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PROVISIONAL SUMMARY RECORD OF THE NINTH MEETING

WHO headquarters, Geneva
Thursday, 26 January 2017, scheduled at 14:30

Chairman: Dr R. BUSUTTIL (Malta)

CONTENTS

NINTH MEETING

Thursday, 26 January 2017, at 14:35

Chairman: Dr R. BUSUTTIL (Malta)

HEALTH SYSTEMS: Item 8 of the agenda (continued)

Human resources for health and implementation of the outcomes of the United Nations' High-Level Commission on Health Employment and Economic Growth: Item 8.1 of the agenda (document EB140/17) (continued)

The representative of the PHILIPPINES said that economic growth was dependent on a healthy population, which in turn necessitated a strong health system with a qualified and capable workforce. The Member States of the South-East Asia Region were studying how best to implement at the national and regional levels the recommendations and immediate actions set out in the report of the High-Level Commission on Health Employment and Economic Growth. His Government accorded high priority to the issue of human resources for health and looked forward to participating in the consultation process for the proposed five-year action plan 2017–2021 through a multisectoral approach at the national, regional and global levels. He called on the Secretariat to provide guidance on retaining a focus on health priorities within the context of the Sustainable Development Goals.

The representative of FRANCE said that the report of the High-Level Commission had strengthened the economic basis for investing in the health workforce and set out an innovative intersectoral approach that was firmly in line with the objectives of the Sustainable Development Goals; the draft decision aimed to facilitate the implementation of that approach. She agreed with the amendments to the draft decision proposed by the representative of the United States of America and requested that the footnote "And, where applicable, regional economic integration organizations" should be inserted after the words "Member States" in paragraphs (2) and (4).

The representative of THAILAND expressed support for the recommendations and immediate actions set out in the report of the High-Level Commission. However, harmonizing the implementation of the recommendations at the country level, increasing fiscal space for health, and providing effective support and facilitating sustainable capacity-building would pose particular challenges. With regard to the draft decision, he proposed incorporating paragraph (1) into the preambular paragraph, to read: "The Executive Board, having noted the report on human resources for health and implementation of the outcomes of the United Nations' High-Level Commission on Health Employment and Economic Growth, and welcoming the report of the High-Level Commission on Health Employment and Economic Growth, decides:". Noting that the draft decision should not pre-empt the actions of the Seventieth World Health Assembly, he proposed the deletion of the phrase "and possible adoption" in paragraph (3) and the deletion of paragraph (4).

The representative of the RUSSIAN FEDERATION said that the full and timely implementation of the recommendations and immediate actions would accelerate the implementation of the Global Strategy on Human Resources for Health: Workforce 2030, contribute to the achievement of the targets of the 2030 Agenda for Sustainable Development and yield positive results in areas including job creation, the promotion of gender equality and the rights of women, the provision of specialized health training, the provision and organization of medical and health services,

the use of technology and the response to crises and humanitarian emergencies. She highlighted the urgent need to implement the recommendations on improving the protection and security of health workers, including those from international humanitarian organizations working in conflict areas and responding to humanitarian emergencies.

The representative of FIJI expressed support for the draft decision and endorsed the amendments proposed by the representative of the United States of America. He was pleased to note that recommendation 9 on international migration highlighted the fact that the international mobility of health workers could yield benefits not only for destination countries but also for source countries and for the health workers themselves. Expressing serious concern about the issue of violence against health workers, both in conflict and non-conflict zones, as well as verbal and non-verbal aggression between colleagues in the health workforce, he noted the need to emphasize that aggressive behaviour towards or among health workers was never acceptable.

The representative of NEPAL, expressing appreciation for the support provided to Nepal, nevertheless noted the need for increased support to be provided to enable the Member States of the South-East Asia Region to deal with the major challenges that they currently faced, including guidance on best practices and the development of a national strategy and plan. The review of the types and number of front-line health care workers was timely, in the light of the predicted rise in noncommunicable diseases, antimicrobial resistance, ageing populations and health emergencies. She requested Member States to reinforce the implementation of the WHO Global Code of Practice on the International Recruitment of Health Personnel.

The representative of the DOMINICAN REPUBLIC said that urgent measures and a continuing dialogue between Member States were necessary in order to mitigate the effects of the migration of health care workers and ensure sufficient human resources for health at the national level.

The representative of LIBERIA, reading out a statement on behalf of South Africa,[1] expressed support for the draft decision. Gaps in human resources posed a serious threat to the ability to ensure the efficiency and effectiveness of health systems, and made it more difficult to improve health outcomes and deal with emergencies. The report of the High-Level Commission was a useful tool for further advocacy and for the implementation of the Global Strategy on Human Resources for Health: Workforce 2030, and it underscored the importance of a multisectoral approach.

The representative of SENEGAL,[1] noting the importance of the issue of human resources for health, welcomed the multisectoral and multidisciplinary approach outlined in the recommendations of the High-Level Commission. Developing countries seemed to be trapped in a vicious circle of insufficient health personnel and poor economic growth, resulting in woefully inadequate health structures and the damaging privatization of health care. Noting that the length and cost of medical training also posed a particular challenge, he called for the adoption of measures to promote both scientific study and professional training, including the development of courses to train community health workers and paramedics.

