# **EXECUTIVE BOARD** 142nd session

EB142/PSR/6 21 May 2018

# PROVISIONAL SUMMARY RECORD OF THE SIXTH MEETING

WHO headquarters, Geneva Wednesday, 24 January 2018, scheduled at 14:30

> Chairman: Dr A. HAFEEZ (Pakistan) Later: Ms S. LAWLEY (Canada)

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#### SIXTH MEETING

Wednesday, 24 January 2018, at 14:35

**Chairman:** Dr A. HAFEEZ (Pakistan) **later:** Ms S. LAWLEY (Canada)

**STRATEGIC PRIORITY MATTERS:** Item 3 of the agenda (continued)

**Health, environment and climate change:** Item 3.5 of the agenda (document EB142/12 and EB142/12 Add.1) (continued)

The representative of the CONGO described the adverse effects of climate change and environmental pollution in countries in his region and their consequences for public health there. All three levels of WHO should increase their presence at international meetings on environmental protection, and the Organization should hold round tables with other United Nations agencies on the health impacts of pollution and climate change. The Secretariat should take urgent action, in coordination with the rest of the United Nations system and civil society, to plan health activities focused not only on emergency response, but also on prevention.

Speaking on an organizational matter, he expressed concern at the number of modifications submitted at very short notice. Amendments were welcome, but representatives needed more time to consider them if they were to have a constructive discussion.

The representative of the DOMINICAN REPUBLIC said that regulating industry, ensuring workplace safety and properly disposing of waste were some of the most daunting challenges related to health and the environment, along with low economic investment in protecting ecosystems and health workers' limited response capacity. A wide range of technical and operational skills would be needed to improve health facility resilience and allow governments and health authorities to take action. He noted the fact that climate change and its impact on health in small island developing States and vulnerable settings was addressed in the draft thirteenth general programme of work 2019–2023, and welcomed the proposal to draft a comprehensive global strategy on health, environment and climate change.

The representative of FIJI voiced concern that the scope of the proposed flagship initiative, or platform, encompassed "vulnerable settings" in addition to small island developing States. The initiative should focus first on small islands, many of which were dealing with front-line climate-related threats to health; lessons learned there could later be applied in other vulnerable settings. The initiative was intended to enhance existing efforts; limiting its scope to small island developing States would not reduce or jeopardize WHO support elsewhere. He therefore suggested that the end of paragraph (1) of the draft decision should be amended to read: "a draft action plan for the flagship initiative to address health effects of climate change initially in small island developing States and subsequently in other vulnerable settings".

The representative of THAILAND said that the Director-General's report did not take proper account of previous Health Assembly resolutions and the existing workplan. Immediate, concrete action would be preferable to yet another global strategy. She outlined ways in which WHO could act as a role model in tackling climate change, as it had during the first carbon-neutral WHO meeting, the 2014 Conference on Health and Climate. In addition, the Organization should introduce more

teleconference and web-based consultations, set targets and track its carbon footprint. It should leverage its social and intellectual capital to advocate for greener health activities worldwide.

The representative of IRAQ stressed the importance of integrating environmental factors into health indicators. Making environmental health an essential part of primary health care would help to fulfil the Alma-Ata Declaration's promise of health for all. Strategic work plans for communicable and noncommunicable diseases, nutrition, food safety and health promotion should all focus on environmental and climate-related factors. He supported the Director-General's focus on preventive measures to address pollution and climate change, and stressed that the Sustainable Development Goals provided momentum to that end.

The representative of the PHILLIPINES endorsed the draft decision. She agreed with the need for a more upstream approach to climate change and said that more specific measures should be taken to hold countries to account for their impact on the health of those affected. She supported the proposal to draft an action plan and a comprehensive global strategy, which should be aligned with existing United Nations Environment Assembly resolutions on the environment and health, among others.

The representative of ALGERIA stressed the importance of expanding the scope of targets related to climate change and environmental risks in the draft thirteenth general programme of work, so as to include as many developing countries as possible.

The representative of PAKISTAN said that improved access to water and better sanitation, hazardous waste disposal, domestic combustion of biomass, food safety and vector control were priority areas. WHO must generate data on the health impacts of environmental degradation and climate change to support evidence-based policymaking. Climate information should be integrated into risk assessments and emergency preparedness. Making climate resilience a building block of health systems would help to advance universal health coverage.

The representative of JAMAICA, speaking on behalf of the Caribbean region, South and Central America, Canada and Mexico, said that the complexity of the relationship between human health, the environment and climate change required intersectoral action aligned with the 2030 Agenda for Sustainable Development. Health care infrastructure must be improved and new health policies developed to increase resilience; their adoption should be a priority at the national and international levels. While he welcomed the initiative to draft an action plan and a comprehensive global strategy, other environmental risks to health – including pollution and threats to biodiversity – must also be addressed. Strategies should be developed to ensure that the interlinkages between health and biodiversity were more widely recognized and reflected in national strategies and plans, with the involvement of local communities. The Secretariat should continue to work with other United Nations entities and report to the governing bodies on the outcome.

Having detailed the human, structural and economic losses incurred in Jamaica and neighbouring islands as a result of extreme weather in 2017, he said that he was in favour of giving priority to small island developing States and other vulnerable settings. The draft comprehensive global strategy should include education and preparedness programmes for the health sector and the general population, to mitigate the impact of disasters on vulnerable groups.

The representative of NEW ZEALAND expressed support for the amendments to the draft decision proposed by the representative of Malta and the suggestion made by the representative of Fiji. The importance of environmental impacts on health was clearly reflected in the draft thirteenth general programme of work; he hoped that the timely development of an action plan and a comprehensive global strategy would be meaningfully reflected in future programme budgets.

The representative of MEXICO said that evidence was key to discussion of the complex relationship between health, the environment and climate change. In terms of health, it was essential to pursue the implementation of National Adaptation Plans following the adoption of the Paris Agreement under the United Nations Framework Convention on Climate Change; to that end WHO should continue to cooperate on environmental issues with other United Nations agencies, funds and programmes, guided by the 2030 Agenda for Sustainable Development. Her country's experience showed that improved cross-sectoral coordination could help to reduce adverse effects on human health and preserve the environment. The proposed action plan would help to tackle the issue in a more holistic manner. She urged WHO to play a more active role in the Fourteenth meeting of the Conference of the Parties to the Convention on Biological Diversity. Her delegation had submitted proposed amendments to the draft decision to the Secretariat.

The representative of the DOMINICAN REPUBLIC expressed support for the amendment to the draft decision suggested by the representative of Fiji.

The representative of COSTA RICA, recalling the wide range of threats that climate change posed to human lives, economic development and health, recommended that the Board should adopt the draft decision. She hoped that, at the forthcoming Health Assembly, Member States would share their best practices on sustainable and equitable development, the use of natural resources, climate change mitigation, and measures to protect biodiversity and ecosystems. All of those issues would have an impact on the achievement of the Sustainable Development Goals, and it was essential to generate the political will to ensure coordination across the public and private sectors.

The representative of GHANA<sup>1</sup> commended the report's emphasis on transformative change, multisectoral approaches, evidence-based debate and the Sustainable Development Goals. Although the environmental impact of climate change did not fall directly under the WHO mandate, the Organization had an important collaborative role to play as the global authority on health. The Secretariat should elaborate on how it intended to address the challenges of burdensome bureaucracy in the United Nations system and vested corporate interests, along with the role it envisaged for civil society. The Framework of Engagement with Non-State Actors could be revised to incorporate compliance with environmental standards, and WHO should ensure that its investments and expenditures were in line with best practice for mitigating climate change. He expressed support for the draft decision.

