# **EXECUTIVE BOARD**144th session

# PROVISIONAL SUMMARY RECORD OF THE TENTH MEETING

WHO headquarters, Geneva Tuesday, 29 January 2019, scheduled at 14:30

Chairman: Ms M.N. FARANI AZEVÊDO (Brazil) later: Ms G. BEAUCHAMP (Australia) later: Ms M.N. FARANI AZEVÊDO (Brazil) later: Dr S.M. ZWANE (Eswatini)

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## **TENTH MEETING**

Tuesday, 29 January 2019, at 14:40

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

Medicines, vaccines and health products: Item 5.7 of the agenda (continued)

• Access to medicines and vaccines (document EB144/17) (continued)

The representative of ROMANIA, speaking on behalf of the European Union and its Member States, said that the candidate countries Montenegro, Serbia and Albania, the country of the stabilization and association process and potential candidate Bosnia and Herzegovina, as well as Ukraine, the Republic of Moldova and Georgia aligned themselves with his statement.

Health system reforms should integrate access to medicines, vaccines and health products into financial protection mechanisms for universal health coverage, for which adequate domestic financing must be ensured. WHO should take a holistic approach to the promotion of universal access to safe, effective, quality-assured and affordable medicines, focusing on good governance, transparency and synergies, fair pricing, adequate regulatory and workforce capacity, and more efficient supply chains.

He welcomed the development of a list of indicators but said that the revised draft road map for access to medicines, vaccines and other health products, 2019–2023 should more clearly describe the budget required for the actions and deliverables and how they were linked to the milestones, particularly in terms of timing. Improving access to medicines required more effective policy debate and interventions from donor and recipient countries, as well as innovative approaches. More details were needed on the scope and timing of the proposed development of incentive mechanisms that delinked the cost of investment in research and development from the price and volume of sales, and on incentives for the development of new products. The draft road map should also include a commitment to ensure equitable access to and stewardship of new medicines. Health systems strengthening, fair pricing and quality of medicines should be among the strategic priorities of WHO and allocation of the necessary resources should be ensured. Countries should put end-users and patients at the centre of efforts to increase access to medicines in order to promote sustainability and ownership.

The representative of VIET NAM welcomed the draft road map and the programme for the prequalification of health products, which would be particularly beneficial in developing countries. Her Government was committed to enhancing cooperation with the Secretariat, Member States and international organizations to improve equitable access to quality, safe, efficacious and affordable medicines and vaccines.

The representative of BAHRAIN expressed support for the draft road map, which highlighted the importance of universal health coverage, health promotion and equitable access to health products in ensuring integrated health systems. Further efforts were needed to tackle the global shortage of medicines and vaccines. The Secretariat should continue to support Member States in capacity-building

and sharing expertise. More information on the success achieved thus far in incentivizing research would be welcome.

The representative of BRAZIL expressed support for the draft road map. However, a clearer articulation of WHO's existing mandates in relation to access to medicines and vaccines would enable the Secretariat to prioritize its actions based on the collective guidance of Member States. With regard to regulatory system strengthening, he expressed doubt as to whether regulatory harmonization, actions to expand reliance on national regulatory authorities and the creation of a global benchmarking tool would actually improve the status quo of regulatory authorities. He looked forward to the concept note on the global benchmarking tool and encouraged the Director-General and senior management to allocate sufficient funding to the draft road map's activities, including through targeted resource mobilization.

The representative of SRI LANKA said that WHO should draw on the experience of the South-East Asia Region in ensuring the availability of quality, safe and effective vaccines when identifying and addressing issues of vaccine affordability and availability in countries that were self-funding and self-procuring. Support should be provided to countries transitioning from eligibility for support from Gavi, the Vaccine Alliance, particularly with regard to ensuring adequate vaccine access and supplies in emergencies and crises. It was also necessary to formulate policies on donations of vaccines and explore other forms of collaboration.

The representative of GERMANY appreciated the emphasis that the draft road map placed on the need for a multidimensional approach and well-functioning health systems. Collaboration between key stakeholders should be aligned with the global action plan for healthy lives and well-being for all. In tackling access to medicines, it was important to take account of legal and cultural barriers faced by populations disproportionately affected by certain diseases, as well as the role of civil society organizations. Given that the procurement of quality-assured health products was a challenge in countries that had transitioned from eligibility for support from global health financing mechanisms such as Gavi, he welcomed the draft road map's recognition of the need to strengthen countries' regulatory systems and procurement capacities. He also appreciated the greater attention that had been accorded to the local production of pharmaceuticals.

The representative of AUSTRALIA said that the draft road map should be expanded to cover other types of health products, specifically diagnostics. Her Government supported the global benchmarking tool, which would help to guide the formulation of country-specific institutional development plans. However, she expressed reservations about whether some of the proposed indicators were fit for purpose.

The representative of SUDAN said that access to medicines, vaccines and health products was a major challenge, in particular in developing countries since they lacked appropriate resources and surveillance and monitoring mechanisms. It was important to: introduce national regulations on the surveillance of pharmaceutical products; implement regional coordination mechanisms with a view to combating falsified medical products; conduct effective immunization campaigns; ensure that health products provided value for money; and draw on the experience of other countries. In addition, countries should be encouraged to participate in WHO's immunization programmes and be made aware of the negative effects of medicines that were not quality-assured. WHO should update its guidelines to improve efforts for monitoring biological products and controlling neglected tropical diseases.

The representative of the UNITED STATES OF AMERICA welcomed the draft road map but expressed disappointment that some areas lacked sufficient clarity and detail. Furthermore, several deliverables, such as those related to intellectual property and international trade, fell outside WHO's

area of expertise and risked going beyond the Organization's mandate; WHO must work closely with WIPO and WTO on such issues.

He therefore requested the Secretariat to prepare an updated version of the draft road map prior to the Seventy-second World Health Assembly. In particular, the Secretariat should revise the deliverables to clearly include WHO's planned actions for each one, as well as objective metrics for success. For example, the deliverable of continued strengthening of the trilateral collaboration between WHO, WIPO and WTO should include a detailed description of the planned capacity-building activities that the three organizations had agreed to undertake, and the related timetable. In addition, Appendix 1 should be updated to clearly indicate which World Health Assembly resolutions, decisions or documents were the source of WHO's mandate for each deliverable. Lastly, the Secretariat should provide a more thorough version of Appendix 2 that clearly stated to which deliverable each milestone applied. Once the draft road map had been finalized, the Secretariat should inform Member States annually about its activities with WIPO and WTO and provide an updated version of Appendix 2.

The representative of FIJI welcomed the draft road map. Equitable access to health products, vaccines and medicines was a challenge in small island developing States, owing to their remoteness, isolation and limited economies of scale. Such countries frequently encountered difficulties in relation to equipment, access to vaccines and medicines, and in ensuring access during emergencies. The rise in noncommunicable diseases and the growing demand for new medicines and health products were putting immense pressure on health systems, making it difficult to achieve universal health coverage.

The representative of INDONESIA welcomed the draft road map and its alignment with the Delhi Declaration on Improving Access to Essential Medical Products in the South-East Asia Region and Beyond. Equitable access to essential medical products could be enhanced through global, cross-sectoral cooperation and a transparent and participatory mechanism for price negotiation and pooled procurement, particularly for cancer medicines. The Secretariat should facilitate dialogue between Member States to develop such a mechanism.

The representative of MEXICO welcomed the draft road map but highlighted the need for it to specify the minimum requirements needed for the achievement of the deliverables. WHO's expectations should be objective and realistic to enable countries to establish their own criteria for attaining the deliverables. The main causes of inappropriate prescribing, distribution and sale of medicines should be identified and the positive effect that competitors had on the development, production and distribution of medicine should be stressed. In addition, the draft road map should: emphasize the benefits of promoting and protecting producers' market access and encouraging economic competition; include information on innovative risk-based practices between pharmaceutical companies and purchasers; highlight the need to strengthen technological capacities for the monitoring of health outcomes; and present the fair pricing model as a priority. The high prices of new medicines also deserved special attention. It was important to promote therapeutic substitutes in addition to generic medicines and biosimilars.

The representative of BENIN, speaking on behalf of the Member States of the African Region, welcomed the draft road map, including its emphasis on improving the competencies of human resources for health. However, the Secretariat should align the draft road map's actions with initiatives of Member States, including those of the African Region. For example, the Secretariat should support the African Union's initiative to establish the African Medicines Agency. He appreciated the inclusion of an impact and outcome framework but called for it to be revised to ensure that the proposed targets covered the entire scope of the draft road map's two strategic areas. He also recommended that the draft road map should include a third strategic area: international advocacy for the availability and accessibility of quality, affordable medicines, particularly in low-income countries.

The representative of the UNITED REPUBLIC OF TANZANIA expressed support for the draft road map, including its proposed priority actions and activity areas and their alignment with key WHO documents. His Government appreciated WHO's continuing efforts to support policy dialogue to ensure the delivery of services and fill critical gaps. Collaboration with regional networks and data- and information-sharing were fundamental to conducting better policy discussions. WHO should therefore continue to support increased collaboration between regions, countries and organizations for networking and sharing best practices and information.

The representative of CHILE said that mechanisms for promoting market competition and transparency should be top priorities. Countries should remain informed about the pricing, availability, quality, safety and efficacy of medicines. Her Government welcomed strategies to monitor the medicines market and the availability of medicines via digital channels. Indicators that measured the impact of activities undertaken by the Secretariat and Member States to improve access to health products should also be established. It was essential to implement mechanisms that encouraged biomedical research for public health needs and to develop a flexible legal framework that would strengthen the ability of governments to negotiate with industry. WHO and PAHO should guide the development of an operating model to rapidly respond to and resolve health product shortages, enhance the product prequalification system and facilitate negotiations and joint procurement, as well as the development of a joint framework for price negotiation.

