreciation for the round-the-clock efforts of the Global Influenza Surveillance and Response System and other stakeholders to ensure continued timely seasonal influenza virus sharing with a view to safeguarding the continued production of vaccines in the northern and southern hemispheres.

The DIRECTOR-GENERAL said that the task force on non-influenza pathogens would discuss how to proceed in accordance with the Nagoya Protocol, but it would be equally important to continue implementing the PIP Framework. In an increasingly globalized world, committed implementation of the Framework and maximum global solidarity to combat pathogens were key to preventing a small-scale disease outbreak from having catastrophic global repercussions. The Ebola virus crisis had highlighted the world's vulnerability to severe outbreaks of disease and the importance of constant preparedness and cooperation. It would be crucial to bear that reality in mind in any discussions on pandemic disease preparedness to be held before the Seventy-second World Health Assembly. Urgent action was needed to protect humanity from the real and constant threat of pandemics.

The CHAIRMAN took it that the Board wished to suspend discussion of the draft decision, pending consultations on the amendments proposed.

It was so agreed.

(For continuation of the discussion and adoption of a decision, see the summary record of the fourteenth meeting, section 2.)

Member State mechanism on substandard and falsified medical products: Item 6.2 of the agenda (document EB144/24)

The representative of the UNITED REPUBLIC OF TANZANIA, speaking on behalf of the Member States of the African Region, fully supported the emphasis on ensuring the financial sustainability of the Member State mechanism. Governments should seek to regulate the manufacture, import, distribution and use of medical products, given that the production and marketing of substandard and falsified products posed a major threat to public health outcomes throughout the Region. It was to that end that African health ministers had established the African Medicines Agency, which would coordinate and strengthen continental initiatives to harmonize the regulation of medical products and provide guidance on improving access to quality, safe and effective medicines. He called on WHO to continue to provide technical leadership on harmonization across national regulatory agencies.

The representative of the UNITED STATES OF AMERICA expressed appreciation for the development and maintenance of the WHO Global Surveillance and Monitoring System. Substandard and falsified medical products were a significant roadblock to the attainment of health goals, such as

health system strengthening and the fight against antimicrobial resistance. He encouraged Member States to actively engage in the Member State mechanism and the Global Surveillance and Monitoring System.

The representative of BAHRAIN supported the agreed list of prioritized activities in the Member State mechanism's 2018–2019 workplan and stressed the importance of their implementation. Regulations must be put in place for the online sale and purchase of medical products. It was also important to improve awareness-raising programmes, ensure comprehensive training for health inspection workers and strengthen systems for reporting on substandard and falsified medical products.

The representative of ALGERIA urged WHO to strengthen market surveillance and improve alert procedures for substandard and falsified medical products. Regulatory systems should engage in timely knowledge exchanges, so as to reduce the number of such products entering the market. The Organization should help countries to improve the quality of medical products and strengthen regulatory systems, in particular in terms of assessing the quality, safety and efficacy of such products.

The representative of BRAZIL expressed support for the activities carried out under the Member State mechanism, which had achieved concrete results in the fight against substandard and falsified medical products.

The representative of COLOMBIA said that the Member State mechanism helped WHO to prevent and monitor the sale of substandard and falsified medical products and to strengthen national and regional capacities. It also served to develop policy recommendations, establish prevention and detection tools, and promote the exchange of good practices and experiences.

The representative of GERMANY said that the problem of substandard and falsified medical products could be addressed by preventing them from entering the legal supply chain and by educating patients about illegal supply chains, such as the illegal internet trade. Her Government fully supported the initiatives to improve cooperation among competent authorities worldwide and to launch awareness campaigns.

The representative of INDONESIA expressed support for the activities of the Member State mechanism, particularly the focus on capacity-building to monitor substandard and falsified medical products, and said that Member States should participate more actively in its work.

The representative of VIET NAM reaffirmed her Government's commitment to implement the prioritized activities in the Member State mechanism's workplan for the current and coming periods, in collaboration with other stakeholders globally.

The representative of FIJI called on WHO, its donors and technical experts to help small island developing States develop quality assurance mechanisms and thus strengthen their regulatory systems.

The representative of MEXICO said that it was important to strengthen implementation of the Member State mechanism. In particular, Member States must be able to detect substandard and falsified medical products when they were already in the supply chain, and to respond swiftly and efficiently. The workplan of the Member State mechanism should be aligned with the Thirteenth General Programme of Work, 2019–2023 and the WHO Impact Framework.