The representative of SWITZERLAND¹ said that the Director-General's report provided valuable direction for collective engagement on health and the environment. Given the significant negative impact of climate change and environmental degradation on mortality and morbidity rates, cooperation should be stepped up in all sectors. Scientific data had demonstrated the importance of a healthy environment for improving overall health, and WHO had a role to play in promoting the Health in All Policies approach. She endorsed the content of the draft decision.

The representative of AUSTRALIA<sup>1</sup> expressed support for the priority accorded by the Director-General to addressing the health effects of climate change and welcomed the focus on small island developing States, noting that her region was particularly vulnerable to the impacts of climate change. WHO should ensure its work was aligned with and complemented existing initiatives; avoid duplication and fragmentation of work; ensure the action plan was founded on solid evidence and informed by lessons learned; and recognize that countries would have to take different approaches

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

based on their individual circumstances. She requested further clarification regarding the initiative's resources, sequence and process.

The representative of NORWAY¹ said that the Director-General's report furthered understanding of climate change, air pollution and environmental destruction as determinants of health. She was strongly in favour of developing and prioritizing an action plan to support small island developing States and drafting a new global strategy. The new strategy should: take into account the scientific developments of the past two decades; detail major risks and co-benefits of action on climate, the environment and health; outline the research and public health capacities required at the country level; and present the updated policy, programming and regulatory capacities required to sustain effective action.

The representative of MONACO¹ encouraged the Secretariat to continue working with other United Nations agencies. In addition to the initiative to support small island developing States, WHO should use hard data to show how health could be improved by combating environmental pollution and climate change. She supported the draft decision and the amendments proposed by the representative of Malta on behalf of the Member States of the European Union.

The representative of PERU<sup>1</sup> said that Member States should reflect their commitment to protecting the environment and combating climate change by implementing public policies that were in line with the 2030 Agenda for Sustainable Development and other multilateral agreements, and outlined his Government's efforts in that regard. He also referred to the expansion of platform 5 of the draft thirteenth general programme of work, which focused on the health effects of climate change, greater efforts by the Organization to prevent illnesses caused by pollution and increased financing to address issues relating to climate and health. It was indispensable that WHO should continue collaborating with UNEP and the secretariats of other key multilateral environmental accords.

The representative of SPAIN<sup>1</sup> said that health systems resilience must be strengthened and a deeper understanding of the impact of health determinants prioritized. Referring to the interdependent and transboundary nature of environmental health risks, she endorsed the draft decision and expressed her Government's wish to play an active part in the development of the comprehensive global strategy.

The representative of LITHUANIA<sup>1</sup> welcomed the report and the fact that health, the environment and climate change had been made a strategic priority. She agreed on the need for more effective upstream action and the implementation of an intersectoral Health in All Policies approach, and advocated engagement with existing health and environmental frameworks and initiatives.

The representative of INDONESIA<sup>1</sup> outlined the various activities his Government had undertaken to tackle the impact of environmental risks on public health, drawing attention to the implementation of the national action plan and intersectoral collaboration to improve water and sanitation and change community behaviour. He supported the draft decision and the amendments proposed by the representative of Mexico.

The representative of the UNITED STATES OF AMERICA<sup>1</sup> said that the suggestion in the report that wealthier countries and multinational corporations were polluting poorer countries was inaccurate and should be corrected to reflect the fact that many multinational corporations operating in developing countries adhered to higher environmental standards than local entities. He requested a

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

comprehensive analysis of data availability and information on the analysis, collection and management of data that would be undertaken to fill any gaps. Although WHO should not encroach on, or duplicate, existing pollution control efforts, it was nevertheless important for the health sector to be involved in relevant decisions made by other sectors. He asked how the global strategy would intersect with existing WHO resolutions on environmental topics and what role environmental health played in preventing health emergencies and advancing global health security.

The representative of PANAMA<sup>1</sup> said that investment in measures to mitigate climate change should be prioritized and that action should be taken to address the preparedness and response gap between countries. She encouraged greater local political determination and international technical cooperation to strengthen health systems, stressing the importance of WHO's normative and coordinating role in international public health matters. She endorsed the draft decision and the amendments proposed by the representatives of Mexico and Malta on behalf of the Member States of the European Union.

The representative of MOROCCO¹ endorsed the evidence-based approach to political decision-making and the proposed in-depth transformation of sector policies, including health policy, with a view to ensuring that health was considered relevant to all the Sustainable Development Goals. Her Government wished to take part in the development of the comprehensive global strategy and suggested that assistance be provided to all countries and regions to monitor climate- and environment-related issues and to manage emerging risks. WHO should continue to promote the sharing of experience, capacity-building and the establishment of a follow-up mechanism. Regional networks should be established for the surveillance of climate-sensitive diseases.

The representative of ECUADOR<sup>1</sup> encouraged WHO to strengthen its leadership, emphasizing its vital role in raising awareness based on scientific evidence and in defending public health interests. A preventive, community-centred approach was fundamental to strengthening primary health care action, and national health authorities needed the Organization's support to increase funding to address environmental risks across all sectors. She fully supported WHO's mandate to compile and notify certain global indicators under the Sustainable Development Goals.

The representative of BANGLADESH,<sup>1</sup> outlining the various activities that his Government had undertaken to build resilient health systems and develop national health adaptation strategies and plans, expressed agreement with the key suggestions in the report and proposed that a regional hub should be established to exchange knowledge on climate change and health. As in the draft thirteenth general programme of work, in the draft decision the wording "small island developing States and vulnerable settings" should be amended to: "small island developing States and vulnerable States".

The representative of the RUSSIAN FEDERATION<sup>1</sup> endorsed the Director-General's report and acknowledged the need to prioritize the prevention of diseases related to environmental degradation and climate change, including in terms of allocation of funds. Success depended on using limited resources efficiently through intersectoral work at the national and international levels. WHO must play a clear coordinating and leadership role within the health sector, adopting an evidence-based approach to address the challenges raised in the report.

The representative of INDIA<sup>1</sup> described measures taken at the national level, including a draft action plan on climate change and human health. He supported the concept of a flagship initiative, or

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

platform, to address the health impact of climate change in small island developing States and vulnerable settings, but suggested that country-specific vulnerable settings should also be included.

Priorities should include providing support for Member States to mainstream environmental issues into existing policy frameworks, so as to foster multisectoral action; developing a research agenda on the link between environment and health; ensuring that health had a suitably prominent place on the climate change agenda; and enhancing the capacity of public health practitioners to reduce health vulnerabilities linked to climate change. He supported the draft decision.

The representative of KUWAIT<sup>1</sup> stressed the need for effective management of environmental risks, which were as serious as other risk factors. She welcomed the report, particularly the reference to the Health in All Policies approach. An intersectoral approach was required since responsibility for addressing many determinants of health lay beyond the remit of the health sector and health was relevant to all of the Sustainable Development Goals. In that context, she stressed the need to focus on health promotion and education, and on research.

The observer of PALESTINE described the adverse effects of climate change in the Eastern Mediterranean Region in general, and the West Bank and Gaza Strip in particular, including drought, saltwater intrusion, desertification and environmental pollution. His Government's climate strategy included a range of projects at the ministerial level and the establishment of an interministerial committee, with support from the WHO Secretariat.

The representative of ILO expressed support for the drafting of a comprehensive global strategy. The inclusion of workers' health and the working environment would provide a powerful link between Sustainable Development Goals 8 (Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all) and 3 (Ensure healthy lives and promote well-being for all at all ages) and help to strengthen cooperation between the health and labour sectors. The future of work, which must be decent work that avoided harm to workers and the environment, would be influenced by environmental and climate change, including extreme weather and environmental pollution. In addition to collective action in the field of occupational safety and health, WHO and the ILO also cooperated on other common issues, including the Sustainable Development Goals. In that context, she urged the Secretariat to support ILO efforts to develop a global occupational health and safety coalition.