The representative of COLOMBIA said that the draft road map would be a useful tool for Member States in strengthening policies and strategies to ensure safe, affordable and quality access to medicines, vaccines and other health products. Nevertheless, the draft road map should be more far-reaching and incorporate the recommendations contained in the report of the United Nations Secretary-General's High-level Panel on Access to Medicines. In addition, more in-depth information was needed on the proposed activities to enhance the efficiency of product registration systems, align the prequalification system with national regulations, and strengthen post-market surveillance. Her Government would submit further recommendations and observations to the Secretariat in writing.

The representative of CHINA said that sustainable financing and human resources development should be incorporated into the activities related to the strategic areas described in the draft road map, which could have an impact on its implementation and measurement. The indicators and targets set out in the draft road map for measuring progress were too limited in scope for such a complex issue, and she urged the Secretariat to quickly formulate other indicators to enhance, monitor and evaluate national policies and programmes. The Secretariat should also strengthen training and information-sharing regarding implementation of the Thirteenth General Programme of Work, 2019–2023, with a view to providing Member States with timely updates on the progress made and enhancing cooperation between countries and regions.

The representative of JAPAN expressed appreciation for the draft road map and said that further consultations on its implementation and improvement would be welcome. To strengthen access to medicines, it was essential to build capacities across all areas, including research and development, regulation, procurement and post-market surveillance. Further discussions were needed on how to harmonize pharmaceutical approval processes and build the capacity of national regulatory systems. His Government would continue to work with the Secretariat to support other Member States in that regard. Underscoring the importance of fostering a dialogue with all stakeholders, including the private sector, he encouraged the Secretariat to promote multistakeholder discussions.

The representative of DJIBOUTI, expressing support for the draft road map, wished to draw attention to the growing number of falsified medicines due to shortages, inequitable access to health care, and the lack of controls in developing countries, especially in Africa. Cross-border controls must

be strengthened. WHO should collaborate with regional organizations, such as the Intergovernmental Authority on Development, in strengthening access, including by creating tools for controlling the quality of medicines and health products and harmonizing pharmaceutical regulations. It was important to raise awareness among communities of the dangers of spurious and falsified medicines and health products. Community pharmacies and medicine depots should be created to reduce the use of falsified medicines and the cost of quality-assured medicines.

The representative of the NETHERLANDS expressed support for the comprehensive draft road map, including its holistic approach to the entire value chain and concrete and constructive actions. He also welcomed its strong focus on the quality of medicines and their rational use, and on building national capacities. Given the importance of fostering a dialogue on medicine shortages and sustainable fair pricing, he thanked the Secretariat and the Government of South Africa for organizing the second Fair Pricing Forum.

The representative of ITALY underscored the importance of a whole-of-system approach to ensuring access to medicines and invited the Director-General to continue discussions on fair pricing and transparency, in line with resolution WHA70.12 (2017) on cancer prevention and control in the context of an integrated approach. She expressed the hope that WHO's role in improving access to medicines, vaccines and health products would be strengthened and that the issue would remain on the agenda at future sessions of the World Health Assembly.

The representative of JAMAICA, highlighting the challenges faced by Member States as a result of the shortage of, and limited access to, medicines and vaccines, expressed appreciation for the collaborative regional and international efforts to facilitate the procurement of medicines, vaccines and other health products. She supported the draft road map, although there was still room for improvement.

The representative of ESWATINI, welcoming the draft road map, asked the Secretariat what was being done to improve access to human papillomavirus vaccine, particularly in terms of its prohibitive cost. Lessons learned from the prevention and control of HIV/AIDS should be used to improve access that vaccine.

The representative of the PHILIPPINES, <sup>1</sup> recognizing the importance of access to medicines and vaccines in attaining universal health coverage, welcomed the draft road map and the sharing of experiences concerning its implementation. Commending WHO and other organizations of the United Nations system for expanding the prequalification scheme, he looked forward to future efforts to include other health products that currently resulted in high out-of-pocket expenditure, especially for middle-income countries. His Government was committed to strengthening global and regional collaboration to improve price transparency, and called on WHO to accord greater attention to health workforce development strategies.

The representative of SWITZERLAND, expressing support for the draft road map, said that ensuring access to medicines required a global response that incorporated all aspects of supply and demand. She therefore called for greater account to be taken of all demand-related factors. Increased attention should be given to combating vaccine shortages and ensuring effective collaboration among international organizations, in keeping with each organization's mandate, and other relevant actors.

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

She asked the Secretariat to provide more information on the draft road map's timeline and monitoring mechanisms.

The representative of CANADA¹ expressed support for the new draft road map, and particularly the focus on collaboration and coordination between WHO, WIPO and WTO. Strong collaboration between WHO and WIPO was essential for ensuring that the relevant intellectual property expertise informed WHO's work and for avoiding the duplication of work. Noting that the draft road map represented a significant undertaking for the Secretariat, she asked for greater clarity as to how it would be funded.

The representative of INDIA¹ said that ensuring the availability, accessibility, affordability and acceptability of medicines and vaccines in low- and middle-income countries was the most topical global health issue. Although the draft road map was comprehensive, it did not contain any budget estimates for the deliverables and timelines described, or a breakdown of the work across the three levels of the Organization. He called on the Secretariat to align the draft road map with the recommendations of the report of the United Nations Secretary-General's High-level Panel on Access to Medicines, particularly with respect to the use of the flexibilities provided in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

The representative of the REPUBLIC OF KOREA, noting the prohibitive costs of medicines for many countries, welcomed the draft road map, its two strategic areas, and its concrete deliverables and indicators, which would serve as effective tools for developing national plans and measuring progress. Her Government would participate actively in WHO projects to strengthen international collaboration in improving access to medicines.

The representative of EGYPT¹ said that the cost of medicines was a major challenge, especially for developing countries. As such, it was important to: take on board the recommendations contained in the report of the United Nations Secretary-General's High-level Panel on Access to Medicines; promote cooperation between WHO, WIPO and WTO; and build the intellectual property capacities of developing countries, particularly through the TRIPS Agreement. In addition, the Secretariat should draw up a list of medicine prices and develop a licensing system that addressed the needs of all Member States.

The representative of the ISLAMIC REPUBLIC OF IRAN¹ said that a number of the activities outlined in the draft road map required further review and attention, including: regulatory system strengthening; health research and development; application and management of intellectual property; ensuring fair pricing; and reducing out-of-pocket payments. Given that there was no common understanding among member States of what constituted fair pricing, the draft road map should refer to "ensuring the affordable price of health products". The draft road map should also be more closely aligned with other WHO policy documents in the areas of cancer medicines, noncommunicable diseases, biomedical research and development, and antimicrobial resistance. He called on WHO to facilitate international cooperation and the transfer of technology from medicine-producing countries to other Member States, and particularly low- and middle-income countries. Given that access to safe, quality and affordable medicines was an essential component of the right to health, he expressed serious concern that access was being denied to large numbers of vulnerable people as a result of unilateral coercive measures and sanctions, and urged WHO to focus on improving access to medicines to ensure that no one was left behind.

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

The representative of the PLURINATIONAL STATE OF BOLIVIA<sup>1</sup> said that ensuring equitable access to essential, effective, safe and quality medicines, and cancer medicines in particular, required the efforts and participation of all sectors and the commitment of the international community. WHO had an essential role to play in rallying efforts to remove the obstacles hindering access to medicines. It was important to support national pharmaceutical industries by providing technical advice on the production of quality-assured, affordable essential medicines, underpinned by international quality standards, and to ensure that patent holders did not set prices based on demand, rather than on fair pricing. The lack of price transparency of medicines must also be addressed.

The representative of PORTUGAL,<sup>1</sup> welcoming the draft road map, said that WHO had a key role to play in addressing the obstacles faced by all countries in accessing safe, effective, quality-assured and affordable medicines, vaccines and other health products. It was essential to promote transparency throughout the value chain, strengthen pricing policies and foster cross-sectoral and cross-border collaboration with regard to information-sharing, regulation and joint procurement. He encouraged WHO to prioritize fair pricing and transparency through multistakeholder dialogue.

The representative of the DOMINICAN REPUBLIC¹ said that the draft road map represented a valuable opportunity to create an effective tool for ensuring access to safe, affordable and quality-assured medicines. While the draft road map would theoretically enable Member States to ensure access to quality, effective and safe medicines, she asked the Secretariat to provide more information on how the draft road map would guarantee and contribute to Member States' efforts to ensure fair and equitable access to essential medicines for all populations. She also wished to know how the draft road map would help to promote research and national production, which were essential to ensuring equitable access to medicines.

# Ms Beauchamp took the Chair.

The representative of the RUSSIAN FEDERATION¹ expressed support for the draft road map but drew attention to the need to develop common approaches to the regulation of medical devices in accordance with the recommendations of the International Medical Device Regulators Forum. It was important to encourage public research in the field of rare diseases and diseases that had a significant social impact, including on quality of life. Greater transparency was also needed in clinical research, including with regard to the publication of negative results to ensure the effective allocation of resources. It was essential that the Information Exchange System was used for the timely detection of falsified medicines. Regarding the cancer medicines included in the WHO Model List of Essential Medicines, Member States should take into consideration therapeutic guidelines, similarly to those regarding antibiotics. He supported both the promotion of the widespread use of generic medicines with expired patent protection so as to optimize resources, and the use of the flexibilities provided in the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health. Fair pricing of medicines and medical products must be ensured.

The representative of the BOLIVARIAN REPUBLIC OF VENEZUELA<sup>1</sup> expressed concern at the rise in the prices of new medicines, noting that shortages and stock outs of essential drugs and medicines posed an unacceptable risk to public health. The recent imposition of unilateral coercive measures on her country had reduced its capacity to provide access to vaccines and medicines, including

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

essential medicines. Such measures must be lifted. Health was a human right that must take precedence over commercial and economic interests.