The representative of JAPAN[1] said that her Government was committed to tackling the issue of human resources for health. It was important for countries both to estimate the demand for health workers and to introduce quality standards. She called on the Secretariat to provide support to Member States in relation to training, equitable distribution and retention of the workforce, which would

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

require a multisectoral approach. The WHO Global Health Workforce Statistics database was a useful tool for networking and information sharing among Member States.

The representative of CUBA[1] said that countries should ensure the availability of sustainable and adequate financial resources to train health workers. Epidemiological transitions, including ageing populations and a concomitant increase in noncommunicable diseases, were set to place an increasing burden on health care systems, underscoring the need to meet health workforce requirements. An innovative, multisectoral, strategic approach was required, including increased cooperation at the national and international levels. Cuba stood ready to share its experiences in that regard.

The representative of NORWAY[1] said that her Government continued to prioritize health workers and their employment as the cornerstone of the health system and looked forward to participating in work on the proposed five-year action plan. The recommendations must be a force for ensuring: the education and employment of women; appropriate labour market interventions and policies; and the attainment of universal health coverage. Clarification was needed on whether the action plan was intended as a tool for ILO, OECD and WHO, or for Member States' implementation. Appropriate indicators, an ambitious timeline for implementation, and a more detailed accountability scheme were needed. She highlighted the need for a whole-of-government approach and for ILO, OECD and WHO to develop appropriate joint working methods when supporting countries in the implementation of the action plan at the national level, including strong and close collaboration on the ground.

The representative of BRAZIL[1] said that the recommendations of the High-Level Commission should be the main focus of efforts to develop a five-year action plan. He questioned why the item under discussion had been included on the agenda, while the proposed item on the report of the United Nations Secretary-General's High-level Panel on Access to Medicines, which also contained a set of recommendations, had not. He welcomed the recommendations, but pointed out that a draft decision on the finalization of a five-year action plan might be premature, as countries had not been given sufficient opportunity to discuss them. The draft decision should distinguish between OECD, which was not a United Nations specialized agency, and WHO and ILO, and should refer to the United Nations regional commissions and the WHO regional committees.

The representative of ILO emphasized the need to scale up investments in the health workforce in order to achieve the Sustainable Development Goals. Investments in health employment were a driver of inclusive economic growth and decent work. An intersectoral, multistakeholder approach was needed to tackle the challenges of health workforce shortages. ILO was committed to working with OECD and WHO to support countries in the implementation of the recommendations and would continue to support the development and implementation of the proposed five-year global action plan. The millions of new jobs created in the health and social sectors must ensure good working conditions, improved occupational safety and health, and the recognition of workers' rights.

The observer of the INTERNATIONAL FEDERATION OF RED CROSS AND RED CRESCENT SOCIETIES, referring to recommendation 4, on health service delivery and organization, said that there was a need to ensure that all task-shifting initiatives were accompanied by quality assurance measures. Governments should develop a legal framework to support volunteers working with local organizations in health and social care. Regarding recommendation 6, on crises and humanitarian settings, she highlighted that the Federation's humanitarian health competency matrix

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was a useful tool in improving the way in which emergency health teams were recruited, trained and evaluated. Governments needed to strengthen domestic legislation to ensure safe access to and the delivery of health care in armed conflicts and other emergencies.

The representative of the INTERNATIONAL COUNCIL OF NURSES, speaking at the invitation of the CHAIRMAN, said that sufficient investment in the health workforce would facilitate the achievement of the Sustainable Development Goals and help to deliver universal health coverage. The Council was committed to supporting the implementation of the recommendations, which would require cross-sectoral collaboration, including with the public and private sectors, civil society, trade unions and training institutions. He urged all stakeholders to implement the recommendations in order to improve public health and unlock the potential of health employment.

The representative of the INTERNATIONAL PHARMACEUTICAL FEDERATION, speaking at the invitation of the CHAIRMAN, said that the achievements of the Federation included the adoption of the Global Vision for a Global Pharmaceutical Workforce and the Pharmaceutical Workforce Development Goals, in line with the principles of the High-Level Commission, the Global Strategy on Human Resources for Health: Workforce 2030 and Sustainable Development Goal 3 (Ensure healthy lives and promote well-being for all at all ages). Pharmacists should be taken into account under indicator 3.c.1 of the Sustainable Development Goals (Health worker density and distribution); the Federation stood ready to provide support to Member States in developing pharmaceutical workforce policies and plans within the framework of that indicator.

The representative of the WORLD MEDICAL ASSOCIATION, INC., speaking at the invitation of the CHAIRMAN, said that the implementation of the recommendations of the High-Level Commission would be achieved only by upholding the fundamental rights of health care professionals. The Positive Practice Environments Campaign that had been initiated by a group of members of the Global Health Workforce Alliance proposed steps to foster satisfaction and resilience among health workers. Professional organizations had a key role to play in health policy-making and regulation.