The representative of WMO said that the years 2015 to 2017 had been the warmest on record, confirming a global warming trend. However, much of the potential damage could be avoided through strategic action and preparedness measures. WMO had an important role to play in that regard, providing data on weather, climate and air quality to help the health sector to monitor, understand, forecast and manage health risks. Through partnerships such as the WMO/WHO Joint Office on Climate and Health, steps could be taken to strengthen national, regional and global capacity relating to climate, health and the environment. She applauded WHO's leadership and indicated that WMO stood ready to support the development of a comprehensive strategy and a joint workplan to promote the flagship initiative on small island developing States, and to address health risks relating to extreme weather and poor air quality, particularly in urban settings. Stressing the importance of cooperation between United Nations agencies, she welcomed the recent WHO/UNEP agreement and the United Nations Environment Assembly resolution on the environment and health, and looked forward to participating in the work of the coalition on health, the environment and climate change.

<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, said that the clear link between health and climate change obliged Member States to cooperate across all sectors of government to ensure that health remained a priority for all. Moreover, including civil society in awareness-raising campaigns would lead to more efficient use of resources. In that context, he urged WHO Member States to support education programmes on the health consequences of climate change. He also expressed support for a new comprehensive global strategy.

The representative of the UNION FOR INTERNATIONAL CANCER CONTROL, speaking at the invitation of the CHAIRMAN, said that he recommended: the implemention of financial policies commensurate with the threat of health-harming industries, including measures to ensure the appropriate pricing of polluting fuels and to withdraw investment from fossil fuel industries; the adoption of appropriate policies and monitoring measures to prevent industrial sector interference; the prioritization of environmental health priorities at the 2018 High-level Political Forum on Sustainable Development and in voluntary national reports on progress towards achieving the Sustainable Development Goals; and action by WHO to facilitate cross-sectoral coordination.

The representative of THE WORLD MEDICAL ASSOCIATION, INC., speaking at the invitation of the CHAIRMAN, expressed concern at the absence of any reference in the Director-General's report to the urgent need to reduce emissions in order to meet targets under the Paris Agreement, or to health-related losses or damage caused by climate change. He urged WHO to acknowledge the powerful vested interests in the continued use of fossil fuels and stressed that it had to clearly distance itself from the activities of the fossil fuel industry. It was hoped that the Framework of Engagement with Non-State Actors would help the Organization to assess potential conflicts of interest before it engaged with such stakeholders.

The representative of the INTERNATIONAL COUNCIL OF NURSES, speaking at the invitation of the CHAIRMAN, called for greater investment in health care personnel, given that the impact of climate change, coupled with an ageing population, would increase demand for well-trained health care providers. Futhermore, Member States needed to allocate a larger proportion of health care funding to public health programmes, in order to mitigate the impact of climate change on health. Building climate change resilience required measures to address all the social and environmental determinants of health. She encouraged Member States and the Secretariat to advocate for including health care professions in policy decisions at all levels and across all relevant sectors. On a related note, given that climate change increased health inequalities for already vulnerable populations, a human rights-based approach focusing on those populations was needed.

The representative of MEDICUS MUNDI INTERNATIONAL – INTERNATIONAL ORGANISATION FOR COOPERATION IN HEALTH CARE, speaking at the invitation of the CHAIRMAN, said that binding international agreements were required to address climate-related problems. In that context, she urged Member States to align themselves with the goals of the Paris Agreement and set ambitious targets in WHO's draft action plan, including the introduction of progressive carbon taxes and the withdrawal of subsidies for fossil fuels, with polluting industrialized countries taking the lead in that regard. Such measures would free up public funds for investment in prevention, health systems, research and climate change mitigation efforts.

The representative of the INTERNATIONAL BABY FOOD ACTION NETWORK, speaking at the invitation of the CHAIRMAN, said that the role of breastfeeding and human breast milk should be reflected in climate-smart development goals at the national and global levels. While breast milk substitutes left a significant ecological footprint, breastfeeding made an important contribution to mitigating environmental harm, especially in the context of growing food insecurity and extreme

weather conditions faced by the most vulnerable women and children. Policies and practices relating to the International Code of Marketing of Breast-milk Substitutes and measures to promote breastfeeding supported climate change mitigation efforts and were key to global measures to work towards Sustainable Development Goal 13 (Take urgent action to combat climate change and its impacts).

The ASSISTANT DIRECTOR-GENERAL (Climate and Other Determinants of Health) said that the scope of the activities implemented relating to climate change and the environment, at both the regional and the national levels, reflected the importance of those issues. She noted the amendments proposed by Member States.

While a number of delegates had stressed the need for WHO to act within its remit and avoid overlaps with the work of other agencies and organizations, statements from the ILO and WMO attested to its close cooperation with other agencies. Moreover, the recently signed WHO/UNEP agreement had established a concrete framework for further joint action. She welcomed calls for increased funding, for effective use of resources, and for measures to strengthen national funding for climate change action, in practicular with respect to health. To date, efforts relating to WHO's accreditation to the Green Climate Fund had involved discussions with the World Bank and States already accredited to the Fund. She acknowledged the need to focus on the Sustainable Development Goals and to avoid increasing Member States' reporting burden. She also agreed that an evidence-based approach was of the utmost importance. In that regard, much work had been done on country profiles. Indeed, a pledge had been made to focus on country profiles for small island developing States, in order to provide a better overview of existing initatives and challenges. She also described several WHO initatives that involved leading by example, including those relating to greening the health sector and ensuring environmentally friendly procurement.

She expressed appreciation for the suggestions made on how to deal with the many amendments proposed. The Secretariat's approach was dictated by the urgent need for progress on the flagship initiative or platform. In that context, it was important to obtain input from Member States; a series of climate change and health conferences had been planned in regions with small island developing States. However, States from all regions were invited to contribute, as it was important to gather information on different regions and vulnerable settings, and to build on existing expertise. Small island developing States were particuarly vulnerable to the impact of climate change and sustained repeated losses. Moreover, only two of the more than 30 States to have benefited from WHO projects in the field of climate change and health had been small island developing States. It was therefore important to focus on those States in particular. In that regard, she welcomed guidance from Member States, especially on the draft decision and proposed amendments.

The REGIONAL DIRECTOR FOR THE WESTERN PACIFIC said that the Western Pacific islands were disproportionately vulnerable to environmental change. Cyclones could erase years of development in the space of hours. Many of the islands rose only a few metres above sea level and climate change threatened their very existence. On the atolls inundated by sea water, living conditions were already akin to those in refugee camps. It was disheartening to see that countries that contributed the least to climate change bore the brunt of its impact. Efforts made to date to address the situation had been inadequate. In other parts of Asia, fast economic growth engendered unplanned urbanization and air pollution. The quality of life in those settings was often characterized by environmental degradation, a lack of basic infrastructure and lack of access to health care. More needed to be done to promote the health of the populations affected, with a special focus on small island developing States.

The DIRECTOR-GENERAL said that additional human resources had been allocated to enhance WHO's work on the health impact of climate change. WHO had signed agreements with both the United Nations Framework Convention on Climate Change and UNEP to facilitate joint action on the environment and health, put the Organization's comparative advantages to best use and avoid

duplication. While climate change concerned all countries, small island developing States suffered disproportionately. The flagship initiative, or platform, referred to in the draft decision should remain focused on small island developing States, rather than encompass "vulnerable settings" in general, on the understanding that WHO's efforts to address the health effects of climate change were global in nature. WHO's work should include both climate change adaptation and mitigation. The Organization's increasing focus on prevention would include advocating mitigation strategies, while adaptation-related activities would build on and strengthen existing initiatives and actions. Donor engagement was crucial, as was obtaining accreditation to the Green Climate Fund to access resources; WHO looked to Member States already accredited by the Fund for support in that endeayour. Other sources of financing would also be explored.