The representative of THAILAND¹ said that good governance was required to support the three pillars of national policy, universal health coverage and strategic purchasing systems. Regarding the draft road map, capacity to implement the proposed actions at the national level was key to achieving improved access. Monitoring and evaluation were likewise important for measuring progress and barriers. There should be a clearer description of the outputs and timeline for the deliverables, as well as stronger alignment of the deliverables with the outcomes of the Thirteenth General Programme of Work. She welcomed the draft road map's focus on appropriate prescribing, dispensing and rational use of medicines, but said that improving knowledge, health literacy and awareness of the rational use of medicines was of equal importance.

The representative of SOUTH AFRICA¹ welcomed the draft road map, including its alignment with the targets of the Thirteenth General Programme of Work, but highlighted the need to accelerate efforts towards implementation of the related actions. She hoped that the draft road map would provide more opportunities to strengthen national efforts to increase access to medicines and health products and emphasized the importance of capacity-building, health workforce training and strengthening surveillance systems and cooperation, especially among regional networks. She commended WHO for working with partners such as Unitaid to address market barriers. Technical and financial support, particularly for low- and middle-income countries, would be important for implementing the draft road map and achieving its objectives and targets.

The representative of ZIMBABWE¹ expressed concern at the limited progress that had been achieved regarding access to safe, effective and quality medicines, vaccines, medical products and diagnostics in most developing countries. High prices and shortages of medicines remained severe threats to health service provision in many countries. The draft road map should include a greater focus on how the Secretariat would provide support to countries in implementing a public health approach to the use of the flexibilities provided in the TRIPS Agreement. In that connection, WHO should take the lead in raising awareness at the country level of the importance and full scope of those flexibilities for access to medicines, including through the provision of technical support. Mechanisms for ensuring fair pricing, in particular for cancer medicines, were crucial. Access to safe, effective and affordable medicines and vaccines was essential to attaining the health-related Sustainable Development Goals and achieving universal health coverage.

The representative of SPAIN<sup>1</sup> described the range of measures taken by his Government, including within the framework of the European Union, on improving timely and secure access to medicines and vaccines; ensuring their quality, safety, efficacy and availability; promoting innovation and access to new medicines; ensuring the correct use of antibiotics; and guaranteeing supply of medicines. He supported the objectives of the draft road map and looked forward to a presentation of the results achieved during future discussions on the matter.

The representative of BANGLADESH<sup>1</sup> welcomed the clear milestones set out in the draft road map. The Secretariat should continue to report to the governing bodies on progress made and challenges faced in implementing the draft road map. Greater emphasis should be placed on the importance of providing technical support to Member States in making effective use of the flexibilities provided in the TRIPS Agreement. The Secretariat should also tailor its capacity-building support to national contexts, without creating additional compliance requirements for the sake of regulatory harmonization.

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

She welcomed the actions to promote transparency of research and development costs and called for WHO to sustain engagement with evidence-based incentives in accordance with the previous work of the Consultative Expert Working Group on Research and Development: Financing and Coordination. She supported the call for the development of guidelines on the fair pricing of medicines, vaccines and other medical products, taking account of specific national contexts, especially in low-and middle-income countries. It was critical to continue promoting the use of quality and affordable generic medicines, while developing guidelines for combating the unregulated sale and proliferation of substandard medicines and health products.

The representative of the UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND¹ welcomed the activities set out in the draft road map but said that further information should be provided before the Seventy-second World Health Assembly on the deliverables and on how each area was linked to the milestones. In addition, a budget should be allocated to each deliverable to enable Member States to assess the resources and priority assigned to each area.

Recognizing the need for mechanisms incentivizing new product development in order to address market failure, she requested clarification of who would be involved in their development, what their scope would be, and when they would be implemented prior to publication of the finalized road map. Her Government supported the use of the flexibilities set out in the TRIPS Agreement, in particular during national health emergencies in developing countries.

The representative of ECUADOR¹ described the efforts made by his Government to ensure timely access to safe and effective medicines. The draft road map should include a greater focus on aspects such as the development of strategies on pooled procurement for purchasing and, in line with the recommendations of the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, strategies regarding the adoption and application of rigorous definitions of invention and patentability that were in the best interests of the public health of the country. The issue of judicialization of medicines should also be considered in the draft road map, as health systems were required to procure certain expensive drugs when their quality, safety and efficacy had not been demonstrated. His Government looked forward to contributing to further discussions on the topic.

The observer of PALESTINE welcomed the draft road map. Lack of access to medicines, vaccines and health products resulting from the Israeli occupation in the occupied Gaza Strip was having a detrimental effect on the health of the population. The recent prohibition by the Israeli authorities of the importation of some vaccines into occupied Palestinian territory had only been alleviated through the actions of WHO, UNICEF and other partners to facilitate the provision of vaccines on humanitarian grounds. He questioned how Member States could discuss health as a fundamental human right amid such a prohibition of access to vaccines for children.

The representative of the INTERNATIONAL SOCIETY OF NEPHROLOGY, speaking at the invitation of the CHAIRMAN, welcomed the draft road map and said that access to treatment for kidney disease remained highly inequitable both within and between countries. She called on all Member States and stakeholders to: promote the rational selection of essential medicines, the implementation of evidence-based clinical practice guidelines, and equitable access to the WHO Model List of Essential Medicines; ensure fair and transparent pricing and reliable quality of medicines; promote integrated care to rationalize access; ensure universal access to essential diagnostics; and build capacity among health workers and health systems.

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

The representative of the INTERNATIONAL FEDERATION OF MEDICAL STUDENTS' ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, called for support to be provided on the use of the provisions of the TRIPS Agreement, including the flexibilities provided therein, in low-and middle-income countries as a key strategy to ensure affordable access to medicines. She supported the implementation of research and development models that promoted innovation and access, and called for a new transparent, sustainable and needs-driven approach to biomedical research and development; WHO should continue to play a leading role at the international level in setting priorities in that regard. Efforts to address access to medicines must be aligned with work towards achieving universal health coverage. She supported the adoption of the draft road map and the role of WHO in facilitating multisectoral collaboration between all stakeholders.

The representative of the INTERNATIONAL PHARMACEUTICAL FEDERATION, speaking at the invitation of the CHAIRMAN, said that, with adequate training, community pharmacists were competent to perform roles that could significantly contribute to improving vaccination coverage. Despite a consolidated global trend towards increased authority being given pharmacists to vaccinate and towards expanding their vaccine-related roles, barriers still existed in some countries. Access to medicines and vaccines should be connected to access to pharmaceutical expertise to ensure their safe and responsible use.

The representative of the INTERNATIONAL ASSOCIATION FOR HOSPICE AND PALLIATIVE CARE INC., speaking at the invitation of the CHAIRMAN, said that her association would continue to work with the Secretariat to refine the indicators contained in the draft road map. She asked whether the new partnership with the World Medical Association, the World Organization of Family Doctors and pharmaceutical professions would include the training of new providers in prescribing and dispensing internationally controlled essential medicines for palliative care. Although the draft road map referred to problems associated with over-stocks, challenges related to under-stocks and stock outs were more pressing and could be remedied by ensuring a strong supply chain and increasing training for medical professionals to prescribe controlled medicines. Her association stood ready to support the Secretariat and Member States in strengthening health systems and the primary care workforce in the provision of palliative care.

The representative of STICHTING HEALTH ACTION INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that, while he endorsed evidence-based interventions as part of national actions to improve access to medicines, more should be done to ensure transparency among all stakeholders, including the private sector, which would be indispensable to ensuring accountability. He noted with satisfaction that the report acknowledged the mandate of the global strategy and plan of action on public health, innovation and intellectual property in tackling excessive intellectual property protection through mechanisms such as the use of the flexibilities provided in the TRIPS Agreement. Recognizing that collaboration with other organizations of the United Nations system was important, he nevertheless highlighted the need for WHO to take the leading role at the national, regional and global levels in intellectual property matters related to public health.

The representative of the WORLD HEART FEDERATION, speaking at the invitation of the CHAIRMAN, said that inequitable access to medicines, particularly in low- and middle-income countries, was preventing people living with cardiovascular and other diseases from accessing essential treatment. She called on Member States to: support access to benzathine penicillin G; ensure sustainable supplies of affordable, accessible and quality medication for cardiovascular disease; support access to quality diagnostics to screen for and detect cardiovascular disease; advocate for the inclusion of essential cardiovascular medicines in WHO's prequalification programme; promote voluntary licensing for access to new cardiovascular medicines; standardize the competencies and increase the transparency of

national selection committees of essential medicines; strengthen procurement models and supply chains; and implement legislation to combat substandard and falsified medicines.

The representative of PATH, speaking at the invitation of the CHAIRMAN, commended the draft road map's focus on stronger regulatory systems and harmonized regulatory review processes, and called on Member States to provide support in that regard. He expressed his appreciation for WHO's role in coordinating needs-based research and development but urged the Organization to take the lead only in areas where it was uniquely placed to do so and to ensure that any new intellectual property management and pricing activities did not jeopardize existing research and development initiatives and partnerships. He sought clarification as to whether the prequalification scheme would be a permanent global regulatory authority or an interim measure pending the strengthening of Member States' capacities.

The representative of the GLOBAL HEALTH COUNCIL, INC., speaking at the invitation of the CHAIRMAN, called on WHO to support a comprehensive approach to improving equitable access to essential health technologies and to promoting innovation. Access to medicines for children was restricted by: failures to adapt adult medicines for use in children; obstacles to successful paediatric clinical trials; and research and development costs. She called on WHO to ensure that applications for the inclusion of medicines in the WHO Model List of Essential Medicines also provided data, or explained that the required data was lacking, for inclusion in the WHO Model List of Essential Medicines for Children.

The representative of THE WORLDWIDE HOSPICE PALLIATIVE CARE ALLIANCE, speaking at the invitation of the CHAIRMAN, underscored the crucial importance of palliative therapy as a means of alleviating pain and suffering. When making policies and plans and setting budgets on access to medicines, WHO must consider people in pain through lack of access to controlled medications, and use its power and influence to stop avoidable suffering worldwide.

