

**PROVISIONAL SUMMARY RECORD OF THE FIRST MEETING**

**WHO headquarters, Geneva  
Wednesday, 29 May 2019, scheduled at 09:30**

**Chairperson: Ms M.N. FARANI AZEVÊDO (Brazil)  
later: Dr H. NAKATANI (Japan)**

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## FIRST MEETING

Wednesday, 29 May 2019, at 09:40

**Chairperson:** Ms M.N. FARANI AZEVÊDO (Brazil)

**later:** Dr H. NAKATANI (Japan)

### 1. **ELECTION OF CHAIRPERSON, VICE-CHAIRPERSONS AND RAPPORTEUR:** Item 1 of the provisional agenda

The CHAIRPERSON drew attention to Rule 12 of the Rules of Procedure of the Executive Board, which set out the procedures for electing Officers of the Board. Following the principle of rotation among WHO regions, Dr Hiroki Nakatani (Japan) had been nominated for the office of Chairperson of the Executive Board.

**Dr Nakatani (Japan) was elected Chairperson.**

**Dr Nakatani took the Chair.**

The CHAIRPERSON thanked the Board for electing him and paid tribute to his predecessor. Referring to Rule 12 of the Rules of Procedure, he said that, following the principle of geographical rotation, and on the basis of consultations in the respective regions, the following nominations had been made for the four Vice-Chairpersons: Dr Codjo Didier Agossadou (Benin), Dr Hussain Al Rand (United Arab Emirates), Dr Päivi Sillanaukee (Finland) and Dr Rajitha Senaratne (Sri Lanka).

**Dr Agossadou (Benin), Dr Al Rand (United Arab Emirates), Dr Sillanaukee (Finland) and Dr Senaratne (Sri Lanka) were elected Vice-Chairpersons.**

The CHAIRPERSON said that, under Rule 15 of the Rules of Procedure, if the Chairperson was unable to act between sessions, one of the Vice-Chairpersons would act in his or her place; the order in which the Vice-Chairpersons would be requested to serve should be determined by lot at the session at which the election had taken place.

**It was determined by lot that the Vice-Chairpersons would serve in the following order: Dr Senaratne (Sri Lanka), Dr Al Rand (United Arab Emirates), Dr Sillanaukee (Finland), Dr Agossadou (Benin).**

The CHAIRPERSON said that, pursuant to Rule 12 of the Rules of Procedure and in accordance with the principle of rotation among geographical regions, Dr Peter Schmeissner (United States of America) had been nominated Rapporteur.

**Dr Schmeissner (United States of America) was elected Rapporteur.**

- 2. OPENING OF THE SESSION AND ADOPTION OF THE AGENDA:** Item 2 of the provisional agenda (documents EB145/1 and EB145/1 (annotated))

### **Opening of the session**

The CHAIRPERSON declared open the 145th session of the Executive Board.

The DIRECTOR-GENERAL congratulated Dr Nakatani on his election as Chairperson and thanked his predecessor for her excellent leadership. Welcoming all participants, he said that the Seventy-second World Health Assembly had been one of the most productive and that he looked forward to working with Board members in the same spirit of constructive collaboration. The Board would be required to undertake highly important work over the coming year, and while the provisional agenda for its current session was relatively short, the issues it contained were of great moment.

The provisional agenda included consideration of a new approach to the standardization of medical devices nomenclature, the current lack of which created confusion and risked patient safety. That provisional agenda item was a perfect example of WHO standard-setting work. The Board would also be considering improvements to WHO governance, including measures to ensure the more meaningful engagement of non-State actors and guidelines for the submission of written statements by Member States to the Health Assembly and the Executive Board. He looked forward to working with the members of the Board to promote health, keep the world safe and serve the vulnerable.

### **Adoption of the agenda**

The representative of ROMANIA, speaking on behalf of the European Union and its Member States, recalled that, as agreed in an exchange of letters in 2000 between WHO and the European Commission on the consolidation and intensification of cooperation, and without prejudice to any future general agreement between WHO and the European Union, the European Union attended sessions of the Board as an observer. He requested that, as at previous sessions, representatives of the European Union should be invited to participate, without vote, in the meetings of the 145th session of the Board and its committees, subcommittees, drafting groups or other subdivisions that addressed matters falling within the competence of the European Union.

The CHAIRPERSON took it that the Board wished to accede to the request.

**It was so agreed.**

**The agenda was adopted.**

### **Organization of work**

The CHAIRPERSON suggested that the Board should proceed in accordance with Rule 28 of the Rules of Procedure relating to time limits.