The representative of MEDICUS MUNDI INTERNATIONAL – INTERNATIONAL ORGANISATION FOR COOPERATION IN HEALTH CARE, speaking at the invitation of the CHAIRMAN, said that the recommendations were based on an investment rather than a social model, wherein health and access to health care were viewed as a fundamental human right. The deployment of a greater number of community health workers would enhance access to health care, provide employment opportunities for women from poorer populations and stimulate economic growth. Tax reforms were imperative to enable countries to invest in the health workforce. She urged Member States to establish governance mechanisms and ensure sustained funding through bilateral agreements that included cost-sharing and progressive taxation measures. To that end, the WHO Global Code of Practice on the International Recruitment of Health Personnel should be reviewed and discussions on compensation and fiscal policies launched. Investment in robust mechanisms was imperative to ensure the implementation of the proposed five-year action plan at all levels.

The representative of the INTERNATIONAL FEDERATION OF MEDICAL STUDENTS' ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, said that a community-oriented, fairly paid health workforce was essential in order to advance human development. She called on Member States to increase investment in health education and to ensure that medical and pharmaceutical training was aligned with the needs of local populations.

The ASSISTANT DIRECTOR-GENERAL (Health Systems and Innovation) said that there was an urgent need to implement the immediate actions recommended by the High-Level Commission and develop innovative methods to address the long-standing challenges related to the health workforce.

The Secretariat would continue to engage in a consultative process with Member States and other stakeholders, such as ILO and OECD, in order to finalize the five-year action plan for submission to the Seventieth World Health Assembly. The report of the High-Level Commission provided a clear case for investment in the health workforce and strengthened the link with the Sustainable Development Goals. An intersectoral and interministerial approach was critical to the success of the recommendations of the High-Level Commission. The work of the High-Level Commission maintained momentum towards and should be strictly aligned with implementation of the global strategy on human resources for health. The five-year action plan would determine actions to facilitate country-driven leadership and implementation. Immediate priorities included job creation, transformative education, an international platform to maximize the mutual benefits of international labour mobility, the security and protection of health workers, and data. The Secretariat would continue to work closely with Member States and counted on their support and commitment.

The Board noted the report.

The CHAIRMAN took it that the Board wished to resume consideration of the draft decision once consensus had been reached on the proposals for amendments.

It was so agreed.

(For adoption of the decision as amended, see below.)

Principles for global consensus on the donation and management of blood, blood components and medical products of human origin: Item 8.2 of the agenda (document EB140/18)

The representative of PAKISTAN expressed support for the principles for promoting ethical practices in the donation and management of medical products of human origin, some of which his country had already adopted, thereby resulting in the containment of misuse and illegal trade. Member States should be assisted in establishing deceased donor procedures, recipient waiting lists, organ banks and consent for organ donation in accordance with the local context. The establishment of an international platform to assess the new opportunities and challenges brought about by emerging technologies in the field of organ donation was essential to enable all Member States to benefit from such developments.

The representative of TURKEY looked forward to finalization of the report of the public consultation on the draft proposal on principles for global consensus on the donation and management of blood, blood components and medical products of human origin. He supported the wording of principle 5, which defined realistic guidelines on remuneration of donation to protect human dignity and prevent exploitation. With regard to principle 10, he expressed the hope that the final report would provide greater clarity regarding the balance between transparency of information and confidentiality of donors.

The representative of BURUNDI, speaking on behalf of the Member States of the African Region, said that most countries of the Region did not have the capacity to separate blood into its component parts. Despite up-to-date equipment, contamination remained a risk. Expressing support for the principles, he underscored the need to provide all regions with the opportunity to adapt them to the local context. WHO should establish a global regulatory framework on ethical principles of human tissue donation for therapeutic use. He requested WHO to provide support for the development of national legal coordination frameworks to manage blood transfusions and organ donations, including information sharing with other countries. Support should be provided to Member States in establishing

a blood donation supervisory mechanism through national blood transfusion centres to ensure the safety of blood donors.

The representative of BAHRAIN underscored the need to further strengthen the principles set forth in the report. National compliance with the principles would require the establishment of adequate regulations and pharmaceutical surveillance. Given that countries encountered difficulties in applying the principles, she called on the Secretariat to provide support to Member States in developing policies and action plans to guarantee access to safe blood, blood components and medical products of human origin.

The representative of CHINA said that his country attached great importance to the management of blood, blood components and medical products of human origin and had set up a comprehensive management and operational system in line with national culture and traditions and WHO guidelines. It was essential to: strengthen cooperation among countries and regions; develop management systems that reflected national contexts; and adopt incentives for donation in accordance with domestic legislation and WHO principles. Organ donation from living persons should be strictly limited to recipients' relatives. She called on the Secretariat to continue to strengthen the technical support provided to Member States, particularly regarding the use of new technologies in developing countries, and to encourage donation.

The representative of MEXICO, welcoming the establishment of the guiding principles in general, noted the importance of measures to protect the dignity and human rights of donors. Principle 2 lent itself to confusion since it stipulated that people should be neither denied the opportunity of donating materials nor encouraged to donate where the opportunity did not exist. His Government had proposed the establishment of a system focused on voluntary and repeat donation. Principle 5 on policies governing payment of donation was not applicable in Mexico as donations were governed by law in line with principles of altruism and absence of financial gain. Remuneration was strictly prohibited for the acquisition and use of medical products of human origin and he could not, therefore, support principle 5. It was essential to continue refining the principles through the development of comprehensive strategic approaches supported by the relevant legislation.