The representative of the MEDICINES PATENT POOL FOUNDATION, speaking at the invitation of the CHAIRMAN, said that her organization would work with the Secretariat and Member States to identify the medicines to be prioritized for affordable access and areas where her organization's licensing model could have the greatest public health impact. Free patent, licensing and regulatory data on essential medicines were available through her organization's patents and licences database and could help efforts to achieve the deliverable on transparency of the patent status of health technologies. She welcomed the draft road map and its inclusion of public health-oriented licensing agreements, but requested further information on the links between the deliverables and the milestones and asked how WHO would monitor their progress, in particular those not reflected in specific milestones.

The representative of OXFAM, speaking at the invitation of the CHAIRMAN, urged WHO to focus on: aligning the milestones on intellectual property with the recommendations of the global strategy and plan of action on public health, innovation and intellectual property; integrating in the draft road map the relevant recommendations from the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines; promoting the use of the flexibilities provided in the TRIPS Agreement; exploring incentives for biomedical innovation based on delinking research and development costs from product prices; and ensuring transparency across the medicine supply chain. She urged Member States to support the adoption of and fully fund the draft road map. Ensuring access to affordable, quality medicines would be key to achieving universal health coverage and the related targets of the Sustainable Development Goals.

## Ms Farani Azevêdo resumed the Chair.

The representative of KNOWLEDGE ECOLOGY INTERNATIONAL, speaking at the invitation of the CHAIRMAN, welcomed the draft road map's suggestions for enhancing the transparency of research and development costs and promoting the development of incentives for delinkage. Evidence-based incentives for research and development investments that were not tied to monopolies and high prices should be explored and implemented. WHO should develop a manual on pricing regulation, describing the mechanisms and methodologies currently used by Member States to ensure fair pricing.

The representative of the INTERNATIONAL PHARMACEUTICAL STUDENTS' FEDERATION, speaking at the invitation of the CHAIRMAN, said that countries should take advantage of the key role played by pharmacists in providing access to medicines, vaccines and health products and protecting patients from the consequences of medication shortages and gaps in the supply chain, by including them in the development of national plans and systems to enhance access. Good governance of medicines promoted transparency throughout the supply chain and the strengthening of regulatory capacity, monitoring systems and workforce capacity. Collaboration across the supply chain was likewise important to ensure timely access to appropriate medicines. She expressed support for the draft road map.

The representative of the EUROPEAN SOCIETY FOR MEDICAL ONCOLOGY, speaking at the invitation of the CHAIRMAN, welcomed the draft road map and offered the use of resources developed by her organization to support WHO's goals to ensure the evidence-based selection, appropriate prescribing and dispensing, rational use, and prevention of shortages of medicines. The first target of the impact and outcome framework should be amended to include secondary health care to ensure that it covered all treatment for cancer patients. In addition, low-cost opioids for cancer pain management and inexpensive essential cancer medicines should be included in the indicator on the core set of relevant essential medicines. Since palliative care was inexpensive and effective, the percentages listed in the second target of the framework on the availability of oral morphine should be raised to "50% to 80%", with an ideal target of 100%, to prevent unnecessary suffering.

The representative of MÉDECINS SANS FRONTIÈRES INTERNATIONAL, speaking at the invitation of the CHAIRMAN, welcomed the draft road map, but expressed concern that it did not reflect several recommendations agreed upon at the Seventy-first World Health Assembly within the scope of the global strategy and plan of action on public health, innovation and intellectual property, in particular those concerning the promotion of technology transfer, the management of intellectual property, and the development of national legislation reflecting the flexibilities provided in the TRIPS Agreement. Fair pricing could only be achieved by ensuring transparency in pricing information. WHO should pay special attention to the procurement needs of countries transitioning from donor support and provide guidance on the development of policies and regulations on health procurement and access to medicines; use of prequalification services would be essential in that regard.

The representative of the UNITED STATES PHARMACOPEIAL CONVENTION, speaking at the invitation of the CHAIRMAN, commended WHO for highlighting and seeking to reduce the global rise of substandard and falsified medical products. However, the draft road map should better explain the links between how strategies to strengthen regulatory systems, maintain and expand the prequalification service, and improve the prevention, detection and response to substandard and falsified health products supported vertical disease programmes and other WHO priorities. The draft road map should also describe how WHO would work with technical partners to support countries in adopting and implementing international standards, tools and best practices to safeguard the quality of medical products.

The representative of the DRUGS FOR NEGLECTED DISEASES INITIATIVE, speaking at the invitation of the CHAIRMAN, welcomed the draft road map and said that the Secretariat, together with political and financial support from Member States, should focus on concrete deliverables that could serve as practical guidance for all stakeholders. In addition to the work planned, WHO should reconvene the Expert Committee on Health Research and Development to identify health research and development priorities, and should produce a list of missing essential medicines. She suggested the inclusion in the draft road map of the development of a repository of legal terms in order to increase knowledge of the research and development process. The draft road map should also include deliverables on the specific needs of children, one of the most neglected populations.

The representative of the UNION FOR INTERNATIONAL CANCER CONTROL, speaking at the invitation of the CHAIRMAN, said that a consistent emphasis on health systems strengthening and timely access to quality medicines would be key to the attainment of the Sustainable Development Goals. She urged Member States to implement the draft road map in order to: ensure the affordability and availability of safe, effective and quality medicines; build capacity for the implementation of intellectual property laws in line with the flexibilities provided in the TRIPS Agreement; address the training needs of the health workforce; and engage civil society. The proposed increase in the availability of essential medicines should be extended to secondary- and tertiary-level facilities to ensure access to effective cancer treatment.

The representative of the INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS AND ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, welcomed the draft road map's emphasis on areas where WHO had a unique mandate. WHO should take a pragmatic approach, focusing on a limited set of measurable priorities on which there was international consensus. Increased engagement with the private sector and other stakeholders would be critical in making progress towards increasing domestic financing for universal health coverage, improving affordability for patients and sustaining health systems. Efforts were required to gain a better understanding of the unintended consequences of price transparency on the ability of manufacturers to offer preferential pricing to developing countries. WHO's technical support on intellectual property and trade issues should be based on broad international consensus, involve WIPO and WTO, and be in line with the mandate provided by the global strategy and plan of action on public health, innovation and intellectual property.

The representative of MEDICUS MUNDI INTERNATIONAL – INTERNATIONAL ORGANISATION FOR COOPERATION IN HEALTH CARE, speaking at the invitation of the CHAIRMAN, said that WHO should take bolder action to improve access to medicines. The Secretariat should actively support Member States in using the flexibilities provided in the TRIPS Agreement to combat high prices of medicines; in that regard, Member States must not threaten against the use of those flexibilities. Support should also be provided to Member States to establish publicly owned pharmaceutical manufacturing facilities and regulate marketing expenditure. WHO should formulate a binding international legal instrument to regulate the marketing of medical products. In addition, regulatory system strengthening should be evidence-based and avoid conflicts of interest and regulatory capture. She called for increased knowledge-sharing and transparency of innovation costs funded by public and private entities.

The representative of the INTERNATIONAL PLANNED PARENTHOOD FEDERATION, speaking at the invitation of the CHAIRMAN, commended WHO for providing strong leadership in ensuring access to medicines, vaccines and health products. Although the draft road map provided a clear structure for addressing the key challenges faced by low- and middle-income countries, greater emphasis should be placed on ensuring access to essential sexual and reproductive health products,

including contraception and maternal health products, which would be key to the achievement of global health targets.

The representative of the THALASSAEMIA INTERNATIONAL FEDERATION, speaking at the invitation of the CHAIRMAN, highlighted the need for equal access to medicines and vaccines for people with thalassaemia and other haemoglobinopathies who were at high risk of blood-borne infections such as hepatitis. He therefore urged Member States to ensure access to quality iron-chelation and hepatitis C therapies, including vaccines, and to encourage the production and procurement of safe and effective generic medicines.

The REGIONAL DIRECTOR FOR SOUTH-EAST ASIA thanked participants for their comments, which would be taken into account in improving the draft road map before the next session of the World Health Assembly. Responding to points raised, she recalled that the Delhi Declaration on Improving Access to Essential Medical Products in the South-East Asia Region and Beyond, adopted at the meeting of the Regional Committee for South-East Asia in September 2018, had included diagnostics in its definition of medical products. Work was also being done at WHO headquarters to incorporate diagnostics within the scope of access to medicines. To promote capacity-building among regulatory authorities, the South-East Asia Regulatory Network supported national regulatory networks in the Region to share information on the quality and safety of medicines, as well as best practices. The PAHO Strategic Fund could be a useful model for WHO's work at headquarters and the regional level to ensure the availability of medicines and vaccines at reasonable prices. Although the PAHO Strategic Fund was restricted to vaccines, it could be expanded to include other medicines. She had discussed ways of strengthening interregional collaboration and sharing experiences with the Regional Director for the Americas.

Efforts towards implementing the draft road map should build on the recommendations in the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, which should also be taken into account in the Secretariat's report to the Seventy-second World Health Assembly. The use of the flexibilities provided in the TRIPS Agreement and increased collaboration with WIPO and WTO had already been considered in the deliverables set out in the draft road map; however, further details would be included in that regard if necessary.

The ASSISTANT DIRECTOR-GENERAL (Access to Medicines, Vaccines and Pharmaceuticals) said that Member States' comments and suggestions would be taken into consideration in further refining the draft road map. Responding to points raised, she said that, following extensive consultations with Member States, national regulatory authorities and the public, the Secretariat had finalized the global benchmarking tool and would soon publish a draft concept note on how the tool would be operationalized. Consultations on the concept note itself would also be undertaken. She assured Member States that the tool would not create additional barriers. Increasing the pool of regulators and quality-assured medicines was a key priority for the Secretariat.

With respect to intellectual property matters, WHO had been given a mandate to work on the relationship between health, intellectual property and trade since the adoption of the TRIPS Agreement. She highlighted the strong collaborative spirit between WHO, WTO and WIPO and other organizations in that regard, and the range of mechanisms for discussing and reporting on that work.