The representatives of GERMANY and BRAZIL endorsed that suggestion.

**It was so agreed.**

The CHAIRPERSON suggested that the Board should take up its agenda items in numerical order and that it should follow the proposed timetable. Under item 9 of the agenda, on future sessions of the

Executive Board and the Health Assembly, the Board would consider a request from observers to attend the Programme, Budget and Administration Committee of the Executive Board in that capacity.

**It was so agreed.**

**3. OUTCOME OF THE SEVENTY-SECOND WORLD HEALTH ASSEMBLY:** Item 3 of the agenda

The representative of BENIN, speaking on behalf of the Member States of the African Region, welcomed the attention given at the Health Assembly to the management of public health emergencies, the eradication of poliomyelitis, universal health coverage, access to medicines and vaccines, the health of migrants and refugees, and the follow-up to the high-level meetings of the United Nations General Assembly on antimicrobial resistance, prevention and control of noncommunicable diseases, and ending tuberculosis. The Member States of the Region requested support for implementing the resolutions and decisions approved at the Health Assembly. Welcoming the adoption of the Programme budget 2020–2021, he encouraged the Director-General to continue to mobilize flexible funding in order to increase the budget allocations for combating noncommunicable diseases. Lastly, he recommended that the WHO public health prizes should be extended to all categories of health workers.

The representative of BRAZIL applauded the positive atmosphere of engagement and dialogue at the Health Assembly. Strictly enforced limits on speaking times and a well-managed agenda had allowed for efficient meetings. The road map for access to medicines, vaccines and other health products, 2019–2023, and resolution WHA72.8, on improving the transparency of markets for medicines, vaccines and other health products, were ground-breaking initiatives. Her Government hoped to work together with Member States, the Secretariat and other stakeholders to make the celebration of World Chagas Disease Day a game changer for the future of people with the disease.

The representative of KENYA, welcoming the efficiency of the Health Assembly, said that he was looking forward to working with all Member States and the Secretariat to champion causes that were of strategic importance to his country and to the Member States of the African Region, such as universal health coverage, access to medicines and essential technologies, and strengthening disease surveillance, preparedness and outbreak management. Referring to the deliberations on access to medicines and vaccines, he said that, although it was true that agenda items could be introduced by Member States during the Health Assembly, adherence to the Rules of Procedure should be encouraged to foster consensus.

The representative of SRI LANKA, speaking on behalf of the Member States of the South-East Asia Region, congratulated the Secretariat for the successful outcome of the Health Assembly, in particular the adoption of resolutions WHA72.6, on global action on patient safety, and WHA72.8. The Member States of the Region had appreciated the opportunity to propose an amendment to decision WHA72(11), on the 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.

The representative of GERMANY expressed appreciation to the Secretariat for the successful outcome of the Health Assembly, welcoming in particular the consensus achieved regarding the Programme budget 2020–2021. Given that much of the funding for the Programme budget would depend on contributions not only from Member States but also from non-State actors, mechanisms to allow for further exchanges with non-State actors should be explored in order to understand their key interests in terms of areas of funding, which would also help to address potential risks. In addition, there

was a need to reflect on why some Member States had dissociated themselves from certain discussions (partly for procedural reasons but also owing to their unease during the negotiations and concern about negative external media campaigns).

The representative of the UNITED STATES OF AMERICA expressed concern at the all-time low level of governing body staffing, especially in the light of the complexity and volume of the governing body agendas and related meetings. With regard to the procedural concerns relating to resolution WHA72.8 and the late publication of several key reports, he suggested that the Secretariat should undertake an internal review to identify areas for improvement. He urged Member States to submit draft resolutions on complex multiagency and multisectoral topics to the Board for consideration before the Health Assembly. He encouraged the Secretariat to provide more support for the governing bodies' critical enabling function. Although non-State actors had a valuable role to play in governing body discussions, they must respect the Organization's processes. His Government strongly denounced the actions of some non-State actors to intimidate Member States during the negotiations on improving the transparency of markets for medicines, vaccines and other health products. The Secretariat should remind non-State actors in official relations with WHO of the privileges and responsibilities that their status entailed.

The representative of MONACO<sup>1</sup> said that the aim of negotiations was to reach consensus, but that events during the Health Assembly had impeded discussions among Member States. It was imperative to ensure discussions remained confidential and unacceptable for Member States to be pressured, targeted or attacked on social media.