The representative of SUDAN said that WHO had a duty to detect substandard and falsified medical products and prevent them from reaching the market. It should continue exchanging expertise,

provide technical support for monitoring such products at the national level and strengthen coordination between the Member State mechanism and technical teams within WHO and at all levels.

The representative of THAILAND,[1] observing that globalization and e-commerce had made the supply chain more complex and thereby allowed medicines, including substandard and falsified medical products, to enter countries illegally, asked what action WHO was taking to address that problem. Given that transboundary movement was crucial to the circulation of substandard and falsified medical products, the global network of focal points should be expanded and coordination at country borders reinforced. WHO must promote good governance, including adequate regulatory capacities and zero corruption.

The representative of SPAIN[1] said that it was vital for all stakeholders to collaborate within the framework of the Member State mechanism.

The representative of the RUSSIAN FEDERATION[1] said that the Member State mechanism could not be effective unless Member States cooperated. Member States should therefore participate actively in the global network of focal points. Looking to the future, it would be important to study cross-platform links enabling reports to regulatory agencies about substandard and falsified medical products.

The representative of the DOMINICAN REPUBLIC[1] described the work being done by her Government, together with PAHO, to help strengthen surveillance and alert systems at the national and regional levels.

The representative of INDIA[1] said that the Member State mechanism should not become a barrier to the international movement or availability of authorized, quality, efficacious, affordable generic medicines, which it could do if the definition of substandard and falsified medical products was misinterpreted. He expressed appreciation for the mechanism's agreed definition of such products and for its technical support activities, and commended WHO for providing funding for its activities.

The representative of FRANCE[1] said that the work of the Member State mechanism was essential to understanding the problem of substandard and falsified medical products, which could not be tackled through repression alone. It was also necessary to ensure that essential medicines were available and that pharmaceutical regulatory systems were robust. All relevant stakeholders must work together to improve the efficiency and capacity of pharmaceutical systems.

The representative of ARGENTINA[1] endorsed the prioritized activities for the 2018–2019 workplan. With regard to Activity A, the *Guidance for registers of manufacturers, importers, distributors and medical products authorized by Member States* and the *Recommendations for health authorities on criteria for risk assessment and prioritization of cases of unregistered/unlicensed, substandard and falsified medical products* should be published on the MetNet platform and WHO website. With regard to Activities G and H, the next meeting of the Member State mechanism should continue to address the sale of products via the internet, television and other media.

The representative of the INTERNATIONAL COUNCIL OF NURSES, speaking at the invitation of the Chairman, said that nurses were well-positioned to detect substandard and falsified medical products, and must therefore be involved in developing and implementing national action plans to address the issue. His organization encouraged the Member State mechanism to engage with the Fight

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the Fakes campaign, particularly in support of Activities E and F. It should also foster collaborative action with major stakeholders.

The representative of the INTERNATIONAL PHARMACEUTICAL STUDENTS' FEDERATION, speaking at the invitation of the Chairman, urged Member States to put in place regulatory frameworks, including for online sales of medical products, and to build capacities by embedding courses about substandard and falsified medical products in school curricula, especially in the light of new technologies.

The representative of MEDICUS MUNDI INTERNATIONAL – INTERNATIONAL ORGANISATION FOR COOPERATION IN HEALTH CARE, speaking at the invitation of the Chairman, expressed disappointment that the Secretariat continued to conflate "substandard" and "falsified" medicines and was providing figures based on unclear methodology. The Member State mechanism should exercise caution when it came to medicines in transit, as interventions during transit could be misused to pursue trade interests, thus compromising access to medicines. The regulatory authority of the country concerned should be the only one to intervene. WHO participation in the Global Steering Committee for Quality Assurance of Health Products, some of whose founders had previously pursued an agenda against "counterfeit" medicine advanced by big pharmaceutical companies, was also of concern. WHO should ensure that its participation as an observer was transparent by publishing its interventions on the website of the Member State mechanism.

The representative of the UNITED STATES PHARMACOPEIAL CONVENTION, speaking at the invitation of the Chairman, said that her organization already offered expertise on detection technologies for Activity C and would welcome the opportunity to collaborate on other activities, especially E and F. Scientists, practitioners, patients and consumers must work together to stem the tide of substandard and falsified medical products.