Access to human papillomavirus vaccine was indeed a problem, particularly in terms of pricing. It was necessary to increase the availability of prequalified products since only two vaccines were currently available. In that connection, countries transitioning away from support from Gavi were receiving support from the Secretariat in negotiating prices as well as in procurement. Elimination of cervical cancer was a flagship initiative for WHO.

She welcomed the suggestions on how the draft road map and the Thirteenth General Programme of Work could be used to better support countries in achieving equity in access to medicines. Inaction in that regard had many human consequences; collaboration on the matter was therefore very important.

The DIRECTOR-GENERAL said that WHO attended trilateral meetings with WTO and WIPO to discuss the interface between public health, intellectual property and trade. In that context, the three organizations carried out their individual mandates, while also recognizing the need to work together. The Secretariat was therefore working within its mandate.

Ensuring access to affordable, quality medicines would be key to achieving universal health coverage; collaborative efforts would be crucial in that regard. The Secretariat and its partners stood ready to support countries in building their regulatory capacities and establishing joint regulatory bodies, in line with the WHO reform agenda.

Work on access to quality and affordable medicines must be categorized into short-, medium- and long-term actions. One action that could be taken immediately was pool procurement, which created economies of scale and thus increased access. PAHO had a successful strategy on pooled procurement that could be replicated elsewhere. In addition, more should be done to build supply chain capacities, which would help to lower the price of medicines.

WHO would expand its prequalification services since it was currently only working with a few select products. Expanding prequalification of medicines was also part of the WHO transformation agenda.

Thanks to the work of partners, such as Unitaid, the cost of many medicines had decreased in recent years. For example, the cost of HIV testing kits had fallen from US\$ 48 to US\$ 2. It was vital that all stakeholders worked together to reduce prices and thus improve access. There was no sense in innovation without access.

# The Board took note of the report.

## • Cancer medicines (document EB144/18)

The representative of IRAQ said that cancer medicines were priced so high that many governments, including her own, were unable to provide them under universal health coverage without an additional charge for patients. The Secretariat should continue cooperating with Member States to optimize the use of resources and improve access to those essential medicines. Member States benefited from guidelines such as the options presented in paragraph 42 of the report contained in the Annex to document EB144/18.

The representative of the NETHERLANDS said that it was worrying that pharmaceutical companies set prices of cancer medicines according to their commercial goals. There should be more transparency in the relationship between the pricing of medicines and research and development. Non-transparent medicine prices could conflict with the principles of good governance. Similarly, confidential agreements could compromise clear lines of accountability. Industry partners and other stakeholders should work closely with WHO and Member States towards a more sustainable model for the development of medicines.

The representative of AUSTRALIA agreed with the analysis in the report and supported WHO's focus on cancer medicines. Cancer medicines were the biggest driver of the overall growth in the cost of medicines. The Secretariat should provide further details on the proposed options so that Member States would be able to assess the merits of the options and how they aligned with domestic policies. More clarification was needed on how the options would be operationalized, particularly where collaboration across national, regional and international agencies was required.

The representative of BRAZIL said that it was vital to examine pricing approaches, such as the relationship between inputs throughout the value chain and price setting. Innovators and WHO must

address the unavailability of effective and affordable medicines for several types of cancer. It would also be possible to apply many of the conclusions of the report to other diseases.

The representative of VIET NAM welcomed the options to enhance accessibility to and affordability of cancer medicines, as proposed in paragraph 42 of the report.

The representative of the UNTED STATES OF AMERICA said that efforts to reduce the costs of pharmaceuticals must not undermine incentives that fuelled the development of new treatments. She supported some of the policy options outlined in the report, but was unable to support others, notably the use of TRIPS flexibilities and increased cost transparency for research and development, as those required more consideration of the economic, public health and innovation impacts. It was also disappointing that the report did not include a systematic analysis of the potential impacts of the policy options on research and development incentives. While WHO asserted that the estimated returns on investment accounted for the costs of failures in research and development, those estimates were based on a study that did not consider the research and development costs incurred by companies that had never successfully marketed a medicine. Further, the report would have benefited from consultation with private sector representatives. WHO should organize information sessions to provide Member States and external stakeholders with more details on the aforementioned issues.

The representative of INDONESIA said that, by performing cost-effective assessments, health facilities would be able to provide fully funded, sustainable and effective cancer care. He supported global efforts to enhance the affordability and accessibility of cancer medicines. It was particularly important to encourage transparency and set a tangible and achievable time frame for improvements.

The representative of GERMANY said that it was essential to address access to cancer medicines in a holistic manner and strengthen the whole health system, not just medicines. WHO must therefore consider the availability and affordability of cancer medicines within a wider context, rather than focusing solely on pricing approaches. The report should take into account the importance of diagnostic tools and introduce a structural distinction between patented and non-patented cancer medicines. WHO should engage with the Medicines Patent Pool to negotiate voluntary licences for cancer medicines. Governments should address price variability as a means to abolishing inequality within their country.

The representative of COLOMBIA said that WHO should pay more attention to industry self-regulation, barriers to the promotion of competition and the use of biosimilar medicines, and value-based pricing. Future reports should contain regulatory guidelines for clinical research, taking into account the benefits for society and the ethical and financial implications. One potential option was to lower prices for cancer medicines when patients had taken part in clinical studies.

The representative of FIJI said that small island developing States faced several challenges concerning access to cancer medicines, including high costs and wastage. Donors and agencies should develop financial and procurement mechanisms for small island developing States. That would help to attain economies of scale and set an affordable global price for cancer medicines.

The representative of ALGERIA said that his Government supported the efforts of WHO to collect information on the availability and pricing of cancer medicines by establishing and strengthening monitoring systems and ensuring that data was shared. He was in favour of strengthening strategic and collective procurement. It was also important to standardize the selection and registration of pharmaceutical products as well as to monitor and analyse them. WHO could play a key role in developing treatment guidelines and influencing political decisions, for instance, on price setting.

The representative of SRI LANKA said that, despite the inclusion of noncommunicable diseases in the Sustainable Development Goals, the high price of cancer medicines meant that they were not easily accessible or affordable, especially to people of lower socioeconomic status. His Government had taken several steps to ensure a continuous supply of cancer medicines. While promoting research in cancer medicines was important, it was necessary to identify ways of not including the cost of the research in the cost of the medicine.

The representative of JAPAN said that knowledge sharing would help to balance innovation with access. For that reason, he agreed that a Member State briefing would be helpful, and that dialogue with industry representatives would be mutually beneficial.

The representative of MEXICO said that including cancer medicines in the WHO Model List of Essential Medicines would contribute to regional collective purchasing decisions. Cancer prevention should be a strategic priority, but clear guidance was also needed on cancer care and control and how to raise awareness of the contribution of the private sector to innovation, development and price setting. He therefore welcomed the options relating to pricing presented by other representatives.

The representative of SUDAN, speaking on behalf of the Member States of the Eastern Mediterranean Region, reiterated the findings contained in the report regarding the uncertain nature of value-based pricing and the lack of correlation between research, development and production costs and the price of cancer medicines. As inequity in the price of cancer medicines and their lack of affordability kept many countries from expanding their health services, there was an urgent need to revisit pricing policies and regulations. The governments in his Region were committed to engaging in open, inclusive and transparent discussions on how to tailor and implement the policy options presented in the report. The Secretariat should scale up its technical support to help Member States identify the most effective and suitable policy options.

The representative of ITALY noted that the report called for international action to make reporting and the production costs of cancer medicines more transparent. Thus, she hoped that WHO would take on a greater role by issuing an appropriate instrument and continuing the discussion at the Seventy-second World Health Assembly.

The representative of THAILAND¹ said that, based on experience gained by her Government, Member States should issue clear treatment guidelines, negotiate prices based on economic evaluations, and procure quality generic medicines through the application of TRIPS flexibilities and collective bargaining. The Secretariat should prioritize sustainable capacity building to support Member States. A global legal framework separating research and development costs from the price of medicines should be adopted to ensure affordable prices and increase access to new, high-cost cancer medicines.

The representative of PERU<sup>1</sup> said that ensuring access to safe, effective, affordable quality medicines for all was particularly challenging when it came to cancer medicines. He supported the policy options presented in the report, and said that Member States should also consider: centralizing procurement of products with a high public health impact; identifying the most common cancers in their national context and centralizing procurement of the corresponding medicines; developing technical guidance on the diagnosis and treatment of different cancers; promoting policies on biosimilar

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

medicines; and conducting joint negotiations on high-cost products with other Member States in their region or subregion, especially for those with a large public health impact.

The representative of PORTUGAL<sup>1</sup> commended the report's emphasis on transparency and said that it was time to put the recommendations into practice. He highlighted the findings on the lack of accountability and good governance when research and development costs were not transparent, which were more relevant when funding came from the public sector. Clarifying the source of research and development funding would indicate respect for tax payers and was ultimately a matter of human rights.

The representative of SPAIN¹ called on the Director-General to continue advocating for access to cancer medicines. The lack of transparency in the pharmaceutical industry affected countries of all income levels, though it particularly restricted access to more innovative therapies in low-income countries. He reiterated the suggestion that WHO should work with the Medicines Patent Pool to negotiate voluntary licenses for cancer medicines.

The representative of ARGENTINA¹ said that risk-share agreements could make medicines more accessible and ensure the sustainability of the health system while still incentivising innovation. The price-setting strategies outlined in paragraph 15 may lead to guidelines on clinical practice and prescriptions being strengthened. She recommended improving compliance with regulations on generic medicines. Medicines to treat rare diseases should be better regulated to avoid excessive prices on their entry into the market. Members of the Southern Common Market (MERCOSUR) had been working on joint procurement of high-cost medicines, and that work was being expanded to include cancer medicines.

The representative of SWITZERLAND¹ noted with concern that the costs of cancer medicines continued to rise at a faster rate than those in the rest of the health sector. The proposed solutions contained in the report were welcome, as they would help Member States ensure that their health systems were sustainably financed and provided necessary, suitable and effective medicines. The actions outlined in the report would require heightened international cooperation in the form of increased information sharing and joint negotiations.