The representative of SWITZERLAND<sup>1</sup> said that the manner in which resolution WHA72.8 had been deliberated was regrettable. The resolution had not been unanimously adopted, which did not reflect the culture of collaboration for which the Organization was known. She underscored the importance of the Executive Board's work, which allowed Member States to prepare for and actively participate in discussions and arrive at constructive solutions by consensus for subsequent consideration by the Health Assembly.

The CHAIRPERSON took it that the Board wished to conclude its discussion of the item.

**It was so agreed.**

#### **4. REPORT OF THE PROGRAMME, BUDGET AND ADMINISTRATION COMMITTEE OF THE EXECUTIVE BOARD:** Item 4 of the agenda (document EB145/2)

The representative of ZAMBIA, speaking in his capacity as Chair of the Programme, Budget and Administration Committee of the Executive Board, said that Committee members had raised concerns about the volume of overdue donor reports, an issue mentioned in the report of the Independent Expert Oversight Advisory Committee. In reply, the Secretariat had confirmed that the number of outstanding reports had been reduced to 10% of all reports due. The Committee had endorsed the Independent Expert Oversight Advisory Committee's intention to take into account the conclusions of the United Nations-wide review of independent oversight bodies carried out by the Joint Inspection Unit in 2019. It had welcomed the work undertaken on compliance, risk management and ethics, and stressed the critical nature of a strong ethical basis for the work of the Organization. Adequate resources should be

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

allocated to advance the work of that function, with particular attention paid to preventing sexual exploitation and abuse and sexual harassment.

The Committee had also conveyed its support for the work of the Joint Inspection Unit, and had requested that the Secretariat should ensure full and quick implementation of key recommendations, including those on legislative bodies and whistle-blowing policies. It had welcomed efforts to promote organizational learning from completed evaluations and participation in joint evaluations, along with the work of the hosted partnerships. It had further emphasized the importance of the reviews of such partnerships, which should continue.

The representative of GERMANY expressed concern about the late issuance of documents, which had made it difficult for members of the Programme, Budget and Administration Committee to prepare for the related meetings. Discussions on programmatic and financial matters should encompass donors in order to enhance understanding of who was contributing to the Organization, how much and why, and whether they would continue to do so.

The representative of SRI LANKA stressed the size of the gap between funding and WHO priorities, particularly the lack of funding for noncommunicable diseases. He congratulated the Director-General on the WHO reform processes, including the transformation agenda and ensuring gender parity at senior management level.

The representative of BANGLADESH expressed appreciation for the work of the Programme, Budget and Administration Committee and supported the implementation of its recommendations.

The representative of ZAMBIA, speaking on behalf of the Member States of the African Region, welcomed the development of risk and ethics training materials, and said that the emphasis should be on face-to-face training. She urged the Secretariat to provide adequate financial, human, technical and material resources for the compliance, risk management and ethics functions. Mandatory training for all staff on sexual harassment and sexual exploitation and abuse should be coupled with periodic capacity-building activities, such as workshops featuring concrete examples of types of harassment and ways to report them. To enable timely decision-making, information should be provided as soon as possible on the action that would be taken by the Secretariat in relation to the Joint Inspection Unit's recommendations, including the time frame for such action. She endorsed the Committee's recommendation to adopt the draft resolution contained in document EB145/13 on amendments to the Staff Regulations and Staff Rules.

**The Board noted the report.**

**5. TECHNICAL AND HEALTH MATTERS:** Item 5 of the agenda

**Standardization of medical devices nomenclature:** Item 5.1 of the agenda (document EB145/3)

The representative of INDONESIA urged the Secretariat to use transparent methods in developing terms, classifications, definitions and hierarchies for the proposed nomenclature system. He supported the development of an international classification, coding and nomenclature system for medical devices, which should take into consideration Member States' varying regulatory readiness and medical device manufacturers.

The representative of IRAQ, speaking on behalf of the Member States of the Eastern Mediterranean Region, said that strengthening the regulation of health products, including medical

devices, was of utmost importance, particularly for low- and middle-income countries. In addition, the Organization's technical support was urgently needed for the development of a comprehensive model list of basic and essential devices, with a focus on nomenclature. Support was also needed to strengthen national capacity.

The representative of FINLAND said that international standardization of nomenclature would help to ensure patient safety, improve the availability of medical devices and enhance health service quality. A common coding system would also have financial benefits, as it would harmonize procurement and supply systems across the United Nations system. She welcomed the cooperation between the European Commission and WHO with a view to setting up a regional database. Her Government supported the proposed establishment of an expert group to further explore options related to the classification, coding and nomenclature of medical devices.