The ASSISTANT DIRECTOR-GENERAL (Access to Medicines, Vaccines and Pharmaceuticals) said that WHO had implemented surveillance systems all over the world and was strengthening the capacities of countries to better prevent, detect and respond to substandard and falsified medical products. All information was transparent and available online. Although great progress had been made – the Secretariat had recently issued alerts on a falsified rabies vaccine and a falsified cancer medicine – the issue was becoming increasingly complex, inter alia because many more such medical products were sold over the internet. The Member State mechanism sought to foster collaboration among Member States, and she encouraged all Member States to participate.

The CHAIRMAN took it that the Board wished to conclude the discussion of this agenda item.

It was so agreed.

Human resources for health: Item 6.3 of the agenda (documents EB144/25 and EB144/26)

The representative of BENIN, speaking on behalf of the Member States of the African Region, said that Member States should use the WHO Global Code of Practice on the International Recruitment of Health Personnel to ensure that their experiences were documented correctly. The forthcoming review of the Code should look at whether it was helping to reduce the shortage in human resources for health. He recommended that the Health Assembly approve the streamlined reporting on health workforce resolutions.

The representative of JAMAICA said that universal health coverage could not be attained without addressing the concerns of nurses and midwives, who had long been undervalued, and giving them the respect and appreciation they deserved. She therefore requested the Director-General's support in declaring 2020 – the 200th anniversary of the birth of Florence Nightingale – to be the Year of Nurses.

The representative of FIJI said that, although the Global Strategy on Human Resources for Health: Workforce 2030 contained strategic directions for nursing and midwifery, his country and other small island developing States still required support in recruiting health workers with advanced technical specializations, such as biomedical engineering and radiology. He supported the two recommendations for action contained in document EB144/26.

The representative of SUDAN, speaking on behalf of the Member States of the Eastern Mediterranean Region, said that the WHO Regional Committee for the Eastern Mediterranean had adopted a framework for action on health workforce development in 2017 that was in line with the Global Strategy. He described the Region's challenges in training and deploying trained medical staff, and in ensuring their safety and security. The Region needed to invest more in training nurses. It was also important to maintain the professional health skills of refugees so that they could continue to practice safely when they returned to their countries.

The representative of INDONESIA noted that reporting under the Global Code of Practice had been improved thanks to the online reporting application rolled out in 2018. He recommended that the Secretariat continue to improve its online reporting system, so as to amass more comprehensive, good-quality data. Referring to the second review of the Code's effectiveness, planned for 2019, he requested that the Secretariat review the criteria and list of countries with critical shortages. Indonesia, for example, had been listed in the *World Health Report 2006* as a country with a critical shortage of health personnel, but was currently over-supplied with nurses.

The representative of AUSTRALIA, underscoring the value of national reporting, endorsed the proposal to streamline reporting on health workforce resolutions and seconded the call to highlight the contributions of nurses and midwives in 2020.

The representative of FINLAND welcomed the Director-General's strong commitment to supporting Member State efforts to manage their health workforces, which played an essential role in accelerating progress on primary health care, universal health coverage and the Sustainable Development Goals. She also welcomed the establishment by ILO, OECD and WHO of the International Platform on Health Worker Mobility, and supported recommending that the Health Assembly should approve streamlined reporting.

The representative of IRAQ said that it was vital to focus on health worker training, particularly in medicine and nursing, to close the gap in health workforce size and skills. Management programmes to produce staff capable of leading health institutions, and measures in primary health care and family medicine, must both be developed. The outflux of trained health workers was also a major challenge, and he urged countries to provide WHO with data on the issue.

The representative of BRAZIL encouraged the Secretariat to continue to assist countries to draft health workforce recruitment policies, in order to help them retain health professionals, especially for emergency situations. The second review of the Global Code of Practice should be conducted in consultation with Member States. He stressed the importance of community health workers as an essential category of health personnel providing primary health care.

The representative of BHUTAN recommended proceeding with the second review of the Global Code of Practice's relevance and effectiveness, as progress had been made in most Member States. For example, her Government had established several nursing training centres and was interested in sending nurses on short-term assignments abroad to gain experience that would enrich the local health system. She therefore supported the suggestion that the Secretariat should revise the criteria and list of countries with critical shortages and report back on its assessment to the Seventy-third World Health Assembly.

The representative of GERMANY requested that the updated report to be submitted to the Seventy-second World Health Assembly include the Secretariat's perspective on the Global Code of Practice's relevance and effectiveness, more information about the two thirds of bilateral agreements that did not take ethical considerations into account, and, in a separate chapter, the recommendations of the United Nations High-level Commission on Health Employment and Economic Growth. The second review of the Code should include a re-evaluation of the criteria for the list of countries with critical staff shortages and the possibility for listed countries to have well-regulated access to the international labour market in the form of pilot projects or bilateral agreements, as requested by the representative of Bhutan and others. She encouraged all Member States to designate a national authority and participate in the third round of reporting.