The representative of INDIA¹ said that to ensure the accessibility and affordability of cancer medicines, the Indian pharmaceutical industry had contributed to the manufacture and export of generic medicines. There was a need to focus on stronger pricing policies, more efficient spending on cancer medicines, demand factors, and incentives for research and development. WHO should continue supporting governments in strengthening their governance capacities, with particular regard to delinking prices from development costs, and encourage the use of TRIPS flexibilities and voluntary license agreements.

The representative of ZIMBABWE<sup>1</sup> said that the agenda of future sessions of the Executive Board and World Health Assembly should be organized in a more integrated and holistic manner. For example, all essential diagnostics, medicines and vaccines could be considered together, or noncommunicable disease control could be discussed under one item. There should be a more comprehensive focus on universal health coverage and access to primary health care.

The representative of the DOMINICAN REPUBLIC<sup>1</sup> said that it was appropriate to establish mechanisms to encourage transparent medicine pricing. The use of generics and biosimilar medicines, under strict quality standards, should be encouraged to ease access to cancer treatment.

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

Pooled procurement should be incentivized to boost purchasing power. Price regulation strategies were needed for research and development. An information-gathering structure should be implemented to improve clinical response monitoring, strengthen drug safety programmes and develop capacities in health technology evaluation for cancer medicines, and countries should exchange best practices.

The representative of the INTERNATIONAL ASSOCIATION FOR HOSPICE AND PALLIATIVE CARE INC., speaking at the invitation of the CHAIRMAN, reminded Member States that her organization had a list of essential medicines for palliative care, including cancer care, which contained internationally controlled substances that were unavailable in more than 70% of countries. She asked WHO to prepare a report on the unique pricing and access issues of controlled medicines.

The representative of KNOWLEDGE ECOLOGY INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that the Executive Board should implement the report's recommendations on transparency and public sources of funding. Companies' potential objections to the report's findings were merely a further argument for more transparency. WHO should host a meeting to explore the feasibility of delinking prices from research and development costs. It should evaluate the use of geneand cell-based cancer therapies, considering in particular how to ensure equal access, the extent to which patent exceptions could be applied, and whether changes would need to be made to research and development incentives.

The representative of OXFAM, speaking at the invitation of the CHAIRMAN, said that high prices for cancer medicines meant that treatment was not universally accessible. WHO should: produce treatment guidelines for different cancers; support countries in implementing national measures to lower the price of cancer medicines; and promote increased transparency in research and development costs and the delinkage of those costs from medicine prices.

The representative of MÉDECINS SANS FRONTIÈRES INTERNATIONAL, speaking at the invitation of the CHAIRMAN, recognized the fundamental, widespread failings in the production of essential medicines. Excessive and non-transparent pricing did not reflect public-sector contributions or research and development incentives, leaving some health needs unmet. She called on WHO and Member States to promote full transparency and innovative needs-based research and development. A decision on concrete action to be taken should be adopted at the Seventy-second World Health Assembly.

The representative of the UNION FOR INTERNATIONAL CANCER CONTROL, speaking at the invitation of the CHAIRMAN, encouraged Member States to include cancer treatment in universal health coverage, use the options presented in the report to improve pricing and procurement strategies, and engage with nongovernmental organizations that supported cancer patients. WHO should integrate the report's findings into its technical guidance and support Member States' efforts to improve access to cancer medicines.

The representative of GLOBAL HEALTH COUNCIL, INC., speaking at the invitation of the CHAIRMAN, said that cancer treatment should be considered part of universal health coverage and that WHO should promote expanded access to the human papillomavirus vaccine in all countries. She recommended ensuring access to cancer treatment, including palliative care for children; enhancing cancer research through country-specific registries of patients of all ages; and securing commitments from innovators to ensure sustainable access and accelerate the development of health technologies for all.

The representative of STICHTING HEALTH ACTION INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that, in order to promote accountability, national authorities should ensure that regulatory entities had access to all relevant information before market authorization was granted. Intensive use of intellectual property incentives seriously hindered competition, and WHO should guide and assist governments in making use of TRIPS flexibilities and support initiatives to delink prices from production costs. The report would be a useful tool when implementing national and regional initiatives such as the draft road map on access to medicines and vaccines, 2019–2023.

The representative of the INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS AND ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, said that consultation with external stakeholders would have ensured that the report fully reflected the economic value of innovation in cancer medicines. The report did not adequately address the unintended negative consequences of full transparency on companies' ability to give preferential prices to developing countries. It underestimated the differences between health care systems in developing and developed countries and the fact that revenue from cancer medicines also funded research into other diseases. The report relied on flawed methodology that overstated biopharmaceutical companies' profit margins. Improving the accessibility and affordability of cancer medicines would require multistakeholder collaboration, investment in health systems and a reduction in patients' out-of-pocket expenses while still supporting innovation.

The representative of the MEDICINES PATENT POOL FOUNDATION, speaking at the invitation of the CHAIRMAN, said that voluntary licence agreements between his organization and patent holders – listed in the report as an option to enhance affordability and accessibility – had played a major role in increasing access to HIV and hepatitis C treatments. Applying such agreements to cancer medicines would require commitment from governments and industry. Voluntary licensing could be applied early in the product life-cycle and did not require prior price negotiations. He was encouraged to see that some companies had committed to developing access programmes before launching their products, to fill health care gaps. He looked forward to working with WHO and its Member States to explore ways to accelerate access to essential medicines in lower-middle-income countries.

The representative of MEDICUS MUNDI INTERNATIONAL – INTERNATIONAL ORGANISATION FOR COOPERATION IN HEALTH CARE, speaking at the invitation of the CHAIRMAN, agreed that the current innovation model, particularly the lack of competition, was inefficient and unsustainable, and said that value-based pricing was making medicines unaffordable. She urged Member States to translate the policy options contained in the report into concrete action. Treatments could be made more affordable through strong pricing regulations, increased competition among companies, transparent research and development costs, and the use of TRIPS flexibilities. She also called on WHO to amend its 2009 guidelines on evaluation of similar biotherapeutic products, as mandated under resolution WHA67.21 (2014).

The ASSISTANT DIRECTOR-GENERAL (Access to Medicines, Vaccines and Pharmaceuticals) said that the scope of the reports on pricing and availability could be expanded to include other medicines and diagnostics, if Member States so requested. The options listed in paragraph 42 of the report were in line with those discussed on previous occasions. However, it was up to Member States to adopt and tailor them, and WHO stood ready to provide technical support in that regard. Experts had provided advice on the content and first draft of the report, and the minutes of those expert meetings had been published in July 2018. An information session for Member States had been held in the same month.

Regarding profit margins, WHO's return-on-investment analysis was based on historical and actual earnings rather than profit or forecasts, and was specific to all cancer drugs approved between 1989 and 2017 by the United States Food and Drug Administration. Pharmaceutical companies had not

been consulted on that occasion because of a strong conflict of interest. However, access to information directly from pharmaceutical companies, such as costs specific to individual cancer drugs and net transaction prices, would have been useful for the analysis. An addendum would be added to the report if such information were provided.

Various guidelines and reports were being developed on areas such as cervical cancer elimination, childhood cancer, and pain management for cancer patients. An information session on those guidelines could be held before or during the Seventy-second World Health Assembly. Prequalification for biosimilar medicines was crucial because of the huge positive impact on pricing. Two biosimilar medicines for cancer had been launched for prequalification in 2018.

# The Board noted the report.

Follow-up to the high-level meetings of the United Nations General Assembly on health-related issues: Item 5.8 of the agenda

• **Prevention and control of noncommunicable diseases** (documents EB144/20 and EB144/20 Add.1)

The CHAIRMAN drew attention to a draft decision on follow-up to the Political Declaration of the Third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, proposed by Argentina, Barbados, Canada, Chile, Colombia, Ecuador, Kenya, Monaco, Panama, Peru, the Russian Federation, South Africa, Sri Lanka, Uruguay and the European Union and its Member States, which read:

The Executive Board, having considered the report on follow-up to the high-level meetings of the United Nations General Assembly on health-related issues: prevention and control of noncommunicable diseases, describing the outcomes of the third high-level meeting of the General Assembly on the prevention and control of non-communicable diseases, decided to recommend to the Seventy-second World Health Assembly the adoption of the following decision:

The Seventy-second World Health Assembly, having considered the report on follow-up to the high-level meetings of the United Nations General Assembly on health-related issues: prevention and control of noncommunicable diseases, describing the outcomes of the third high-level meeting of the General Assembly on the prevention and control of non-communicable diseases, decided:

OP1. to welcome the political declaration of the third high-level meeting of the General Assembly on the prevention and control of non-communicable diseases (2018) adopted by the General Assembly in resolution 73/2, and to request the Director-General to support Member States in its implementation;

OP2. to confirm the objectives of WHO's global action plan for the prevention and control of noncommunicable diseases 2013–2020 and the WHO's comprehensive mental health action plan 2013–2020 as a contribution towards the achievement of Sustainable Development Goal target 3.4 (by 2030, reduce by one third premature mortality from noncommunicable diseases through prevention and treatment and promote mental health and well-being) and other noncommunicable disease-related goals and targets, and to

<sup>&</sup>lt;sup>1</sup> Document EB144/20.

extend the period of the action plans to 2030 in order to ensure their alignment with the 2030 Agenda for Sustainable Development;