The CHAIRMAN said that the Secretariat would prepare a revised version of the draft decision contained in document EB142/12.

## It was so agreed.

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

Addressing the global shortage of, and access to, medicines and vaccines: Item 3.6 of the agenda (document EB141/13)

The CHAIRMAN drew attention to a draft decision on addressing the global shortage of, and access to, medicines and vaccines, proposed by Algeria, Brazil, Chile, Colombia, Costa Rica, the Netherlands and Portugal, which read:

The Executive Board, having considered the report on addressing the global shortage of, and access to, medicines and vaccines, decided to recommend to the Seventy-first World Health Assembly the adoption of the following decision:

- (1) The Seventy-first World Health Assembly, having considered the report on addressing the global shortage of, and access to, medicines and vaccines, decided to request the Director-General:
- (2) to elaborate a roadmap report, in consultation with Member States, outlining the programming of WHO's work on access to medicines and vaccines, including activities, actions and deliverables for the period 2019–2023;
- (3) to submit this roadmap report to the Seventy-second World Health Assembly for its consideration in 2019, through the Executive Board at its 144th session.

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<sup>&</sup>lt;sup>1</sup> Document EB142/13.

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

**Decision:** Addressing the global shortage of, and access to, medicines and vaccines

### A. Link to the programme budget

1. Programme area, outcome and output(s) in the Programme budget 2018–2019 to which this draft decision would contribute if adopted

**Programme area:** 4.3. Access to medicines and other health technologies, and strengthening regulatory capacity

**Outcome:** 4.3. Improved access to and rational use of safe, efficacious and affordable quality medicines and other health technologies

**Output:** 4.3.1. Access to and use of essential medicines and other health technologies improved through global guidance and the development and implementation of national policies, strategies and tools

**Output:** 4.3.3. Improved quality and safety of medicines and other health technologies through norms, standards and guidelines, strengthening of regulatory systems, and prequalification

2. Short justification for considering the draft decision, if there is no link to the results as indicated in the Programme budget 2018–2019:

Not applicable.

3. Brief description of any additional Secretariat deliverables during the biennium 2018–2019, which are not already included in the Programme budget 2018–2019:

Not applicable.

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

18 months.

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

US\$ 0.6 million.

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

US\$ 0.6 million.

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

Not applicable.

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

Not applicable.

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

Not applicable.

- 5. Resources available 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\$ 0.6 million.

- Remaining financing gap in the current biennium:

Zero.

 Estimated resources, foreseen but not yet available, which would help to close the financing gap in the current biennium:

Zero.

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

Biennium	Costs	Headquarters	Region						Total
			Africa	The Americas	South-East Asia	Europe	Eastern Mediterranean	Western Pacific	
2018-2019	Staff	0.4	0.0	0.0	0.0	0.0	0.0	0.0	0.4
resources already planned	Activities	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.2
	Total	0.6	0.0	0.0	0.0	0.0	0.0	0.0	0.6

The ASSISTANT DIRECTOR-GENERAL (Access to Medicines, Vaccines and Pharmaceuticals) noted that the sheer volume of resolutions and technical documents reviewed while preparing the Director-General's report illustrated the complexity of the issues at stake. It was also an indication of the need to streamline and focus on actions that would have the greatest impact and would ensure that patients had access to the health technologies that they needed, when they needed them, at the right level of care and without suffering financial hardship. The Secretariat had to strengthen its normative role and step up its technical support to countries, in partnership with Member States and other stakeholders, in order to ensure that guidance and standard-setting resulted in better health policies and outcomes at the country level.

The representative of COLOMBIA described the measures his Government had taken to improve equitable access to medicines. All WHO processes and initiatives designed to improve access to medicines should be maintained. Continued implementation of resolution WHA67.21 (2014) on access to biotherapeutic products, including similar biotherapeutic products, and ensuring their quality, safety and efficacy, was highly relevant in that regard. He supported the idea of a road map report, which would make WHO's work more effective.

### Ms Lawley took the Chair.

The representative of MALTA, speaking on behalf of the European Union and its Member States, said that the candidate countries Montenegro and Albania and the country of the stabilization and association process and potential candidate Bosnia and Herzegovina, as well as Ukraine, aligned themselves with her statement. WHO's comprehensive health system approach to the pharmaceutical value chain was commendable and a debate within the framework of WHO's mandate and responsibilities was certainly beneficial. Access to safe, effective and quality essential medicines and vaccines was key to attaining target 3.8 of the Sustainable Development Goals on universal health coverage. Action had to be taken to overcome the serious shortage of essential medicines to treat

noncommunicable diseases in some countries, including prioritization based on return on investment. WHO must respond to the ongoing rapid transformation of biomedical research, development and innovation. Antimicrobial resistance was a crucial factor. Although different solutions might be needed in different regions to increase access to medicines and vaccines, good governance, adequate regulatory and workforce capacity, local pharmaceutical production in line with international standards and more efficient supply chains constituted essential tools.

In order to reduce the burden of costly innovative medicines on health systems, transparency, synergies and fair pricing policies must be promoted. Innovation had a crucial role to play and it was important to finance, stimulate and improve research to address current and future medical needs, with a special emphasis on affordable and effective solutions for diseases that were particularly prevalent in developing countries, including noncommunicable diseases. The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property provided an overarching framework to guide WHO's work in those three areas, in respect of which WHO should pursue its cooperation with WIPO and WTO. Expressing support for the draft decision, she said that access must be viewed through the lens of public health and human rights. It was good that access was being discussed as a separate agenda item, given WHO's essential role in helping Member States to address barriers thereto.

The representative of JORDAN, speaking on behalf of the Member States of the Eastern Mediterranean Region, said that the Region suffered from recurrent shortages of many essential medicines and vaccines, in particular in conflict situations. Rising cost was another obstacle. He commended proposals to document best practices, establish regulatory mechanisms for essential medicines susceptible to shortages, and develop guidance on alternative channels of access to medicines and vaccines in short supply. Cooperation and joint stockpiling of essential medicines would be useful. WHO support was vital to improve governance, build national regulatory capacity and strengthen procurement and supply chain management. More should also be done to find lasting solutions to supply shortages and identify good financing practices and policies. Support for local production and the development of a skilled workforce to support all aspects of adequate and equitable access were crucial.

The representative of ZAMBIA, speaking on behalf of the Member States of the African Region, said that the prioritization of, and investment in, areas that would lead to improved access to medicines and vaccines were highly relevant. He welcomed the planned assessment of the magnitude of shortages and stock outs of essential medicines and drew attention to the importance of diagnostics when it came to setting priorities. Political will at all levels was crucial to successful implementation of fair pricing and domestic investment policies. It would also be useful to identify the policies that were most effective in ensuring the availability of medicines. Quality control capacities needed to be strengthened to curb the proliferation of fake medicines, including by accelerating the establishment of the African Medicines Agency. Other priorities included capacity-building to ensure the proper implementation of intellectual property legislation in line with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), data collection and the establishment of a global database on prices. WHO should also push for research and development principles that ensured the affordability and availability of products. At future meetings, access to, and shortages of, medicines should be addressed under separate agenda items, in order to ensure that both received due consideration.

The representative of the UNITED REPUBLIC OF TANZANIA said that WHO must prioritize and invest in those areas where it had comparative advantages. Its normative work and technical support were particularly relevant. Many countries, including his own, had ambitious plans to improve regulation, procurement and supply management, and to promote domestic pharmaceutical production. He called on WHO to continue to support Member States' efforts to strengthen their regulatory systems and build capacity to ensure access to safe and effective medicines and vaccines.