The representative of SRI LANKA said that it was critical to develop a standardized nomenclature and coding system, particularly given the increasing use of electronic data for sharing and storing patient information. Such a system needed to have clear, unambiguous terminology; accurate and informative descriptions; comprehensive coverage to encompass new and innovative devices; a structure with appropriate hierarchies and flexibility; a suitable level of granularity and specificity; and interoperability with other systems used by health care providers and stakeholders.

The representative of JAPAN said that without a universal classification and nomenclature system it was difficult to measure and compare the availability and use of medical devices at the global level and to share information on adverse events. When developing a new system, it was important to keep in mind that many Member States and other international organizations used existing nomenclature systems, such as the Global Medical Device Nomenclature. The Secretariat was therefore encouraged to adopt an open, transparent and inclusive approach to promoting harmonization, in order to avoid creating confusion or placing an additional burden on Member States and the private sector.

The representative of CHINA, welcoming the work on establishing a standardized classification and nomenclature system, requested the Secretariat to collect further relevant data, including on the financial implications of a new system, and to conduct a systematic review and comparative study of existing systems to inform decision-making. His Government was willing to participate in that undertaking.

The representative of ITALY said that the medical devices sector was complex and fragmented; a common nomenclature would therefore improve patient safety and health system quality by facilitating the global sharing of information. The international system should be developed on the basis of broad participation and cooperation, and made freely available. The Italian medical devices classification system had been adopted by the European Commission as the standard for the European Union; his Government was currently working with the Commission to update the system and map other existing nomenclature systems. He encouraged cooperation on a standardized international classification system for medical devices.

The representative of CHILE said that the lack of a common nomenclature for medical devices hindered the development, authorization and classification of health technologies. The proposed international classification, coding and nomenclature system was critical to ensure patient safety, effective monitoring, market authorization, price comparisons, information-gathering and quality. Her Government looked forward to collaborating in the development of such a system.

The representative of SINGAPORE said that a harmonized system to facilitate tracking and traceability of medical devices would enhance patient safety. In order to keep pace with rapidly evolving technology, the Secretariat should ensure that the proposed standardized nomenclature system was designed and developed to be sustainable and accessible, and that it took into consideration existing classification systems. The proposed system should be easy to use and minimize the administrative burden for health care professionals and administrators.

The representative of BRAZIL said that the absence of a universal classification and nomenclature system gave rise to various challenges, including supply-chain management difficulties. Several standardized nomenclature systems were currently in operation, including the Global Medical Device Nomenclature, which was used in Brazil and a number of other countries. It would be appropriate to offer Member States a comprehensive range of options on which to base an informed decision. In that context, it was important to examine potential platforms for dialogue among the different systems, such as correlation tables, without prejudice to an assessment of whether, or under what conditions, developing and updating a universal nomenclature system would be the most cost-effective response. His Government looked forward to participating in the follow-up to the discussion.

The representative of the UNITED STATES OF AMERICA said that his Government did not support the development of an international classification and nomenclature system, as it was not harmonized with the existing Global Medical Device Nomenclature, currently used by a number of major regulatory authorities, including in his country. As of March 2019, Global Medical Device Nomenclature codes had been freely available to stakeholders. There was therefore no need for WHO to create another nomenclature system, which would only confuse and complicate matters, and would ultimately hinder patient access and increase costs. He encouraged the Organization to participate in the International Medical Device Regulators Forum in order to develop a harmonized approach to the nomenclature of medical devices.

The representative of TUNISIA said that it was important to cooperate on developing a common nomenclature, harmonized with other existing systems, which would facilitate monitoring of medical devices and enhance patient safety. It would also improve the management and quality control of internationally available medical devices and facilitate follow-up.

The representative of SUDAN, expressing support for the development of standardized medical devices nomenclature, said that a freely accessible database of available medical technology should be created and used to develop guidelines for the use of medical devices. Given the wide range of devices available, lists and databases of medical devices should be regularly updated. She requested the Secretariat to develop guidance for Member States, for example in the form of a handbook. Her Government was willing to participate in such an endeavour.

The representative of AUSTRALIA expressed concern that the proposed nomenclature system did not include cooperation with established nomenclature providers or a comprehensive analysis of existing systems, such as the Global Medical Device Nomenclature. In that regard, the Secretariat should engage with those members of the International Medical Device Regulators Forum that had an established nomenclature system. It would be useful to know whether the Secretariat had undertaken a risk–benefit analysis to evaluate the proposed system and alternatives, such as bringing together existing data sets in a single system. Without such work, there was a risk of creating further inconsistency and confusion in the identification of medical devices across jurisdictions and undermining global harmonization and standardization efforts.