## OP3. to request the Director-General:

- (a) to propose updates to the appendices of WHO's global action plan for the prevention and control of noncommunicable diseases 2013–2020 and WHO's comprehensive mental health action plan 2013–2020, as appropriate, in consultation with Member States and taking into account the views of other stakeholders,¹ ensuring that the action plans remain based on scientific evidence for the achievement of previous commitments for the prevention and control of noncommunicable diseases, including Sustainable Development Goal target 3.4 (by 2030, reduce by one third premature mortality from noncommunicable diseases through prevention and treatment and promote mental health and well-being) and other related goals and targets;
- (b) building on the work already under way, to prepare and update, as appropriate, a menu of policy options and cost-effective interventions to support Member States in implementing the commitments included in the political declaration of the third high-level meeting of the General Assembly on the prevention and control of non-communicable diseases (2018) to promote mental health and well-being, for consideration by the Health Assembly in 2020, through the Executive Board;
- (c) building on the work already under way, to prepare a menu of policy options and cost-effective interventions to support Member States in implementing the commitments included in the political declaration of the third high-level meeting of the General Assembly on the prevention and control of non-communicable diseases (2018) to reduce the number of premature deaths from noncommunicable diseases attributed to air pollution, while recognizing the importance of addressing all environmental determinants, for consideration by the Health Assembly in 2020, through the Executive Board;
- (d) to report to the Health Assembly in 2020, through the Executive Board, on the implementation of WHO's global strategy to reduce the harmful use of alcohol during the first decade since its endorsement, and the way forward;
- (e) to consolidate reporting on the progress achieved in the prevention and control of noncommunicable diseases and the promotion of mental health with an annual report to be submitted to the Health Assembly through the Executive Board,

<sup>&</sup>lt;sup>1</sup> In accordance with WHO's Framework of Engagement with Non-State Actors.

from 2021 to 2031, annexing reports on implementation of relevant resolutions, action plans and strategies, <sup>1,2</sup> in line with existing reporting mandates and timelines;

- (f) to provide further concrete guidance to Member States in order to strengthen health literacy through education programmes and population-wide targeted and mass- and social-media campaigns to reduce the impact of all risk factors and determinants of noncommunicable diseases, to be presented to the Health Assembly in 2021:
- (g) to present, in the consolidated report to the Health Assembly in 2021, based on a review of international experiences, an analysis of successful approaches to multisectoral action for the prevention and control of noncommunicable diseases, including those that address the social, economic and environmental determinants of such diseases;
- (h) to collect and share best practices for the prevention of overweight and obesity, and in particular to analyse how food procurement in schools and other relevant institutions can be made supportive of healthy diets and lifestyles in order to address the epidemic of childhood overweight and obesity and reduce malnutrition in all its forms, for inclusion in the consolidated report to be presented in 2021 in line with paragraph 3 (e);
- (i) to provide the necessary technical support to Member States in integrating the prevention and control of noncommunicable diseases and the promotion of mental health into primary health-care services, and in improving noncommunicable disease surveillance;
- (j) to make available adequate financial and human resources to respond to the demand from Member States for technical assistance in order to strengthen their national efforts for the prevention and control of noncommunicable diseases, including by identifying voluntary innovative funding mechanisms, such as a multi-donor trust fund, building on ongoing relevant work.

<sup>&</sup>lt;sup>1</sup> Including resolution WHA53.17 (2000) on prevention and control of noncommunicable diseases; resolution WHA57.17 (2004) on global strategy on diet, physical activity and health; resolution WHA63.13 (2010) on global strategy to reduce the harmful use of alcohol; resolution WHA65.6 (2012) on comprehensive implementation plan on maternal, infant and young child nutrition; resolution WHA66.8 (2013) on comprehensive mental health action plan 2013–2020; resolution WHA66.10 (2013) on Follow-up to the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases; resolution WHA68.19 (2015) on outcome of the Second International Conference on Nutrition; resolution WHA70.12 (2017) on cancer prevention and control in the context of an integrated approach; decision WHA70(17) (2017) on global action plan on the public health response to dementia; decision WHA70(19) (2017) on report of the Commission on Ending Childhood Obesity: implementation plan; resolution WHA71.6 (2018) on WHO global action plan on physical activity 2018–2030; and resolution WHA71.9 (2018) on infant and young child feeding.

<sup>&</sup>lt;sup>2</sup> Including on the findings of a mid-point and final evaluation in accordance with paragraph 60 of WHO's global action plan for the prevention and control of noncommunicable diseases 2013–2020, and on the findings of a preliminary and final evaluation in accordance with paragraph 19 of the terms of reference of the WHO Global Coordination Mechanism on the Prevention and Control of Noncommunicable Diseases.

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

**Decision:** Follow-up to the political declaration of the third high-level meeting of the General Assembly on the prevention and control of non-communicable diseases

## 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:
  - 2.1.1. Development and implementation of national multisectoral policies and plans to prevent and control noncommunicable diseases accelerated
  - 2.1.2. Countries enabled to implement strategies to reduce modifiable risk factors for noncommunicable diseases (tobacco use, diet, physical inactivity and harmful use of alcohol), including the underlying social determinants
  - 2.1.3. Countries enabled to improve health care coverage for the management of cardiovascular diseases, cancer, diabetes and chronic respiratory diseases and their risk factors, including in crises and emergencies
- 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.

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:

Seven years. All activities referred to in the draft decision will be carried out from 2019 during the bienniums 2018–2019, 2020–2021, 2022–2023 and 2024–2025 until the fourth high-level meeting of the General Assembly on the prevention and control of non-communicable diseases in 2025.

- B. Resource implications for the Secretariat for implementation of the decision
- 1. Total resource requirements to implement the decision, in US\$ millions:

US\$ 602 million (2019–2025).

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

US\$ 86 million.

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

Not applicable.

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

US\$ 172 million.

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

US\$ 344 million.

- 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:

US\$ 10 million (12% of US\$ 86 million) at the time of writing.

- Remaining financing gap in the current biennium:

US\$ 76 million (88% of US\$ 86 million).

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

US\$ 76 million – the amount is increasing on a rolling basis throughout the biennium, based on continuous resource-mobilization efforts.

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

Biennium	Costs	Region						Headquarters	Total
		Africa	The Americas	South-East Asia	Europe	Eastern Mediterranean	Western Pacific		
2018–2019 resources already planned	Staff	11.5	5.5	5.5	5.5	5.5	5.5	18.0	57.0
	Activities	5.5	3.0	3.0	3.0	3.0	3.0	8.5	29.0
	Total	17.0	8.5	8.5	8.5	8.5	8.5	26.5	86.0
2018–2019 additional resources	Staff	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Activities	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Total	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
2020–2021 resources to be planned	Staff	23.0	11.0	11.0	11.0	11.0	11.0	36.0	114.0
	Activities	11.0	6.0	6.0	6.0	6.0	6.0	17.0	58.0
	Total	34.0	17.0	17.0	17.0	17.0	17.0	53.0	172.0
Future bienniums resources to be planned	Staff	46.0	22.0	22.0	22.0	22.0	22.0	72.0	228.0
	Activities	22.0	12.0	12.0	12.0	12.0	12.0	34.0	116.0
	Total	68.0	34.0	34.0	34.0	34.0	34.0	106.0	344.0

The representative of ITALY, stressing the need to fully implement the Political Declaration of the Third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, noted that documents EB144/20 and EB144/20 Add.1 did not contain references to empowering individuals, strengthening health literacy or education. However, he was pleased that the draft decision referred specifically to the Secretariat supporting the strengthening of health literacy. Emphasizing the importance of robust evidence-based recommendations, he recalled that his Government had previously expressed reservations about the WHO list of best buys, such as taxation on specific foods. Promoting a balanced, healthy and sustainable diet was the only way to tackle nutrition-related noncommunicable diseases. Annex 1 to document EB144/20 should use the exact wording of the Political Declaration for clarity, while Annex 2 should be removed before the report was submitted to the World Health Assembly because it was too limited in scope and did not present new scientific evidence. In document EB144/20 Add.1, the implementation of the best buys as a strategic priority should be replaced with a more general focus on achieving the six objectives of the global action

plan for the prevention and control of noncommunicable diseases 2013–2020. He agreed that national multistakeholder dialogue mechanisms should be strengthened but did not support the implementation of the technical packages, specifically the SHAKE technical package for salt reduction, the reference to which should be removed from the report.

The representative of BURUNDI, speaking on behalf of the Member States of the African Region, said that, although multisectoral and multistakeholder solutions were the preferred method for preventing and controlling noncommunicable diseases, the international community had not always upheld its commitment to reducing the risks of premature death and disability from such diseases. The limited financial and human resources of some Member States and interference from the alcohol and tobacco industries also had an impact on progress. Acknowledging the support provided to Member States by the Secretariat, he urged WHO to ensure that the international community respected its commitments and to closely monitor multinational companies that had a negative effect on health.

The representative of ROMANIA, speaking on behalf of the European Union and its Member States, said that the candidate countries Montenegro, Serbia and Albania, the country of the stabilization and association process and potential candidate Bosnia and Herzegovina, as well as the Republic of Moldova aligned themselves with his statement. Efforts must be stepped up substantially to tackle the significant burden of noncommunicable diseases and achieve the health-related Sustainable Development Goals. Those efforts should focus on exercise, healthy diets, harmful alcohol use and tobacco use. He encouraged the Secretariat to enhance action to address mental health and air pollution and to identify good practices in that regard. WHO resources should be allocated to noncommunicable disease programmes according to the evolving challenges being faced by each Member State.

The representative of VIET NAM said that Annex 2 to document EB144/20 would be useful for her Government's proposed taxation policy on sugar-sweetened beverages. She appreciated the plan to publish a new set of indicators to monitor the progress of noncommunicable disease prevention and control and prepare for the fourth High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases. WHO should continue to support the mechanisms that collected data on existing noncommunicable disease indicators.

The representative of FINLAND, speaking on behalf of Estonia, Finland, Iceland, Ireland, Latvia, Lithuania, the Netherlands, Norway, Panama, Sri Lanka, Sweden and Thailand, underlined the need to accelerate efforts to fulfil commitments on noncommunicable diseases on the basis of established cost-effective interventions. She looked forward to the integration of mental health and air pollution into noncommunicable disease initiatives. While she welcomed WHO dialogue with non-State actors in accordance with the Framework of Engagement with Non-State Actors, she remained concerned about the proposed dialogue with representatives from the alcohol industry. Lessons learned from similar meetings in the past highlighted the need to establish clear public health objectives so as to ensure that limited resources were channelled towards the achievement of those objectives; and to oversee that the resources allocated were borne fully by WHO and did not compromise technical collaboration with Member States. Appendix 3 to the global action plan should be updated in line with WHO's normative mandate; however, the Secretariat should not enter into further negotiation with Member States on its content. She supported the draft decision.