The representative of the NETHERLANDS said that, given the range and complexity of obstacles to access to medicines, bold steps were needed. He urged WHO to provide comprehensive guidance and assistance on issues such as fair pricing, quality and appropriate use. Knowledge was power, and the Secretariat's work to compile and analyse Member State experiences was critical. The sharing of experiences and data on innovation pipelines, pricing, market power and patterns, and licencing was crucial to achieving target 3.8 of the Sustainable Development Goals. Participants in the first-ever Fair Pricing Forum, held in the Netherlands in May 2017, had agreed that the exercise had been useful and should be repeated. Member States looked to the Director-General for guidance and support. Public health should be at the heart of the debate.

The representative of SRI LANKA, noting that improved access to affordable medicines was critical to achieving universal health coverage, expressed support for the draft decision and for the development of the road map report. Her Government had recently managed to reduce the cost of some 500 essential medicines, improving logistics management, promoting local production and enhancing quality control. Action on pricing, regulations and strategic procurement and transparency throughout the value chain must be a priority for all Member States. Promoting rational use of medicines, especially antimicrobials, and monitoring access to them would also help to reduce costs and out-of-pocket payments. WHO should pursue its normative work to set standards and provide guidance for the development, regulation, production, selection, pricing, procurement and rational use of medicines.

The representative of the PHILIPPINES supported the recommendation to scale up potentially high-impact actions, specifically those regarding capacity-building at the country and regional levels for the proper implementation of intellectual property regimes in line with the TRIPS Agreement, expansion of the Medicines Patent Pool to cover medicines on the WHO Model List of Essential Medicines, and efforts to generate the political will to implement policies encouraging fair pricing and investment in universal health coverage. Her Government looked forward to working with WHO to scale up pooled procurement and other collaborative approaches to securing lower prices. The momentum created by applying the WHO research and development blueprint to Zika virus disease could be used to address noncommunicable diseases, cancer and mental health.

The representative of JAMAICA shared the view expressed in the WHO report entitled "Ten Years in Public Health 2007–2017" that international conventions for the control of narcotic drugs could be a barrier to access. Her Government had encountered obstacles because of the current designation of cannabis under the United Nations international drug control conventions. It therefore attached particular importance to the work of the Expert Committee on Drug Dependence, especially its recent recommendation to the United Nations Commission on Narcotic Drugs that preparations containing almost exclusively cannabidiol be critically reviewed. Her Government stood ready to contribute to that review process, which would provide useful data to support the plant's medicinal use and facilitate efforts to produce a wider range of cannabis-based medicines.

The representative of BRAZIL welcomed the Director-General's report, especially its detailed description of WHO's work and recognition of the recommendations made in the report of the United Nations Secretary-General's High-level Panel on Access to Medicines. Her Government was ready to engage in a broader discussion that encompassed all aspects of the value chain, without precluding more specific discussions on important aspects such as fair pricing, transparency, delinking the costs of research and development from end prices and reducing out-of-pocket payments. Member States should always bear in mind the importance and cross-cutting nature of the issue of access, given that every topic considered at WHO depended on the availability and affordability of medicines and vaccines. She called on Member States to support the draft decision, which took a balanced and comprehensive approach, as borne out by the broad support it had received. Supporting comments

made by the representative of the Netherlands, she said that her Government hoped that lives would be saved by reducing the high prices of medicines.

The representative of THAILAND said that it was important to reinforce resolutions and plans with effective action. It was crucial to prioritize access to essential medicines, particularly for rare diseases, leverage the key role of universal health coverage in ensuring access to medicines, develop an approach that encompassed all aspects of the value chain, and use strategic purchasing to promote access to quality essential medicines at affordable prices; those four priorities had to be grounded in good health system governance. She highlighted the important role that strategic purchasing played in stockpiling certain rare medicines and called on WHO to take steps to create a sustainable global stockpile.

The representative of JAPAN said that shortages of, and access to, medicines were key factors of universal health coverage. While he welcomed the Director-General's report, he expressed concern about the ambiguous use of the word "scaling up" in paragraphs 6 and 8 and asked the Secretariat to clarify the scope of the actions listed therein, to ensure that they fell within WHO's mandate and could be implemented with available resources. He asked the sponsors of the draft decision to clarify whether the term "road map" corresponded to an "action plan".

The representative of MEXICO expressed concern about the limited access to certain vaccines, which threatened the progress made in immunization coverage and heightened epidemiological risks. Immunization against preventable diseases was a responsibility shared by individuals, communities and governments across borders and sectors. Despite shortages, her Government had taken various steps to ensure that immunization coverage met international and regional objectives and monitored the supply, demand for and availability of vaccines and medicines, giving priority to the most vulnerable members of the population. She called on WHO to address the shortages by cooperating with all relevant partners, reiterating the need to strengthen communication with vaccine producers.

The representative of IRAQ said that procurement and supply chain management policies should place greater emphasis on prioritizing medicines and ensuring regular and sustainable procurement of medicines and vaccines at affordable prices, for both middle-income and high-income countries. This should be achieved through greater cooperation with the GAVI Alliance and other partners. WHO should facilitate capacity-building for personnel with regard to procurement and supply chain management, including by producing guidelines for personnel. It should support capacity-building and advocacy for the rational use of medicines and take steps to prevent companies from curtailing access to medicines and vaccines. Intersectoral collaboration and community participation should be incorporated into procurement and supply chain management strategies, with greater integration between the public and private health sectors.

The representative of BAHRAIN expressed support for the draft decision and said that shortages of, and access to, medicines and vaccines affected all Member States. To reduce the impact of such shortages, national and regional procurement processes and practices, such as those currently employed by the Gulf Cooperation Council, should be implemented, and efforts to coordinate with supervisory bodies on medicine imports, customs duties and clearance should be harmonized. Member States should have access to technology that would enable them to produce essential medicines locally, and obtain sufficient financial support to enable them to import life-saving and rare medicines where needed. Quality control should be ensured through an oversight mechanism.

The representative of BHUTAN said that the issue of access to medicines and vaccines was a crucial concern, as it had a direct impact on the achievement of universal health coverage and the Sustainable Development Goals. His country, like many others, was vulnerable to shortages of

medical supplies owing to its reliance on imports. He hoped that WHO would help vulnerable Member States to build their capacities and enhance their access to medicines and vaccines. He recommended that WHO should encourage Member States to create joint purchasing systems to improve access and affordability, and endorsed the draft decision.

The representative of KAZAKHSTAN endorsed the draft decision and said that he shared the concerns raised by the representative of Brazil, particularly with regard to fair pricing. It was important to consider how countries could mobilize their own resources to produce certain medicines locally, given the high dependence of some Member States on imported medicines. A regional approach was therefore crucial, and more could be done in that area. Particular attention needed to be paid to research and development, and the production of new medicines. The Medicines Patent Pool was an important mechanism for many countries, and WHO needed to consider how countries could become part of that pool. Appropriate support should be given to national oversight and accreditation entities to ensure compliance with international standards and to facilitate the training of laboratory staff and those working in the pharmaceutical sector. He expressed support for WHO's work and policy in that regard.

The representative of FIJI said that his Government faced major challenges in ensuring a reliable supply of medicines and therefore welcomed the Director-General's report. However, while the report provided useful recommendations on procurement and supply chain management, it failed to give due consideration to the negative impact of whole-of-government procurement policies on the supply of medicines, particularly in small, remote countries. WHO should broaden its focus to include dialogue with finance ministries and foster the development of more flexible procurement policies, an area in which expertise in public management and administration was arguably more important than technical public health skills.

The representative of CANADA asked the Secretariat for information on how the road map would be developed and wished to know whether it would involve an analysis of WHO's existing mandate in that area.