The representative of ESWATINI said that, despite the global shortage of human resources for health observed in the report, some health professionals remained unemployed in every country. He asked the Secretariat to advise Member States on how to address that problem and whether it reflected a weakness in the Global Code of Practice. He also enquired as to whether medical training standards were being monitored at the global level. The year 2020 should be dedicated to recognizing the work of nurses and midwives, as proposed by the representative of Jamaica.

The representative of the PHILIPPINES[1] recommended adding more content from the country perspective to the updated report. The Secretariat should support capacity-building for developing, implementing and monitoring health policy instruments with a health labour component; a mechanism to promote exchange and information-sharing on international recruitment and health workforce mobility; and a global health education databank accessible to all Member States.

The representative of HONDURAS[1] outlined the work being done with regard to the health workforce in her country. Concrete action was being taken to spur progress towards attainment of Sustainable Development Goal 3 (Ensure healthy lives and promote well-being for all at all ages) through international technical cooperation, in particular with Taiwan.[2]

The representative of PANAMA[1] said that data obtained from the International Platform on Health Worker Mobility would serve to develop health workforce policies and boost capacity. Timely updates to the information in the national health workforce accounts would be essential if the four strategic objectives of the Global Strategy were to be achieved. Member States should continue to report, and the Secretariat should provide technical assistance in coordination with ILO and OECD.

The representative of INDIA[1] seconded calls to revise the list of countries with a critical shortage of health personnel, from which his country should be removed. The global lack of trained health

[1] Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

[2] World Health Organization terminology refers to Taiwan, China.

workers was a serious obstacle to health care for millions of people, and he supported WHO's work to address the issue at the national and international levels.

The representative of NORWAY[1] said that it was encouraging to see that the recommendations of the High-level Commission on Health Employment and Economic Growth seemed to be influencing policy-making and investment decisions in countries at all levels of development. She encouraged all Member States to make use of their national health workforce accounts to make more data available and enable evidence-based policy decisions. She also urged donors to support the newly established Working for Health Multi-Partner Trust Fund.

The representative of ARGENTINA[1] said that the report contained in document EB144/25 did little to present the overall migratory flow of health professionals. Qualitative studies should be conducted to provide a comprehensive understanding of migration in each country. WHO technical support for national reporting was essential, especially for the countries most affected by migratory flows. Reporting and the designation of national authorities under the Global Code of Practice were also relevant to the Global Strategy and were linked to the national health workforce accounts and strengthening of governance.

The representative of the INTERNATIONAL FEDERATION OF MEDICAL STUDENTS' ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, said that Member States must do more to recognize the qualifications of health workers trained abroad. Community health workers should receive proper remuneration and incentives for working in remote areas, and female and non-binary health workers must receive equal pay and the opportunity to take on leadership roles. Young health professionals also had a crucial role to play, not only in providing care but in developing and implementing health policy.

The representative of FDI WORLD DENTAL FEDERATION, speaking at the invitation of the CHAIRMAN, urged Member States to implement the policy options contained in the Global Strategy. She supported streamlined reporting on health workforce resolutions, but the information must be collected without placing an additional burden on health professionals. Governments should work with health professionals to better understand and meet the needs of their health systems and workforces.

The representative of the INTERNATIONAL COUNCIL OF NURSES, speaking at the invitation of the CHAIRMAN, said that he fully supported the request from the representative of Jamaica to make 2020 the Year of the Nurse. In partnership with WHO, his organization had launched the Nursing Now campaign to raise the profile of nursing, and together they were developing the first State of the World's Nursing report. He commended the appointment of a WHO Chief Nursing Officer and encouraged all countries to invest in and support nursing leadership.

The representative of WORLD VISION INTERNATIONAL, speaking at the invitation of the CHAIRMAN, noted the inconsistent design, support and functionality of community health worker programmes, and called on Member States to review available functionality standards and ensure comprehensive implementation.

The representative of the INTERNATIONAL PHARMACEUTICAL STUDENTS' FEDERATION, speaking at the invitation of the CHAIRMAN, called on countries to agree a core set of national and international indicators to effectively monitor and evaluate human resources for health,

[1] Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

and encouraged the Secretariat and Member States to include pharmacy practice when developing health workforce strategies.