The representative of FRANCE, welcoming the proposed principles, which echoed those set out in the Council of Europe Convention on Human Rights and Biomedicine, commended in particular the inclusion of principles on donor protection. She expressed reservation, however, concerning the use of the ambiguous term "financial neutrality" in principle 5, since it might legitimize payment for donation. In France, the donation of medical products of human origin was governed by principles of anonymity, consent and non-remuneration. She thus did not support principle 5 as it stood. In addition, further emphasis should be placed on the principles of "ethical donation" and "prohibition of financial gain". Noting that the French version of the report contained several discrepancies, she wished to submit a list of proposed amendments to the Secretariat.

The representative of the DOMINICAN REPUBLIC, noting the importance of the issue, said that his Government was developing policies and implementing measures to ensure the quality of donated blood, and was committed to implementing the recommended principles. Principle 2 on promoting equity in donation was linked to the national context, where efforts to improve the quality and availability of medical products of human origin, especially blood, were being undermined by the lack of coherence among the different constituents of the health sector.

The representative of the NETHERLANDS said that the proposed principles were essential in order to guarantee the best quality of blood and medical products of human origin for all recipients and donors worldwide, regardless of their socioeconomic background, and to safeguard vulnerable

individuals susceptible to financial incentives. The availability of such products depended largely on the willingness of individuals to donate without remuneration. Any actions that endangered the principle of financial neutrality should be opposed.

The representative of the RUSSIAN FEDERATION agreed with the comments made by the representatives of France, Mexico and the Netherlands. Welcoming the proposed principles, she nevertheless expressed concern that the report did not refer to key international instruments such as the Charter of Fundamental Rights of the European Union, and the Council of Europe Convention on Human Rights and Biomedicine. The report should also include clear definitions of "biological materials", "medical products of human origin" and "bioimplants". Further elaboration of the principles relating to donation was required, taking into account the informed consent of donors before donation and the importance of providing safe, high-quality materials. Her Government had already implemented legislation on the use of human organs and blood and was preparing an instrument on the use of human tissue. It was willing to share its expertise in the further elaboration of the principles.

The representative of CANADA expressed support for the proposed principles and for the collaborative approach taken by the Secretariat to consult with Member States on the development of the principles. Her Government had already implemented aspects of the principles in areas within its jurisdiction, such as maximizing product safety, quality and efficacy, and maintaining post-market surveillance and vigilance systems.

The representative of THAILAND said that, in the light of rising demand, decreasing numbers of donors and increasingly innovative manufactured medical products of human origin, a comprehensive and inclusive framework was essential to protect against exploitation and harm. There was a fine line between ethical support of donation of medical products of human origin and exploitation, particularly when remuneration was involved. His Government had already implemented proactive measures to ensure financial neutrality, such as mobile donation units, which reduced transportation expenses and prevented lost wages of donors. Regarding principle 9 on traceability, Member States should establish and maintain well-functioning registries of all recipients and living donors, as they were essential for the monitoring of health consequences, the early detection of complications, and the prompt provision of treatment. The Secretariat and other stakeholders should simplify the proposed principles, for example by using infographics, to ensure their practical implementation at the country level.

The representative of the CONGO said that significant progress had been made in the African Region over the past decade in terms of blood donation and the use of human blood in treatment and research, including the elaboration of a new regional strategy. Systems for human tissue and organ donation were being developed in Kenya, Nigeria and South Africa, and transplant programmes had been established. Those programmes should be developed into subregional hubs in order to support countries lacking the necessary technical capacity and address the needs arising from the increase in noncommunicable diseases. Organ donation in Africa needed to be regulated, taking into account ethical principles, voluntary consent, anonymity and infection risks. Obligatory organ donation in other countries led to the removal of organs without premortem consent, undermining ethical principles, and could result in abuses. The Secretariat should provide support to the Member States of the Region to establish a harmonized regional organ donation plan. His Government stood ready to participate in further elaboration of the proposed principles.

The representative of COLOMBIA said that the proposed principles were consistent with initiatives implemented in his country, such as the national blood system and national donation and transplant system, and would serve as a frame of reference for national regulations in economic, legal, ethical, technical and public health matters. Given the rise in health tourism in Colombia, it was

crucial to protect the principle of financial neutrality in relation to medical products of human origin, in order to combat organ trafficking. To ensure transparency, the safety, quality and efficacy of procedures involving the use of medical products of human origin needed to be guaranteed. It was also important to prevent misleading advertising on cell therapy. Clarification of whether the proposed principles replaced, expanded or supplemented the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation was necessary. For example, while the Guiding Principles indicated that donations should be non-remunerated, the proposed principles stated that donors could receive remuneration.

The representative of NEW ZEALAND, expressing support for the adoption of the principles, said that they were aligned with existing practice in his country, including the reimbursement of lost wages. Member States should rapidly introduce the principles into their national regulatory and ethical frameworks to protect the health and welfare of donors and recipients.