The representative of BENIN said that urgent action was needed to address access to, and availability of, essential medicines in order to achieve universal health coverage. He endorsed the draft decision.

The representative of ALGERIA expressed concern that certain life-saving vaccines, such as those for poliomyelitis and yellow fever, remained in short supply despite the absence of an emergency and the low cost of the vaccines in question. The issue needed to be addressed in order to make progress towards universal health coverage. To that end, investment in research and development should be encouraged by delinking the costs thereof from end prices, in line with the recommendations of the High-level Panel on Access to Medicines. Furthermore, pricing needed to be made more transparent, particularly by expanding the Vaccine Product, Price and Procurement (V3P) Web Platform and drawing on the flexibilities set out in the 2001 Doha Declaration on the TRIPS Agreement and Public Health. Implementation of the Prequalification of Medicines Programme and the 33 recommendations issued by the panel of experts established to review the global strategy and plan of action on public health, innovation and intellectual property should be accelerated. Measures relating to innovation and intellectual property rights must also be considered. He expressed concern about the difficulties faced by a large number of middle-income countries in rolling out new medical products at affordable prices. WHO should step up its cooperation with the GAVI Alliance, with a view to considering ways of allowing middle-income countries to also benefit from appropriate pricing. Finally, the Middle-income Country Task Force should be revived.

The representative of the CONGO welcomed the efforts made to reduce the cost of hepatitis C treatment. Further improvements were nonetheless required: there were shortages of paediatric medicines; certain treatments, for haemophilia B for instance, remained unaffordable for many African countries; some essential medicines and vaccines, such as the pneumococcal vaccine, were unavailable because the countries manufacturing them had halted production; and generic forms of innovative medicines required to treat noncommunicable diseases were not available. He urged WHO to step up its efforts to ensure greater access to medicines and vaccines and endorsed the draft decision, provided that the term "road map" was clarified.

The representative of the DOMINICAN REPUBLIC endorsed the draft decision, particularly the preparation of a road map.

The representative of NEW ZEALAND called for the rapid adoption of the draft decision, subject to clarification by the Secretariat of the various points raised.

The representative of BELARUS¹ welcomed the Director-General's report and noted that equal access to essential medicines and vaccines without economic discrimination was crucial to achieving universal health coverage. His Government welcomed the recommendations on fostering and expanding the work of the Medicines Patent Pool. In its experience, it was possible to bring down prices, expand access to and increase the affordability of medicines by making greater use of voluntary licencing agreements for the production of generic medicines. He supported the Secretariat's future work in that area.

The representative of PORTUGAL<sup>1</sup> agreed that access to medicines constituted an essential component of universal health coverage and the right to health; a human rights-based approach was therefore crucial. However, greater transparency was needed to determine whether the cost of research and development was fairly reflected in end prices, especially where it was conducted and financed by Member States. His Government therefore fully supported WHO's proposed actions to promote transparency throughout the value chain and foster collaborative approaches to strategic procurement. He welcomed WHO's review of the recommendations in the report of the High-level Panel on Access to Medicines, since that objective approach represented the best way to build consensus around the report.

The representative of the UNITED STATES OF AMERICA<sup>1</sup> said that improving access to medicines was a priority for his Government. True barriers to access should be addressed; a global shortage notification system would be an invaluable tool in that regard. Consideration should also be given to building regulatory capacity, collecting data on the availability, quality and safety of medicines, and strengthening WHO's Prequalification of Medicines Programme. He expressed disappointment regarding other aspects of the Director-General's report, particularly certain proposals relating to intellectual property, international trade and political advocacy, which did not have the support of all Member States and went beyond WHO's mandate and its normative, core functions. The importance of intellectual property as an incentive for innovation had been affirmed on numerous occasions, and it was alarming that words to that effect had disappeared from the report. To ensure WHO's credibility, it was essential to speak to all stakeholders and to highlight the continued importance of innovation and intellectual property. The report of the High-level Panel on Access to Medicines was not an appropriate starting point for a discussion on that issue, as it had not been requested by Member States and had not garnered consensus support. His Government was prepared

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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.

to support the draft decision provided that the Director-General held full consultations with Member States on the preparation of the workplan.

The representative of GHANA, noting that access to medicines and vaccines was an important aspect of achieving universal health coverage, asked the Secretariat to provide more details on the WHO activities outlined in the Director-General's report and expressed concern about funding for the efforts they would require. He also asked for more information on how WHO intended to assist developing countries and on the challenges it faced in implementing the recommendations set out in the report of the High-level Panel on Access to Medicines.

The representative of BANGLADESH<sup>1</sup> expressed support for the draft decision. Collecting and monitoring data on medicines and vaccines would be pivotal to improving evidence-based policies. Technical support was also needed to bolster the pharmaceutical workforce, in particular in developing countries. His Government had developed a number of national plans and had implemented initiatives to ensure the supply of safe and effective medicines. It also practiced fair pricing to promote affordability. Notwithstanding, there was a need to improve the practices of community pharmacists.

The representative of ANGOLA¹ expressed support for the draft decision. She underscored the importance of national and regional capacity-building in the pharmaceutical sector, specifically in the areas of local production of medicines and vaccines, research and development, health technologies and innovation. Access to medicines embodied people's right to health; it should be granted to everyone, irrespective of their origin or location. Africa faced many challenges arising from the financial interests of pharmaceutical companies; sustainable solutions involving global industries and developing countries were essential. Her Government had made considerable efforts to step up production of high-quality medicines and to develop the country's pharmaceutical sector.

The representative of GREECE<sup>1</sup> reaffirmed that access to health care and medicines was a basic and fundamental human right. In Greece, free and equal access to the national health system was available to all. Free health care, medicines and vaccines were also provided to thousands of migrants and refugees. His Government was participating in a regional initiative aimed at strengthening such efforts and enhancing the sustainability of health systems. Access to innovative products and health system sustainability were pivotal to meeting the growing health needs of populations, respecting the rights of patients and providing further social protection to disadvantaged people. His Government wished to be added to the list of sponsors of the draft decision.

The representative of MOROCCO¹ underlined that access to medicines and pharmaceutical technologies was key to facilitating the enjoyment of the highest attainable standard of health by all, as provided for in WHO's Constitution and the Universal Declaration of Human Rights. Access was a critical concern in Africa, which faced the growing, dual burden of communicable and chronic diseases. By the end of 2018, WHO should develop a strategic framework for action and accountability to fulfil the recommendations of the report of the High-level Panel on Access to Medicines, relating in particular to cooperation between developing countries, sharing of experience on access to medicines and universal health coverage, and technical assistance to help governments to ensure price control and promote the local production of medicines.

The representative of ARGENTINA<sup>1</sup> expressed support for the draft decision and said that it was important for the actions proposed in the Director-General's report to be aligned with the global

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

strategy and plan of action on public health, innovation and intellectual property and the recommendations of the Consultative Expert Working Group on Research and Development: Financing and Coordination. She welcomed efforts to consolidate prioritization through the Global Observatory on Health Research and Development. The support provided by the Secretariat to Member States for the proper implementation of intellectual property laws should be strengthened. TRIPS mechanisms, particularly the flexibilities set out in the 2001 Doha Declaration on the TRIPS Agreement and Public Health, should be used to guarantee access to essential medicines. She expressed concern at the limited use of compulsory licenses compared to TRIPS-plus provisions, which reduced access to medicines, as described in the Director-General's report under "Public health-oriented intellectual property and trade policies". WHO should continue to support Member State acquisition of essential medicines and strengthen its Prequalification of Medicines Programme and regional procurement mechanisms.

The representative of PANAMA<sup>1</sup> stressed the importance of access to, and affordability of, medicines in the context of palliative care. She requested that Panama should be added to the list of sponsors of the draft decision.