The representative of PUBLIC SERVICES INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that the Global Code of Practice could be used to meet several objectives of the Global Compact for Safe, Orderly and Regular Migration. He commended the International Platform on Health Worker Mobility as a good example of dialogue and cooperation.

The representative of the UNION FOR INTERNATIONAL CANCER CONTROL, speaking at the invitation of the CHAIRMAN, said that investment in the health workforce must be increased to achieve universal health coverage. She applauded Member States that had contributed workforce data and encouraged countries to develop systems for informing the effective and equitable deployment of the health workforce.

The representative of MEDICUS MUNDI INTERNATIONAL – INTERNATIONAL ORGANISATION FOR COOPERATION IN HEALTH CARE, speaking at the invitation of the CHAIRMAN, noted that the Global Code of Practice did not oblige Member States to take responsibility for the uncompensated and aggressive recruitment by high-income countries of health workers from low-income countries; international recruitment needed to be regulated. He welcomed the recommendations on proper remuneration and employment regularization set out in the WHO guidelines on health policy and systems support to optimize community health worker programmes.

The representative of the GLOBAL HEALTH COUNCIL, INC., speaking at the invitation of the CHAIRMAN, stressed the importance of simplified and complete data and accurate reporting on health workers to address gaps. WHO should also focus on gender equality in the health workforce.

The ASSISTANT DIRECTOR-GENERAL (Universal Health Coverage and Health Systems), responding to comments and questions, confirmed that the criteria and list of countries with critical shortages would be revised as part of the second review of the relevance and effectiveness of the Global Code of Practice, which would involve dialogue with the regional committees and consultations with Member States. Clearer guidance and more detailed data on health workforce migration would be provided at the Seventy-second World Health Assembly. Her department would work with governments to analyse unemployment among skilled and qualified health professionals at the national level, but it would be a challenge to analyse the disconnect between the global shortage and such unemployment. Accreditation was being considered for training in quality assurance at the national and global levels, and Member States would be asked to report on that. She thanked the Government of Norway for its strong contribution to the Working for Health Multi-Partner Trust Fund.

The DIRECTOR-GENERAL strongly encouraged Member States to endorse 2020 as the Year of the Nurse and the Midwife, in recognition of the vital role of nurses in achieving universal health coverage and of individuals such as Florence Nightingale, who had contributed greatly to humanity. In low- and middle-income countries in particular, nurses were the bridge between communities and health institutions and played a critical role in front line services as members of multidisciplinary teams. He expected 2020 to be a game changer in terms of universal health coverage.

The CHAIRMAN took it that that the Executive Board agreed to recommend to the Seventy-second World Health Assembly the designation of 2020 as the Year of the Nurse and the Midwife.

It was so agreed.

The Board noted the reports.

Accelerating cervical cancer elimination: Item 6.5 of the agenda (documents EB144/28)

The CHAIRMAN drew attention to a draft decision on accelerating the elimination of cervical cancer as a global public health problem proposed by Australia, Brazil, Canada, Colombia, Ecuador, India, Kenya, Monaco, Mozambique, New Zealand, Peru, the Republic of Korea, South Africa, Sri Lanka, Ukraine, the United States of America, Uruguay and the European Union and its Member States, which read:

> The Executive Board, having considered the report on accelerating cervical cancer elimination,[1] decided:
>
> (1) to note that urgent action is needed to scale up implementation of proven cost-effective measures towards achieving the elimination of cervical cancer as a global public health problem, including vaccination against human papillomavirus, screening and treatment of pre-cancer, early detection and prompt treatment of early invasive cancers and palliative care, which will require political commitment and greater international cooperation and support for equitable access, including strategies for resource mobilization;
> (2) to request the Director-General to develop, in consultation with Member States and other relevant stakeholders, a draft global strategy to accelerate cervical cancer elimination, with clear goals and targets for the period 2020–2030, for consideration by the Seventy-third World Health Assembly, through the Executive Board at its 146th session.