The representative of ESWATINI, speaking on behalf of the Member States of the African Region, said that although progress had been made in ensuring affordable, safe and quality-assured



essential medical devices, much remained to be done, especially in view of the rapid technological advances in that field. Existing international classification systems provided an opportunity to fast-track the standardization of medical devices nomenclature. The Member States of the African Region commended the work of WHO in developing a model list of medical devices for Ebola virus disease, cancer, and maternal and child health, and its efforts to draw up a list of health products for primary health care. The challenges faced by some Member States in the Region – relating to procurement, unreasonably high costs, lack of standardized nomenclature and poor quality assurance – hindered access to essential medical services and adversely affected efforts to achieve universal health coverage. Given the complexity of the task ahead, he called for the promotion of interagency and regional collaboration. The Secretariat should expedite the formation of a reference group of editorial experts and undertake comprehensive consultations to ensure maximum participation. It should also provide financial and technical support, and a time frame to finalize the work.

The representative of ARGENTINA supported the establishment of regional and subregional networks of regulatory bodies and the establishment by the Secretariat of a group of editorial experts in order to effectively govern the international classification, codification and nomenclature of medical devices.

The representative of the UNITED ARAB EMIRATES fully supported the standardization of medical devices nomenclature, which would help to improve the recording system currently in place in his country.

The representative of the UNITED REPUBLIC OF TANZANIA highlighted the complexity of ensuring global standardization of the multiple systems already in place. She therefore agreed that WHO should spearhead the development of an international classification and nomenclature of medical devices. A phased approach should be used, whereby existing essential devices were the first to be attributed common standard names, coding and classification. Furthermore, she preferred the term “essential medical devices” over “priority medical devices”, which was too subjective. All countries, both developed and developing, should be actively consulted during the standardization process, as the nomenclature should be applicable in all health systems, irrespective of economic status. WHO country offices should facilitate Member States’ engagement, where applicable.

The representative of BANGLADESH said that the continuous invention of new medical devices and improvement of existing ones represented a challenge to their successful standardization and called for a dynamic nomenclature system that was constantly updated. He requested the Secretariat to strengthen the system for the prequalification of medical devices, as it had the system for the prequalification of medicines.

The representative of AUSTRIA, welcoming efforts to standardize medical devices nomenclature, strongly encouraged the Secretariat to take into consideration the National Classification of Medical Devices nomenclature system established in the European Union. Cooperation with the International Medical Device Regulators Forum and engagement with various stakeholders was essential for the successful development of a global harmonized nomenclature.

The representative of KENYA urged the Secretariat to adopt an international classification system for the standardization of medical devices nomenclature, incorporating the existing WHO lists of essential diagnostics and medical devices. The lack of a global standardized nomenclature hindered the provision of essential medical devices and opened the door to substandard and falsified medical products and technology waste dumping, particularly in the African Region. The process of adopting the system must be flexible and transparent, as it would entail close interaction with numerous non-State actors and entities.

The representative of TAJIKISTAN noted the importance of a standardized nomenclature system. Without such a system, the relevant national authorities would find it a challenge to register medical devices, which might in turn allow for the production and use of falsified medical products in health systems. He requested an editorial change in the Russian language version of document EB145/3.

The representative of TONGA supported the proposal to develop an international classification and nomenclature of medical devices that encompassed work already accomplished in that area. The challenge presented by the issue was magnified for small and resource-challenged countries like Tonga and other Pacific island countries. Without a standardized classification system, his country struggled to stay abreast of the diversity of equipment available, particularly where biomedical engineering capacity was limited or non-existent.

The representative of COSTA RICA<sup>1</sup> recognized the importance of a nomenclature that would allow countries to take stock of the biomedical equipment available within their own health systems. Such a nomenclature would enable the international health system to respond more quickly to health emergencies and natural disasters, and ensure that countries benefiting from international cooperation received exactly what they needed, while simultaneously avoiding technology dumping.

The representative of CANADA<sup>1</sup> supported WHO's overarching objectives in working towards greater alignment of the international classification of medical devices. However, the report did not provide a full picture of the current landscape of medical devices nomenclature. His Government used the Global Medical Device Nomenclature, which was well established, effective and in alignment with several key regulators. He requested additional details and an analysis of options, including on how the proposed approach would recognize and build on existing systems already in use and avoid placing an undue burden on those using them.

The representative of the UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND<sup>1</sup> expressed support for WHO's work on international standardization of medical devices nomenclature. In view of the complexity of the medical devices market and the range of uses for a harmonized international medical devices nomenclature, further analysis to fully understand the current and future needs of the various users of that nomenclature would be beneficial. Her Government was very keen to make better use of data in order to strengthen understanding of the patient safety impact of medical devices and was willing to collaborate in such research. Cooperation with regulators of medical devices was essential in the development and use of medical devices nomenclature.