The representative of the RUSSIAN FEDERATION<sup>1</sup> said that it was essential to ensure that the Member State mechanism on substandard and falsified medical products functioned and that the prioritized activities proposed under its workplan were fully implemented. When it came to combating falsified and substandard medical products, much could also be learned from the States parties to the Medicrime Convention of the Council of Europe, one of which was the Russian Federation. Mass production of medicines and harmonization of relevant standards could make medicines safer and lower transportation costs.

The representative of SWITZERLAND<sup>1</sup> highlighted the potential obstacles standing between the development of medicines and their use by patients, which included the physical availability of medicines, approval for their marketing, their financial and geographical accessibility, and their social acceptability. WHO efforts to facilitate access to medicines should reflect all of the facts available on the issue and the challenges encountered. She supported the draft decision.

The representative of INDIA<sup>1</sup> said that his Government had launched various national schemes to make medicines accessible and affordable. The global shortage of, and access to, medicines and vaccines should be treated as two separate issues and presented as separate agenda items. In his view, access to medicines was limited by market distortions, tight regulatory standards, monopolies and other factors. A detailed discussion was needed of the recommendations of the report of the High-level Panel on Access to Medicines, particularly with respect to TRIPS flexibilities. The Director-General's report should be based on a broader view of shortage causes, and should not focus solely on supply chain malfunctions. WHO should also set up a special fund to advance research and development.

The representative of EGYPT<sup>1</sup> underscored the need to address limited access to new and existing medicines and vaccines and to research and development, in particular in developing countries. He welcomed the approach adopted in the draft thirteenth general programme of work 2019–2023, under which access to medicines was treated as an essential component of universal health coverage. He emphasized the right to access to medicines in vulnerable States, especially those undergoing conflicts and humanitarian emergencies. The priority actions proposed in the

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

Director-General's report should be further elaborated, with clear targets set for 2019 to 2023. He welcomed the draft decision and requested that his Government be added to the list of sponsors.

The representative of SPAIN<sup>1</sup> welcomed the establishment of priorities regarding access to medicines and looked forward to the development of a clear and precise road map for future work. His Government wished to be added to the list of sponsors of the draft decision.

The representative of INDONESIA<sup>1</sup> said that her Government had introduced a number of initiatives to improve the quality and accessibility of medicines and to promote the availability of new medicines. Regional and international collaboration was needed to facilitate information-sharing on the accessibility and quality of medicines. She expressed support for the development of a global medicine shortage notification system, but said that further discussion was needed on the definitions of "shortage" and "stock out".

The representative of HAITI<sup>1</sup> expressed support for the draft decision and said that access to medicines was essential in developing countries.

The representative of SOUTH AFRICA<sup>1</sup> said that outstanding funding issues should not prevent the Secretariat from proceeding with its work as swiftly as possible. Her Government had taken innovative approaches to lower the prices of medicines, namely by engaging patent holders and encouraging competition from producers of generic medicines, in particular antiretroviral medicines. National policy reforms had led to price regulation throughout the supply chain and other improvements. Her Government had also benefited from cooperating with trade partners and international organizations. She supported the draft decision.

The representative of PERU<sup>1</sup> said that the geographical scope of the Medicines Patent Pool should be expanded to include low- and medium-income countries. He expressed concern that the prolongation of patent regimes in line with TRIPS-plus provisions would have negative effects on the availability of, and access to, medicines and other health products. Regarding WHO's Prequalification of Medicines Programme, the prequalification process should include essential high-cost medicines and biosimilars. As for medicine pricing policy, it would be useful to assess the impact of different pricing models on access to medicines. Finally, with respect to procurement and supply chain management, countries might benefit from an observatory for essential medicines at risk of supply shortages, whereby countries with greater capacities to produce such medicines could be identified and regional strategies developed accordingly.

The representative of the UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND¹ said that she was pleased that the Director-General's report addressed the importance of antimicrobial resistance in respect of access to medicines. Strategies to tackle antimicrobial resistance should be included in any road map for future work. Cross-cutting actions were needed to coordinate efforts, consolidate research and development for new products – including antimicrobials, diagnostics and vaccines – implement the One Health approach and ensure links across the WHO Secretariat. WHO's work should continue to be evidence-based and driven by Member States. Any activities related to intellectual property should be coordinated with WIPO and WTO to ensure policy coherence. He agreed that WHO's work on public health, innovation and intellectual property was predicated on its global strategy and plan of action in that area.

<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 ISLAMIC REPUBLIC OF IRAN<sup>1</sup> expressed appreciation for the Secretariat's continued efforts to address the global shortage of, and access to, medicines and vaccines, and for the draft decision.

The representative of UNICEF underscored her organization's close collaboration with WHO, not only in addressing vaccine shortages and availability, but also in shaping global markets. Marketshaping activities had generated cost savings of over US\$ 1.5 billion between 2012 and 2016. UNICEF and WHO worked together, documenting and analysing information on the causes of vaccine stock outs and on strengthening supply chains. Indeed, immunization was both a driver and a key indicator of health equity.

The representative of the INTERNATIONAL PHARMACEUTICAL FEDERATION, speaking at the invitation of the CHAIRMAN, acknowledged the importance of a global reporting system for medicine shortages. Access to safe, effective and quality medicines and vaccines could not be achieved, however, without supply chain integrity and efficiency, and her organization had recently examined the optimal role of pharmacists in the pharmaceutical supply chain in different environments. Pharmacists remained committed to addressing the global shortage of, and access to, medicines and vaccines.

The representative of the INTERNATIONAL FEDERATION OF MEDICAL STUDENTS' ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, said that intellectual property rights were a major barrier to access to medicines. The patent system had been ineffective for the production of medicines aimed at populations representing an unprofitable market for the pharmaceutical industry. There had to be fair compensation for the development of new therapeutics and vaccines, and new mechanisms, such as a flexible fair pricing model, were needed to facilitate access to medicines and vaccines.

The representative of the UNION FOR INTERNATIONAL CANCER CONTROL, speaking at the invitation of the CHAIRMAN, expressed concern about shortages of the human papillomavirus vaccine, and urged WHO to work with the GAVI Alliance, Member States and vaccine manufacturers to ensure that the vaccine was available, affordable and integrated into national immunization schedules. Member States should develop their national essential medicines list as a critical tool for analysing, selecting and prioritizing the purchase of medicines and vaccines, and for collecting data on the cost and effective use of medicines.

The representative of the INTERNATIONAL ASSOCIATION FOR HOSPICE AND PALLIATIVE CARE INC., speaking at the invitation of the CHAIRMAN, said that the Association was committed to helping Member States implement resolution WHA69.25 (2016) on access to medicines, including those for the relief of pain and palliative care. It had recently worked with UNODC to produce technical guidance on access to, and availability of, controlled drugs for medical purposes, which would be discussed with WHO at the next regular meeting of the Commission on Narcotic Drugs.

The representative of the WORLD HEART FEDERATION, speaking at the invitation of the CHAIRMAN, called on Member States to allocate more resources to improving access to medicines and to prioritize three actions: investment in health information systems to monitor and report the burden of cardiovascular disease, so as to match the supply of essential medicines with demand;

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

support for the development, implementation and monitoring of national medicines policies; and cooperation with all stakeholders, including the pharmaceutical industry, to support the development of local and regional manufacturing and supply capacity.

The representative of the GLOBAL HEALTH COUNCIL, INC., speaking at the invitation of the CHAIRMAN, agreed that stronger regulatory systems and harmonized processes were needed to boost access to essential health technologies. Additional support from Member States should build on the progress made by platforms like the African Vaccine Regulatory Forum towards strengthening local capacity and streamlining regulatory review. WHO should leverage the expertise and experience of innovative structures like product development partnerships in securing sustainable commitments. Research and paediatric data were needed on medicines submitted by companies for inclusion in the Model List of Essential Medicines for Children.