The representative of FIJI expressed support for the proposed principles. Historically, access to medical products of human origin in Pacific Island countries had been limited, largely due to geographical location, poorly developed systems for the management of such products and a consequent lack of supply. However, that situation was changing as countries began to build local capacity, notably in transplantation. It was essential for legislative and regulatory arrangements to keep pace with the adoption of new clinical practices. The framework of principles came at an opportune moment for small developing countries, which were beginning to prepare national policies and legislation on the issue. His Government requested WHO and other development partners to continue providing support to help to improve access to such products.

The representative of PERU[1] said that it was his understanding that the proposed principles were rules to be followed, with a view to achieving a specific purpose. Their wording, in some cases, should refer to the competent authority responsible for attaining the proposed objectives. He therefore proposed amending the first line of principle 2 to read: "Governments are responsible for promoting equity in donation".

The representative of BURKINA FASO,[1] while acknowledging the importance of the proposed principles, underscored the problems linked to the availability of and access to blood and medical products of human origin. In Burkina Faso, all patients requiring transfusions could obtain blood free of charge, and donations were voluntary and anonymous. Although the country had national and regional blood transfusion centres, the need for transfusions remained extremely high, and was even greater in winter due to increased numbers of cases of malaria. She urged the Secretariat and the international community to provide support to developing Member States, where limited access to blood and blood components remained a major concern.

The representative of SLOVAKIA[1] said that the report should include a reference to international instruments relating to biological materials and human rights. Donor selection should be clearly addressed under the essential safety mechanisms outlined in the report. Equity in donation did not mean that everyone automatically had the right to donate. A prudent approach should be advocated, with the possibility of accepting or declining donors based on factors such as medical history, health status and age. She requested the Secretariat to explain why the terms "blood and blood components" were included in the title, while greater reference was made in the report to "medical products of human origin".

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

The representative of GERMANY[1] said that his country was concerned that an approach establishing common principles for all medical products of human origin would weaken the fundamental principles for organ, tissue and cell donation that had been established at international level. It was questionable whether the key considerations for implementation outlined in the document allowed for the necessary scope for application; for example, the stringent ethical requirements to which organ donation was subject could not be applied to donations of hair and urine. Industrially prepared plasma products were not adequately addressed in the document; donation and processing steps should be clarified. Principle 5, which allowed countries to choose whether or not to apply the principle of financial neutrality, infringed upon the principle of the prohibition of financial gain in organ, tissue, cell and blood donation enshrined in the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation and the Council of Europe Convention on Human Rights and Biomedicine, and therefore could not be supported. He would submit a proposed amendment in writing to the Secretariat.

The representative of MOROCCO[1] proposed that the heading for principle 9 should be amended, by replacing the words "vigilance and surveillance programmes" by "pharmacovigilance, haemovigilance and surveillance programmes".

The observer of the HOLY SEE said that basic consensus on the proposed principles should be forthcoming, as they represented traditional values that underpinned both medical practice and the social fabric of human communities. While recognizing the severe lack of available donations, he said that procedures should be established to prevent the exploitation of vulnerable individuals, and noted that Pontifical Academy of Sciences would be holding a summit on organ transplant tourism in February 2017.

The observer of the INTERNATIONAL FEDERATION OF RED CROSS AND RED CRESCENT SOCIETIES expressed support for voluntary non-remunerated blood donation, which provided the foundation for safe and sustainable blood supply, helped guard against coercion and exploitation of vulnerable potential donors, and promoted equity in donation by engaging donors from all segments of society. Many countries still experienced chronic shortages of safe blood and blood products, and blood transfusions were not available for many of the world's most vulnerable populations. Expanded global commitment was therefore needed to support all governments in providing essential blood services to their populations.

The ASSISTANT DIRECTOR-GENERAL (Health Systems and Innovation) said that she had taken note of the comments made, in particular in refining the wording of some principles to balance the need for confidentiality and accountability. The report by the Secretariat was the product of a global consultative process, and the Secretariat was committed to conducting additional consultations with interested Member States, which would be used to draft an addendum to the report of the public consultation process. While the report by the Secretariat covered all medical products of human origin, paragraph 12 noted that the application of the principles might require different operational systems and regulatory oversight. She stressed that the report contained principles, not guidelines, which might have to be adapted in the light of national legislation or regional preferences. Principle 5 was particularly complex: a balance must be struck between establishing financial neutrality while taking care not to interrupt the supply of blood products to patients in need. The Secretariat would work with interested delegations to draft more consensual language on that principle.

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

The Board noted the report.