The representative of the EUROPEAN UNION said that the European Commission, with significant support and resources from the Government of Italy, had established a harmonized, open-access system that levied no cost for registering devices and was compatible with WHO's existing international classifications, driven by regulator rather than industry needs, and governed by regulators rather than the private sector. The system had proven useful, and the European Union and its Member States would be willing to make it available to WHO. They also intended to provide a document comparing that system with others, including the Global Medical Device Nomenclature, for reference.

The ASSISTANT DIRECTOR-GENERAL (Prequalification and Technology Assessment) highlighted the complexity of global standardization owing to the breadth and variety of medical devices available and the multitude of existing systems. The Secretariat would continue to assess existing systems and strengthen coordination with them. The overarching aim was to support the procurement of quality-assured products and to involve all relevant parties in a transparent and inclusive process

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

towards global convergence and harmonization. Addressing the needs of countries that currently had no system in place was of particular importance.

**The Board noted the report.**

**6. MANAGERIAL, ADMINISTRATIVE AND FINANCIAL MATTERS:** Item 6 of the agenda

**WHO governance reform processes:** Item 6.1 of the agenda

• **Involvement of non-State actors** (document EB145/4)

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. He expressed support for enhanced, more meaningful engagement of non-State actors with WHO, in accordance with the Framework of Engagement with Non-State Actors. Grouping non-State actors into constituencies might encourage them to consolidate their positions and make a more effective contribution to the debate. The idea of a world health forum required further discussion based on an analysis of the financial and governance implications. He welcomed the efforts to improve engagement through a joint working group and the WHO-Civil Society Task Team and requested further information on the recommendations generated by those efforts, including the establishment of an advisory committee on WHO-civil society organization engagement. He would welcome a discussion on those recommendations in the meetings of the governing bodies.

The representative of SINGAPORE said that interactions with non-State actors should be useful to all parties, and need not be confined to governing body sessions. A world health forum could provide a way for non-State actors to participate meaningfully without the procedural limitations of governing body sessions, but would require a structure that yielded value for all parties and drove consensus between the Secretariat, Member States and non-State actors. He asked whether and how non-State actors' participation in such a forum would contribute towards the fulfilment of WHO's constitutional mandate with respect to non-State actor engagement.

The representative of CHINA said that non-State actors could make a positive contribution to global health governance, but their engagement needed to respect WHO's intergovernmental nature and comply with all established rules of the Organization. The Secretariat should assess the necessity, effectiveness and financial implications for the Organization of the measures proposed in the report, such as the creation of a world health forum. His Government endorsed the proposed organization of a web consultation with non-State actors, with a view to drawing up a proposal for consideration by the Board at its 146th session.

The representative of BRAZIL noted the importance of meaningful exchange with non-State actors, but said that the report went beyond the request set out in decision EB144(3), namely to draw up recommendations on an informal meeting or forum to bring together Member States and non-State actors in official relations. Such a forum would be valuable, but the lack of information on its potential format, participants, timing and duration, or on how its results would be presented to the governing bodies, was regrettable. The forum could take place annually and be an additional tool to enhance implementation of the outcomes of governing body meetings, but it should not interfere with WHO's intergovernmental

decision-making process. His Government did not favour linking the forum with the WHO Partners' Forum, which had different purposes and objectives. With regard to the timing of the proposed forum, a one- or two-day meeting before a governing body session would enable Member States and non-State actors to come together to debate the main agenda items. There should be a transparent and inclusive process for non-State actors to express their views on how to improve their participation. Consultations should be held with Member States in Geneva prior to further consideration of the matter by the Board.

The representative of BANGLADESH said that, given the already numerous contributions from Member States and existing time management issues, it was not practical for all non-State actors to speak at governing body meetings. Although his Government was in favour of encouraging the involvement of non-State actors, their engagement must not violate the Constitution, rules, norms or ethics of WHO. His Government did not currently endorse the organization of an annual conference for non-State actors.

The representative of the UNITED STATES OF AMERICA welcomed measures to stimulate participation of non-State actors. The previous weeks and months had revealed a deeply flawed process. It was therefore urgent to find ways for non-State actors to participate meaningfully, respectfully and appropriately in WHO's governing bodies and provide timely input for Member States' consideration. He encouraged Member States to replicate his Government's practice of organizing listening sessions for all interested stakeholders ahead of the Health Assembly. Ultimately, Member States retained the prerogative of governance and setting policy for the Organization. He asked the Secretariat for information on the timing, cost, nature and focus of the proposed informal meeting or forum, whether it would be limited to a specific theme or cover all the topics considered by the Health Assembly, and how the Secretariat would ensure that the governing bodies took account of the outcome.