The representative of THE SAVE THE CHILDREN FUND, speaking at the invitation of the CHAIRMAN, highlighted the need to secure sustainable prices for middle-income countries as they transitioned from eligibility for GAVI Alliance support. Reaching the target of 5 million fewer child deaths from pneumonia by 2030 would require strong health systems and universal access to essential vaccines and medicines. The cost of vaccines could be reduced in four ways: by including the pneumococcal conjugate vaccine in national immunization programmes; by improving competition through market-shaping with dedicated financing; by ensuring patents did not obstruct market entry by new suppliers; and by enhancing price transparency to allow countries and the GAVI Alliance to negotiate prices that were affordable and sustainable.

The representative of the EUROPEAN SOCIETY FOR MEDICAL ONCOLOGY, speaking at the invitation of the CHAIRMAN, said that the global medicine shortage notification system should not be limited to medicines on the WHO Model List of Essential Medicines, but include all medicines that provided a significant clinical benefit in cancer care. Other recommendations included clearly defining "medicine shortage"; introducing legislation for early notification; establishing strategic plans for shortages at national and institutional level; developing a harmonized web-based platform; assessing the risks of shortages for medicines on the WHO Model List of Essential Medicines; introducing production incentives; and establishing procurement models.

The representative of KNOWLEDGE ECOLOGY INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that WHO should continue the conversation begun at the Highlevel Panel on Access to Medicines on the incoherency of policies that pitted access and innovation against one another. WHO should examine how incentives to invest in research and development could be delinked from high prices, for example in areas such as cancer, HIV/AIDS, rare diseases and antimicrobial resistance. Delinkage feasibility studies should compare current incentives, which were based on the grant of temporary monopolies, to delinkage mechanisms featuring significant research and development subsidies and robust market entry rewards or prize funds, with a view to eventually replacing monopolies and high prices.

The representative of OXFAM, speaking at the invitation of the CHAIRMAN, said that governments needed to know the real research and development costs of medicines in order to decide whether prices were fair. In order to act on the recommendation of the High-level Panel on Access to Medicines that WHO establish an international database of medicine prices, governments and companies needed to provide WHO with accurate price information and WHO required adequate funding to carry out the necessary work. Transparency was also needed regarding information on patents, clinical trials and free trade agreements.

The representative of MEDICUS MUNDI INTERNATIONAL – INTERNATIONAL ORGANISATION FOR COOPERATION IN HEALTH CARE, speaking at the invitation of the CHAIRMAN, said that the Director-General's report had not adequately addressed the issue of delinking the cost of research and development from the end prices of health technologies. Strategies and approaches with the highest impact should be prioritized, not merely the least complex actions requiring the fewest resources. Transparency in research and development did not require greater complexity or additional resources, but rather political will and WHO's norm-setting capabilities, and should be addressed as soon as possible. She urged WHO to establish a strategy and action plan in order to align its activities with the recommendations of the High-level Panel on Access to Medicines. WHO should take bold steps to delink the cost of research and development from the end prices of health technologies and consider a global convention on research and development, as suggested by the High-level Panel.

The representative of the INTERNATIONAL UNION AGAINST TUBERCULOSIS AND LUNG DISEASE, speaking at the invitation of the CHAIRMAN, said that universal health coverage and the Sustainable Development Goals needed to be linked with strategies to increase both affordable access to medicines, and research and development for new health technologies. The Union's Life Prize represented a practical example of research and development costs delinked from the final regimen cost, as it rewarded and funded developers and pooled intellectual property to develop a treatment regimen for all types of tuberculosis.

The representative of MÉDECINS SANS FRONTIÈRES INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that access policies should consider not only access to existing products, but also needs-driven research and development for new products. The Secretariat had to continue its work to increase transparency in all aspects of research and development. Strategies to promote innovation and access should be coherent across WHO initiatives and should also support and build on the global strategy and plan of action on public health, innovation and intellectual property and the work of the Consultative Expert Working Group on Research and Development: Financing and Coordination and the High-level Panel on Access to Medicines.

The representative of the INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS AND ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, said it was unfortunate that the Director-General's report focused on the protections that drove discovery of new health technologies. It was also unfortunate that the discussion had focused on the report of the High-level Panel on Access to Medicines, as the Panel's mandate was too narrow and based on a false premise. Its report failed to address key barriers to access and had never been endorsed by United Nations Member States; its recommendations were therefore not a sound basis for further consideration or action by WHO.

The representative of STICHTING HEALTH ACTION INTERNATIONAL, speaking at the invitation of the CHAIRMAN, expressed hope that synergies could be found with other global initiatives and said that she supported the Secretariat's efforts to provide technical assistance to Member States on management of health-related intellectual property rights, especially during trade negotiations. Transparency remained an issue, and should be adopted as a core value in order to achieve equitable access to medicines.

The ASSISTANT DIRECTOR-GENERAL (Access to Medicines, Vaccines and Pharmaceuticals) said that, even though more than 50 resolutions that touched on access had been adopted in the preceding 10 years, insufficient progress had been made. Unacceptable gaps in access persisted within and between countries. Initially a matter of concern for middle- and low-income countries, access had become a global issue requiring global solutions tailored to each country's needs.

Responding to the points raised, she said that the Secretariat had started work on an essential diagnostics list and hoped to establish an expert working group in the first half of the year. The road map, for its part, should cover inter alia supply chain problems, transparency, pricing, research and development and TRIPS facilities, all of which had been raised in the discussion and in the Director-General's report. The road map would focus on supporting the specific needs of countries and be prepared in consultation with Member States; it should be flexible, nimble and action-oriented. With regard to pain relief in palliative care, there would be a meeting of the Expert Committee on Drug Dependence in May 2018, at which pain relief drugs, opioids and cannabidiol would be discussed. To clarify what was meant by scaling up access, she provided the examples of expanding support to networks of regulatory agencies and broadening the scope of prequalification to encompass the entire Model List of Essential Medicines.

The REGIONAL DIRECTOR FOR SOUTH-EAST ASIA said that countries in the Region had made progress towards expanding access to medicines. However, barriers including pricing and supply chain and production issues, remained. The Region was a major producer of essential medicines and vaccines used around the world, which had helped to increase the availability of low-cost quality generic medicines, at the national and the international level. The fact that the Region encompassed countries with large and small populations posed challenges in terms of economies of scale. Experience had shown that lower prices did not suffice to improve access; increased health care budgets were equally important, and would result in reduced out-of-pocket expenditures. Most essential medicines were no longer under patent, but there was a need for continued research and development for new medicines and vaccines. For patented medicines, the aim was fair price and fair profit. The right balance had to be struck between rewarding innovation, improving trade, and responding to public health priorities, an endeavour that involved appropriate use of TRIPS facilities and trade agreements. Improved data were essential, and more rational use of medicines was an integral part of assuring the quality of medicines, in particular antimicrobials.

The DIRECTOR-GENERAL thanked participants for their comments and said that universal health coverage was not possible without access to medicines. In the past, WHO had been sidelined regarding issues of access to medicines, and was committed to ramping up its activities in that area. The Organization's approach should be a holistic one, as access to medicines involved more than single elements such as pricing. Meetings with private sector stakeholders had been fruitful; both sides had made a commitment to take action on the issues on which they agreed, and to continue discussing points of disagreement.

#### The Board noted the report.

The CHAIRMAN said that she took it that the Board wished to adopt the draft decision.

The decision was adopted.1

The meeting rose at 19:45.

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<sup>&</sup>lt;sup>1</sup> Decision EB142(3).