Addressing the global shortage of medicines and vaccines: Item 8.3 of the agenda (document EB140/19)

The representative of MALTA, speaking on behalf of the European Union and its Member States, said that the candidate countries Turkey, the former Yugoslav Republic of Macedonia, Montenegro, Serbia and Albania, the country of the stabilisation and association process and potential candidate Bosnia and Herzegovina, as well as Ukraine and Georgia, aligned themselves with her statement. The European Union welcomed the proposed definitions of "shortage" and "stock out" and commended collaborative work on health data management. Shortages and stock outs of medicines and vaccines had a significant impact on health systems, populations and patients. She called on the Secretariat to identify ways, within existing resources, of providing support to Member States in preventing and addressing stock outs, noting the importance of timely exchanges of information and mapping of the situation. Availability of medicines depended on all stages of the value chain. Medicines could not be treated as ordinary goods; the right balance must be struck between promoting and financing research and development of new and better medicines for all, while ensuring that medicines were accessible and affordable for those in need. Shortage management plans should be elaborated under the aegis of WHO. Health systems must be strengthened and procurement and supply capacity at the country level must be improved, including through in-country donor coordination. Access to medicines in small markets was particularly important, and the challenges related to lack of authorization applications for essential medicines should be recognized.

The representative of ERITREA, speaking on behalf of the Member States of the African Region, said that while the technical definitions were welcome, the report did not provide sufficient information about the activities undertaken to assess the magnitude and nature of shortages of medicines and vaccines. The Secretariat should therefore prepare a comprehensive report on that issue while taking measures to optimize support for Member States in strengthening procurement and supply management systems, and improving quality control. Consideration should be given to increasing programme budget allocations for access to medicines and health technologies for the biennium 2018–2019, and support should be provided for ongoing efforts at the regional level.

The representative of BAHRAIN said that the global shortage of medicines and vaccines constituted a major challenge for health systems, which must be overcome by measures such as reducing wastage, rationalizing supply, promoting domestic production and research and development, and granting market authorizations. Vaccine production was crucial, and joint efforts were required to control medicine and vaccine prices. WHO should provide a list of products at risk of shortage and offer appropriate guidance. Noting the importance of regional cooperation to avoid shortages, she said that the countries of the Gulf Cooperation Council were working together to develop alternative medicines and vaccines.

The representative of MEXICO said that the proposed definitions were welcome. His country had faced problems related to shortages, in particular of vaccines, which could threaten the implementation of its national vaccine schedule. Information sharing and communication with regard to potential shortages should be strengthened.

The representative of THAILAND said that the definitions provided in the report were useful and noted that the oligopoly and monopoly status of certain medicines had a major impact on shortages. The Secretariat should review country experiences and synthesize good practices. Joint work between WHO and the Health Data Collaborative to gather and publish reliable data on

shortages and stock outs was particularly welcome. Capacity-building for procurement and supply chain management was also essential.

The representative of CHINA welcomed the role of WHO in addressing the global shortage of vaccines and medicines. She outlined some of the steps being taken in her country to tackle the issue, including adapting procurement modalities, improving health insurance to include orphan drugs, completing national stockpile schemes, implementing medicine production plans and encouraging research and development. The Secretariat should collect and publish data on shortages and provide technical support to help Member States to ensure a timely response. She called for the establishment of a global priority framework to coordinate the response to shortages at the global, regional and national levels.

The representative of CANADA said that efforts were being made in Canada to address shortages through mandatory reporting requirements, and her country would willingly share its experience in that regard. While the harmonization of terminology was crucial to establish a common understanding, differences in regulatory frameworks could present challenges for the development of common definitions. The draft definition of shortage might be broadened to include medicines, health products and vaccines identified as non-essential, in line with the definition used in Canada.

The representative of KAZAKHSTAN said that he welcomed the proposed definitions. Shortages could be caused by monopolization of the market by certain pharmaceutical companies, as well as the imposition of certain patent policies to increase prices artificially and reduce supply. It was important to maintain open channels of communication with those producing medicines and vaccines and applying for patents, to negotiate prices and improve accessibility. The distribution and acquisition of medicines and vaccines should not be dictated by market forces alone; WHO leadership was essential.

The representative of JORDAN said that the report was timely. In Jordan, routine vaccinations were provided free of charge. Given the complex situation in the Middle East, and the heavy burden of refugees on Jordanian resources, considerable challenges had arisen. His Government wished to benefit from support from the GAVI Alliance to procure vaccines at reasonable prices.

The representative of the DEMOCRATIC REPUBLIC OF THE CONGO said that measures needed to be taken and opportunities grasped in countries, with the assistance of intergovernmental organizations, to help national governments establish the necessary mechanisms to ensure provision of essential medicines. Some countries already had experience in that regard and international partners existed. The time had come to establish a coordination mechanism to ensure that all opportunities for overcoming shortages and stock outs were optimized.

The representative of the RUSSIAN FEDERATION said that the rational use of resources was essential to overcome the challenges of shortages of medicines and vaccines. A national strategy had been adopted, through which models for pricing and procurement of medicines and costs of outpatient care were being set, with a view to increasing accessibility of treatment. An automated data collection and processing system was being set up to monitor public spending on medicines at the national, regional and municipal levels, which should be combined with efforts to develop local pharmaceutical production and coordinate price policies with producers and distributors of medicines.

The representative of FIJI said that, as a small island developing State, Fiji faced the dual challenge of being a small market for pharmaceutical suppliers and having a geographically remote location, with long lead times and high costs for the delivery of medicines. The views and experiences

of small, remote countries must be given due consideration in the further consultations on the global shortage of medicines and vaccines.

The representative of the UNITED STATES OF AMERICA said that more data on potential medicine and vaccines shortages was essential, along with clear technical definitions. WHO's continued efforts to establish a framework for measuring shortages and develop a notification system were welcome.