The representative of ARGENTINA said that the participation of non-State actors should be improved, while respecting WHO's intergovernmental nature. In principle, her Government supported the proposals for individual non-State actors to continue posting their statements on a dedicated website two weeks before governing body sessions, and for non-State actors to meet before or during those sessions to decide on which agenda items they would deliver statements. Her Government had no initial objections to the proposals set out in the report, but required further information to conduct a proper analysis.

The representative of INDONESIA said that the engagement of non-State actors should advance public health, respect WHO's intergovernmental nature and maintain WHO's integrity, credibility, independence and reputation. Member States should play a key role in monitoring and evaluating non-State actors' engagement through consultations organized by the Secretariat. WHO's decision-making process must remain intergovernmental.

The representative of AUSTRALIA highlighted the need to respect both the diversity of non-State actors and WHO's intergovernmental nature and strongly agreed with the objectives set out in the report. In refining the proposals for further discussion, the Secretariat should consider the efficiency and cost-effectiveness of the proposed measures, in particular the world health forum. The focus should be on enhancing participation of non-State actors in governing body meetings. Before further steps were taken, input should be sought from a diverse range of non-State actors. She therefore welcomed the proposed web consultation.

The representative of the UNITED REPUBLIC OF TANZANIA, speaking on behalf of the Member States of the African Region, said that the participation of non-State actors should be consistent with the WHO Constitution. WHO's intergovernmental nature and the diversity of non-State actors must be respected. Given the limited time allocated to Member States, the existing practice should be

continued, with non-State actors making their statements after Member States. She encouraged the delivery of group statements on each agenda item, the posting of statements two weeks before governing body sessions, and the establishment of constituencies, although thorough consideration should be given to how they would be formed. Further work was needed to show the added value of a world health forum, consultations at the national level with non-State actors before governing body sessions, and the inclusion of civil society and youth representatives in delegations. More proposals from non-State actors on how to improve their engagement without compromising the principles governing WHO meetings would be welcome.

The representative of IRAQ endorsed the need for engagement between WHO and non-State actors. However, to make the involvement of non-State actors more productive, their interventions should be more focused, directly relevant to the agenda item and informed by evidence. Interventions not directly relevant to agenda items could be posted online to avoid taking up time during deliberations. The proposed organization of an annual stand-alone world health forum in November was not practical for many Member States in the light of global and regional commitments, country capacity and financial implications. He encouraged the Secretariat to explore options for hosting the forum immediately after other relevant events, but cautioned against the fragmentation of issues.

The representative of JAPAN said that collaboration with non-State actors was important, but their engagement in governing body meetings could be improved. Good communication with non-State actors was needed in order to limit their interventions during governing body meetings. He therefore endorsed the proposal to organize a web consultation before the next sessions of the regional committees. All governing body documents should be issued at least six weeks before meetings to enable non-State actors to provide their comments two weeks prior to the meeting. He asked how the output of the proposed world health forum would feed into governing body meetings.

The representative of KENYA encouraged the Secretariat to continue to engage and promote dialogue with non-State actors at all levels through established channels. She endorsed the proposal for non-State actors to publish their statements in advance, to allow Member States to take their comments into consideration ahead of governing body meetings. Her Government welcomed the proposal for non-State actors to form constituencies, and requested that they should be well balanced and ensure global representation. The proposed world health forum warranted further analysis; such a forum should not be held in parallel or very close to major governing body meetings, given the risk of reduced Member State participation.

The representative of GERMANY highlighted the need for non-State actors to engage responsibly. From a timing perspective, the current participation model for non-State actors was not meaningful, since Member States were only informed of non-State actors' viewpoints after their own discussion. The focus must be on the relevance of non-State actors' statements. He expressed interest in the proposal to set up a world health forum, but said that its focus should be on information-sharing, not decision-making. At governing body meetings, non-State actors should work together to produce a statement to be shared with Member States and delivered before the relevant agenda item was opened. Since a number of governments were already consulting with non-State actors, he questioned the need for Member States to attend the proposed forum, which was a step in the right direction, but required further work.