The representative of SRI LANKA, noting the advocacy campaign on harmful sugar use, said that WHO should develop customizable strategies for controlling sugar consumption. She welcomed the commitment to reduce air pollution and promote mental health and well-being but said that technical assistance would be needed in order to develop comprehensive plans. The reference to the WHO SAFER alcohol control initiative in document EB144/20 should be retained.

Speaking on behalf of the Member States of the South-East Asia Region, she said that the three strategic priorities set out in the proposed workplan for the global coordination mechanism on the prevention and control of noncommunicable diseases were timely and essential.

The representative of ISRAEL said that a multisectoral approach would be vital in tackling the noncommunicable disease burden. He supported the proposed workplan for the global coordination mechanism and asked that his Government be added to the list of sponsors of the draft decision. It was time to translate high-level political commitment into concrete action. Governments had a responsibility to tackle the key challenge of obesity by fostering a culture of health. Citing the planned introduction of mandatory food labelling in Israel, he expected WHO to support and develop similar strategies.

The representative of JAMAICA noted WHO's proposal to hold six-monthly dialogues with representatives of non-State actors and the private sector, she recommended that guidance should be provided on governments' engagement in that context. A global noncommunicable diseases fund to support small island States and low- and middle-income countries was long overdue, and she called on other Member States to join her Government in supporting such an initiative. She requested that her Government be added to the list of sponsors of the draft decision.

The representative of the UNITED STATES OF AMERICA welcomed WHO's flagship programmes on mental health, cervical cancer and the global hearts initiative, and the increased focus on mental health and air pollution. Engagement with a broad range of stakeholders, including the Independent High-level Commission on Noncommunicable Diseases, was welcome as it would expand interventions to improve health outcomes; educating people to make healthy choices was a widely-shared responsibility. He welcomed the extension to 2030 of the global action plan and the comprehensive mental health action plan 2013–2020 and the updating of the annexes to both documents. He requested that Annex 2 to document EB144/20 on the taxation of sugar-sweetened beverages be removed from the report, as there was insufficient evidence in that regard. Noting the importance of the global coordination mechanism as an example of the effective implementation of the Framework of Engagement with Non-State Actors, he asked for further details on the activities planned under the proposed workplan for the global coordination mechanism.

The representative of GERMANY welcomed the timely expansion of the agenda on noncommunicable diseases and the scaling up of WHO's flagship programmes. While supporting WHO's work on noncommunicable diseases at both the financial and political level, he said that the failure to finalize the mid-point evaluation on the implementation of the global action plan was a cause for concern, as evaluation was critical and should be covered by the programme budget. The gender dimension should be reflected in strategic priority 3 of the global coordination mechanism. More information would be welcome on the collaboration between the global coordination mechanism, other United Nations and WHO technical programmes, and the United Nations Inter-agency Task Force on the Prevention and Control of Non-communicable Diseases. He expressed concern that the implementation of the global action plan was underfunded.

The representative of INDONESIA recognized that increased efforts were needed to prevent alarming rates of morbidity, disability and early mortality as a result of noncommunicable diseases. He supported the policy options and cost-effective interventions for the prevention and control of noncommunicable diseases, and the related efforts to help Member States achieve the nine voluntary targets under the global monitoring framework for prevention and control of noncommunicable diseases. He asked that his Government be added to the list of sponsors of the draft decision.

The representative of CHILE, speaking on behalf of the Member States of the Region of the Americas, reaffirmed her support for the Political Declaration. She welcomed its broad approach, which

encompassed all risk factors for noncommunicable diseases, including air pollution. Heads of State and Government should continue to provide strategic leadership and policy coherence, promoting the Health in All Policies approach and ensuring a balance between monitoring, prevention and treatment of noncommunicable diseases. Member States should build capacity and exchange good practices to facilitate multisectoral and multistakeholder action on noncommunicable diseases, and WHO should support Member States to coordinate activities, including through the global coordination mechanism and the Inter-agency Task Force.

The representative of IRAQ said that, despite the inadequate action and insufficient investment to prevent and control noncommunicable diseases acknowledged in paragraph 4 of the Political Declaration, the latter did not include a commitment to implement the WHO list of best buys in all Member States by 2020. She asked how WHO would continue to monitor progress prior to the fourth High-level Meeting. WHO's report to the Seventy-second World Health Assembly should contain information on: planned reporting to the United Nations General Assembly in 2024 on the implementation at the global, regional and national levels of the commitments contained in the Political Declaration; which Member States had implemented national frameworks for noncommunicable disease surveillance; the lessons learned in that regard; and how WHO planned to support Member States to strengthen those national frameworks.

## Dr Zwane took the Chair.

The representative of AUSTRALIA asked that her Government be added to the list of sponsors of the draft decision. Noting that more needed to be done to achieve target 3.4 of the Sustainable Development Goals, she welcomed the Secretariat's proposal to identify a specific subset of noncommunicable disease accelerators, which should be tailored to national contexts. A balanced approach should be adopted when engaging with the private sector, and commitments to engage with non-State actors on noncommunicable diseases should be made in line with the Framework of Engagement with Non-State Actors and in cooperation with the United Nations Inter-agency Task Force. Her Government fully supported the proposed workplan for the global coordination mechanism and the strategic priorities therein.

The representative of MEXICO recognized WHO's efforts to support Member States in fulfilling the commitments made during the high-level meetings on noncommunicable diseases. However, despite the seriousness of the issue, as reflected in the Thirteenth General Programme of Work, 2019–2023 and the proposed workplan for the global coordination mechanism, funding for noncommunicable disease activities in the Programme budget 2018–2019 was inadequate. He therefore reiterated the importance of ensuring that WHO's resource allocations matched its priorities.

The representative of CHINA said that aligning noncommunicable disease objectives with the Sustainable Development Goals would improve the overall coordination of noncommunicable disease prevention and control, especially with regard to administration and budget planning. The Secretariat should continue to strengthen financing and provide technical support in that regard. He asked that his Government be added to the list of sponsors of the draft decision.

The representative of COLOMBIA said that the availability of reliable information on noncommunicable diseases, their risk factors and their economic and social impact, was fundamental to inform decision-making at national levels, for which WHO support and the sharing of good practices was also essential. She called for innovative cooperation to assist Member States in building regulatory, implementation, research, and monitoring and evaluation capacities. Cooperation also ensured access to more effective technologies and practices to strengthen governments' management of

noncommunicable disease agendas. She encouraged WHO and all stakeholders to pursue the targets under the global monitoring framework.

The representative of FIJI supported the statement made by the representative of Australia. He asked that his Government be added to the list of sponsors of the draft decision. Given the numerous challenges in effectively tackling noncommunicable diseases, comprehensive support for the strengthening of health systems was essential to prevent noncommunicable diseases.

The representative of URUGUAY¹ emphasized that preventing noncommunicable diseases was a shared responsibility, as highlighted in the Political Declaration. She called on all stakeholders, under the leadership of WHO, to contribute to national objectives to eliminate noncommunicable diseases. She welcomed the work under the global coordination mechanism and the strategic priorities contained in the proposed workplan. She agreed that it was necessary to expand the global coordination mechanism to include other priorities, including mental health and air pollution, in line with the Political Declaration. She urged Member States to support the draft decision.

The representative of PANAMA, referring to the planned mid-point evaluation of progress on the implementation of the global action plan, said that it was important to highlight the difficulties faced by Member States in fulfilling their commitments, which included financial constraints and industry interference. It was therefore important to accelerate the implementation of the Framework of Engagement with Non-State Actors to assess and manage potential risks related to working with non-State actors.

The representative of LEBANON¹ expressed his appreciation for the Political Declaration. Welcoming the proposed workplan for the global coordination mechanism, he said that a multisectoral and multistakeholder approach was key to combating noncommunicable diseases. Member States must continue striving for radical lifestyle change by encouraging healthy balanced diets and exercise. He expressed the hope that the technical support provided by WHO to help Member States prevent and control noncommunicable diseases would continue, particularly in his Region.

The representative of ARGENTINA¹ said that the report should include additional actions to strengthen the implementation of evidence-based public policies to reduce the risk factors associated with noncommunicable diseases. She proposed that the planned dialogues outlined in paragraph 13 of document EB144/20 should be extended to include civil society representatives. She welcomed the inclusion of Annex 2 to that document on taxation on sugar-sweetened beverages. A paragraph should be added to Annex 3 guaranteeing the participation of civil society, philanthropic foundations and academic institutions in efforts to achieve target 3.4 of the Sustainable Development Goals and establishing transparent protocols for such activities. She supported the three strategic priorities of the proposed workplan for the global coordination mechanism but underlined that it did not take into account the agendas for healthy eating and the prevention of obesity.

The representative of KENYA<sup>1</sup> said that action should be intensified to combat noncommunicable diseases at the country level to meet target 3.4 of the Sustainable Development Goals. She welcomed the expansion and extension of the global action plan in line with the 2030 Agenda for Sustainable Development. WHO should support Member States by providing resources and technical assistance to

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

strengthen national noncommunicable disease activities. She supported the proposed workplan for the global coordination mechanism.

The representative of THAILAND¹ welcomed Annex 2 to document EB144/20 on taxation on sugar-sweetened beverages, the proposed workplan for the global coordination mechanism and the Political Declaration. However, he expressed concern regarding the proposed dialogues with representatives of economic operators in the area of alcohol production and trade, which would use WHO's limited resources without much benefit for Member States. WHO should reconsider that proposal or establish clear public health objectives for those dialogues, ensuring transparency to avoid conflicts of interest. He supported the draft decision.

The meeting rose at 20:30.

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