The representative of COLOMBIA said that access to and availability of effective, safe and cost-effective medicines was essential to the enjoyment of the right to health. The factors affecting access to medicines, such as problems in procuring raw materials, must be addressed, including through effective price negotiations. Welcoming the efforts to develop the proposed definitions, he drew attention to the report of the United Nations Secretary-General's High-level Panel on Access to Medicines, which afforded an opportunity for States to enter into a frank and constructive discussion and build consensus on the issue.

The representative of PANAMA[1] said that the global shortage of medicines and vaccines constituted an impediment to universal health coverage. Despite not having its own definitions, her country was taking steps to improve the supply chain for health products. Welcoming the efforts to develop the definitions set out in the report, she said that Panama would assist the Secretariat to broaden participation in the stakeholder consultations and to develop a notification system for medicines and vaccines at risk of shortage.

The representative of FINLAND[1] said that his country had established, under national law, a system of mandatory reserve supplies of certain medicines; the greater the use of those medicines, the more would be kept in stock. While that approach would not address the root causes of medicine shortages, it provided a useful buffer at the national level, which could serve as an example for other countries.

The representative of INDIA[1] said that the report did not cover issues related to innovation failure, manufacturers' decisions to discontinue production of less-profitable drugs, market distortions and price barriers. He highlighted the relevance of recommendations of the United Nations Secretary General's High-Level Panel on Access to Medicines, notably that governments should require manufacturers and distributors to disclose information pertaining to the costs of research and development, production, marketing and distribution of health technology, as well as any public funding received. WHO should maintain an accessible international database of the prices of patented and generic medicines and biosimilars. The technical definitions must take due account of issues relating to access and availability.

The representative of CUBA[1] said that efforts to combat shortages should focus on such key areas as renewed production of discontinued medicines, protection of essential medicines, development of new medicines, and fair pricing policies ensuring that medicines were available at lower cost in developing countries. Access to essential medicines must be guaranteed for all, and national and regional capacities to produce high-quality medicines should also be supported. The global shortage of medicines and vaccines must be addressed from a public health perspective, with a frank dialogue involving all stakeholders, increased cooperation and regulatory frameworks appropriate to the needs of each country.

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

The representative of NORWAY[1] said that the draft definitions required further work. The proposed definition of shortages should be broadened to cover products without marketing authorization in a given country and should not be restricted to products already approved and marketed nationally. The establishment of an information exchange system between Member States should also be explored.

The representative of BANGLADESH[1] said that the proposed definitions should be expanded to reflect the actual situation in developing countries, where shortages could be triggered by factors other than those related to the supply chain or production. Numerical scoring systems that would allow for international comparisons across countries were needed. Reliable data on the risk of supply-chain failure and the likelihood of stock outs should be available online. Countries should consider keeping reserve stocks of essential medicines, and governments should work with WHO to periodically update the Essential Medicines List. Pricing controls should be reviewed. The Interagency Supply Chain Group must become operational in the near future, and WHO must help countries to obtain prequalification for locally produced medicines and vaccines.

The representative of BRAZIL[1] thanked the Secretariat for taking a leadership role on the important issue. Examination of the relationship between the definitions of medicines and vaccines shortages and access and affordability would be appreciated. He supported the development of a notification system, and called for discussions on fair pricing to be made more visible and transparent.

The representative of INDONESIA[1] said that clear and functional definitions of stock outs and shortages, which included context-appropriate guidance, were crucial for developing a notification system for medicines and vaccines at risk of shortage. Supply chain data must be used to facilitate planning and managed appropriately to improve access to medicines and vaccines. Her delegation looked forward to participating in the consultation of Member States in 2017.

The representative of the BOLIVARIAN REPUBLIC OF VENEZUELA[1] said that WHO should provide support to Member States in evaluating obstacles to supply, including those linked to intellectual property, research and development, and the high costs of medicines. WHO should also facilitate bilateral dialogue for Member States to share expertise in shortage notification systems, and more should be done to ensure the involvement of manufacturers, wholesalers, procurement agencies and other stakeholders in those systems. Countries and national regulatory authorities should be empowered to implement regulations on reporting to mitigate the impact of shortages.

The observer of the INTERNATIONAL FEDERATION OF RED CROSS AND RED CRESCENT SOCIETIES said that the demand-side definitions should: emphasize the need to ensure that shortages and stock outs could be identified at any point in the supply chain, including at community level; and provide guidance on how to incorporate displaced and migrant populations in dose estimates. The latest guidance on dose-sparing strategies for vaccines should also be incorporated. Shortages were often more related to inequitable pricing structures than to poor stock management or availability.

The representative of the INTERNATIONAL ASSOCIATION FOR HOSPICE AND PALLIATIVE CARE, INC, speaking at the invitation of the CHAIRMAN, said that the Secretariat should consider access to controlled medicines in its broader Member State consultation in 2017 since the shortage notification system must also include controlled essential medicines. Examples of best

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

supply chain and regulatory practices should be taken into account, as should the opioid price watch report, which had found that generic essential controlled medicines were often unaffordable and unavailable in the poorest countries.