The representative of the UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND<sup>1</sup> recognized the important contribution made by non-State actors and the need for improved

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

engagement. Her Government engaged regularly with partners in advance of governing body meetings so as to inform its decisions. She expressed interest in the proposal for non-State actors to coordinate statements among constituencies, but noted the need for guaranteed time limits. Her Government strongly encouraged the Secretariat to ensure that the proposal to organize a world health forum was developed in full consultation with non-State actors, and to address the potential disconnect between non-State actors' input and governing body meetings.

The representative of CANADA<sup>1</sup> said that his Government engaged with civil society organizations and other stakeholders when preparing for sessions of the Executive Board and the Health Assembly, to develop its positions. He welcomed measures for more meaningful dialogue with non-State actors and supported the inclusion of non-State actors in discussions on their engagement with WHO. Enhanced dialogue with non-State actors should be as inclusive as possible and not in lieu of their participation at the Health Assembly. He suggested exploring opportunities for enhanced engagement of non-State actors on the margins of governing body meetings, in order to avoid the creation of parallel forums for discussion. Although the forum was an interesting idea for engagement, Canada was concerned about timely alignment with issues being discussed on the agendas of the governing bodies must be ensured.

The representative of MONACO<sup>1</sup> said that current engagement with non-State actors and civil society could be improved; most interventions by non-State actors were made after Member States, thus limiting the opportunity for constructive dialogue. The proposals for group statements by non-State actors and more in-depth dialogue between the Secretariat and non-State actors throughout the year were interesting. The proposed forum could be held with the WHO Partners' Forum, or could take the form of a world forum festival, bringing together the many side events that were held concurrently with the Health Assembly. She supported the proposed organization of a web consultation with non-State actors, with a view to drawing up a proposal for consideration by the Board.

The representative of SPAIN<sup>1</sup> said that the proposed forum could be held in March or April, so as to take account of the Executive Board's deliberations and prepare for the Health Assembly.

The representative of MEDICUS MUNDI INTERNATIONAL – NETWORK HEALTH FOR ALL, speaking at the invitation of the CHAIRPERSON, said that WHO needed strong, vocal and meaningful engagement from civil society. He welcomed the report by the Secretariat, but had certain questions and reservations. His organization looked forward to subsequent consultations with civil society on the issue and stood ready to discuss concrete proposals from the Secretariat and Member States.

The representative of the INTERNATIONAL BABY FOOD ACTION NETWORK, speaking at the invitation of the CHAIRPERSON, said that partnerships with organizations that threatened health through harmful marketing led to misplaced trust and weaker WHO resolutions. Non-State actors in official relations with WHO must be free from concerns that were primarily of a commercial or for-profit nature. The risks of the Framework of Engagement with Non-State Actors had to be evaluated and addressed before further discussions on a possible global health forum could take place, and the Framework's definition of conflict of interest must be corrected. Using the same definition and same coloured badges for all non-State actors, whether they were corporations or civil society organizations, was dangerous. WHO's independence and role as the coordinating authority in global health was at stake.

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

The representative of IOGT INTERNATIONAL, speaking at the invitation of the CHAIRPERSON, said that non-State actors should be differentiated as public or private interest groups and that regular national civil society consultations should be held with Member States ahead of governing body sessions. Although it would be seriously challenging to group civil society interventions, her organization was willing to help find effective channels to do so, with a view to facilitating meaningful engagement. Transparent consultations ahead of governing body meetings should be a recognized mechanism involving maximum engagement by the Secretariat and Member States.

The representative of the UNITED NATIONS FOUNDATION, INC., speaking at the invitation of the CHAIRPERSON, recommended establishing dedicated seats for civil society organization constituencies, with voting rights, at the Executive Board and the Health Assembly as the most effective way of ensuring meaningful engagement. The Secretariat should invite a wide range of civil society organizations to participate in the Health Assembly and the regional committee meetings and should develop technological means of gathering their input for those meetings. It should also help civil society organizations organize themselves into constituencies by geographical region, thematic area or representation, and invite input from each constituency through an elected representative.

The representative of the UNION FOR INTERNATIONAL CANCER CONTROL, speaking at the invitation of the CHAIRPERSON, said that the current statement model and full agendas of the governing bodies did not facilitate meaningful engagement of non-State actors with WHO. Her organization considered that the measures proposed were not sufficient and could undermine the ability of civil society organizations to support WHO's work. She encouraged the Secretariat to consider new opportunities and leverage new technologies to facilitate the engagement of civil society organizations through timely and open consultations; statements should not be grouped by constituency, given the diverse topics under discussion and the large number of civil society organizations. Earlier involvement of civil society organizations through open consultations could reduce the demand for statements at governing body meetings.

**The meeting rose at 12:30.**

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