The financial and administrative implications of the draft decision for the Secretariat were:

Decision:	Accelerating the elimination of cervical cancer as a global public health problem
A.	**Link to the approved Programme budget 2018–2019**
1.	**Output(s) in the approved Programme budget 2018–2019 to which this draft decision would contribute if adopted:** 1.5.1. Implementation and monitoring of the global vaccine action plan with emphasis on strengthening service delivery and immunization monitoring in order to achieve the goals for the Decade of Vaccines 2.1.1. Development and implementation of national multisectoral policies and plans to prevent and control noncommunicable diseases accelerated 2.1.5. Enhanced coordination of activities, multistakeholder engagement and action across sectors in collaborative work with relevant United Nations system organizations, other intergovernmental organizations and non-State actors, to support governments to meet their commitments on the prevention and control of noncommunicable diseases 3.1.2. Countries enabled to implement and monitor effective interventions to cover unmet needs in sexual and reproductive health
2.	**Short justification for considering the draft decision, if there is no link to the results as indicated in the approved Programme budget 2018–2019:** Not applicable.

[1] Document EB144/28.

3. Any additional Secretariat deliverables during the biennium 2018–2019, which are not already included in the approved Programme budget 2018–2019:

Not applicable.

4. Estimated implementation time frame (in years or months) to achieve the decision:

12 months.

B. Resource implications for the Secretariat for implementation of the decision

1. Total resource requirements to implement the decision, in US$ millions:

US$ 1.97 million.

2.a. Estimated resource requirements already planned for in the approved Programme budget 2018–2019, in US$ millions:

US$ 1.97 million.

2.b. Estimated resource requirements in addition to those already planned for in the approved Programme budget 2018–2019, in US$ millions:

Zero.

3. Estimated resource requirements in the draft Proposed programme budget 2020–2021, in US$ millions:

Zero.

4. Estimated resource requirements in future programme budgets, in US$ millions:

Zero.

5. Level of available resources to fund the implementation of the decision in the current biennium, in US$ millions

– **Resources available to fund the decision in the current biennium:**

Zero.

– **Remaining financing gap in the current biennium:**

US$ 1.97 million.

– **Estimated resources, not yet available, if any, which would help to close the financing gap in the current biennium:**

US$ 1 million.

Table. Breakdown of estimated resource requirements (in US$ thousands)

Biennium	Costs	Region						Headquarters	Total
		Africa	The Americas	South-East Asia	Europe	Eastern Mediterranean	Western Pacific		
2018–2019 resources already planned	Staff	–	–	–	–	–	–	605	605
	Activities	100	100	100	100	100	100	760	1360
	Total	100	100	100	100	100	100	1365	1965

The representative of AUSTRALIA said that the tools for eliminating cervical cancer as a public health concern already existed but their implementation needed to be scaled up. The report acknowledged the challenges to implementation of the three accelerators for elimination identified and the need for approaches tailored for different countries and contexts; the development of a global strategy on cervical cancer elimination would be a valuable guide for countries in that respect and promote attainment of the Sustainable Development Goals.

The representative of BENIN, speaking on behalf of the Member States of the African Region, expressed support for the draft decision and observed that existing strategies to combat cervical cancer, such as human papillomavirus vaccination for girls, and screening and early treatment of pre-cancerous lesions, were hampered by weak health systems and insufficient human and financial resources. He therefore requested the Secretariat's assistance to strengthen the early screening strategy in the African Region and to mobilize resources. The Region's Member States pledged to draw up a regional cervical cancer elimination framework and to work together to produce elimination plans tailored to each country's context and sociocultural reality.

The representative of FIJI said that cervical cancer, which was the leading cause of death among women on small island developing States, remained a challenge in terms of primary health care through universal health coverage. He requested that his Government be added to the list of sponsors of the draft decision.

The representative of SRI LANKA, outlining action taken at the regional and national levels, said that cervical cancer prevention was a priority in the South-East Asian Region. WHO should act to reduce the price of the human papillomavirus vaccine, in order to facilitate its introduction and the achievement of high coverage rates in all countries.

The representative of JAMAICA said that, in addition to the measures outlined in the report, the Board should consider recommending that Member States integrate human papillomavirus vaccination into routine immunization schedules, and mounting a global communication campaign to address public concerns about the vaccine's safety. The discontinuation of the bivalent vaccine in 2019, combined with scaled-up national vaccination campaigns, could lead to shortages and higher costs, and steps had to be taken to address any shortfall. An investment case should be made to identify the costs and return on investment of scaling up national investment in cervical cancer elimination and to garner funding for the response.

The representative of BRAZIL, outlining action taken by his Government to eliminate cervical cancer, highlighted the importance of greater integration of surveillance and health care action to promote comprehensive care and stronger health systems. Prevention, including screening and human papillomavirus vaccination for girls, was vital, as was access to vaccination for women who had undergone chemotherapy and radiotherapy for cancer.

The meeting rose at 17:30.

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