The representative of the INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS AND ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, said that trigger points within the supply chain should be identified to determine better the common causes of shortages, which might include unpredictable country demand, complex regulatory requirements, and lack of timely communication. She called for dialogue between manufacturers and public health authorities to address challenges before shortages occurred. Collaborative efforts should be made to reduce and harmonize times for post-approval changes and in-country testing for lot release, and reduce the number of specific national product and packaging requirements. All stakeholders must be involved in developing solutions to ensure a sustainable and flexible supply of good-quality medicines.

The representative of the INTERNATIONAL PHARMACEUTICAL FEDERATION, speaking at the invitation of the CHAIRMAN, said that a coordinated global approach was required to address the shortage of medicines and vaccines, and recognized the leadership of WHO on the issue. The Federation was working with the Government of South Africa to organize a side event on shortages during the Seventieth World Health Assembly. That event would allow the sharing of best practices and consideration of next steps in the implementation of resolution WHA69.25 (2016).

The representative of MÉDECINS SANS FRONTIÈRES INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that, since the adoption of resolution WHA69.25 (2016), little progress had been made on addressing the global shortage of medicines and vaccines, including in assessing the magnitude of the issues, initiating a global notification system and detecting shortages and stock outs at country level. The resolution on the issue that would be considered at the Seventieth World Health Assembly must be broadened to address vaccines and a response strategy within the global shortage notification system, cover diagnostics and ensure greater focus on in-country supply-chain issues, as opposed to manufacture-related issues. Member States had a responsibility to fund vital work at WHO on global shortages.

The representative of MEDICUS MUNDI INTERNATIONAL – INTERNATIONAL ORGANISATION FOR COOPERATION IN HEALTH CARE, speaking at the invitation of the CHAIRMAN, said that issues relating to barriers associated with intellectual property and high prices imposed by monopolies were not clearly addressed. Innovation and access to medicines should also be considered. Without sufficient public health safeguards, the benefits of the large sums invested in research and development by the public sector would be reaped by the private sector. Novel incentives, such as granting prizes to innovators, would enable generic production of medicines from the outset, and would de-link the price of medicines from the cost of research and development. WHO and Member States should endorse the final report of the United Nations Secretary General's High-Level Panel on Access to Medicines and work to implement its recommendations.

The representative of the WORLD HEART FEDERATION, speaking at the invitation of the CHAIRMAN, said that people living with cardiovascular disease acutely felt the impact of global shortages. Member States should prioritize the procurement of cardiovascular disease medicines; shortages could be avoiding by combining cost-effective, generic cardiovascular disease medicines into one single medicine, known as a fixed-dose combination or a polypill. WHO should work with all stakeholders to increase manufacturing capacity of generic formulations of essential medicines.

The ASSISTANT DIRECTOR-GENERAL (Health Systems and Innovation) thanked the representatives for their comments. The report was the first progress report and focused, as requested, on the definitions of shortages. Work on other aspects of resolution WHA69.25(2016) would be reported on subsequently. The process of developing the definitions had illustrated the complexity of the topic, and further consultations would be held, taking into consideration activities by global partners in improving procurement and supply chains. WHO would be serving as the secretariat for the Interagency Supply Chain Group for the next two years, which would allow close collaboration with relevant stakeholders. Notification systems had been discussed extensively at the 2016 International Conference of Drug Regulatory Authorities, and the potential of linking national reporting systems to regional and global systems had been considered. The need to identify vulnerable products had been highlighted, as had the importance of identifying shortages, and she noted the importance of early warning systems. She acknowledged the challenges associated with different-sized markets and remote island States, the importance of addressing access to medicinal products, needs-driven research and development, and pricing policies. WHO would, in cooperation with the Netherlands, be holding a fair-pricing forum to discuss options for improving transparency of price-setting mechanisms and policies for managing them in such a way as to ensure sustainable health systems and a continued supply of affordable medicines and vaccines. She looked forward to input from all Member States on that critical issue and to further cooperation with all stakeholders to address shortages of medicines and vaccines.

The Board noted the report.

Human resources for health and implementation of the outcomes of the United Nations' High-Level Commission on Health Employment and Economic Growth: Item 8.1 of the agenda (document EB140/17) (resumed)

The representative of FRANCE read out the proposed amendments to the draft decision. Paragraph (1) would be incorporated into the preambular paragraph, using the formulation "having welcomed" and the subsequent paragraphs would be renumbered accordingly. In the renumbered paragraph (1), the words "and relevant regional and specialized entities" would be inserted after "OECD" and "in keeping with the objectives of the Global Strategy on Human Resources for Health: Workforce 2030" would be added after "in consultation with Member States". Paragraph (2) would read "to request the Director-General to submit the five-year action plan for consideration by the Seventieth World Health Assembly". The beginning of paragraph (3) should read: "to further request the Director-General to work with Member States to adopt measures focusing on the key recommendations…". The footnote "And, where applicable, regional economic integration organizations" would be inserted added after "Member States" in paragraphs (1) and (3).

The decision, as amended, was adopted.[1]

The meeting rose at 17:30.

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[1] Decision EB140(3).