

Informal, focused consultations

Report by the Bureau of the Intergovernmental Negotiating Body

Background

1. At its second meeting, the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (INB) agreed on a process for intersessional work leading up to the third meeting of the INB (document A/INB/2/5). As part of this process, the INB Bureau was requested to conduct informal, focused consultations on selected key issues, including with experts invited by the Bureau, open to all WHO Member States and relevant stakeholders.

2. The INB Bureau would consolidate the outcomes of the informal, focused consultations together with the outcomes of the public hearings, written input from Member States and relevant stakeholders on the working draft, and additional input from the second meeting of the INB and the regional consultations held during the regional committee meetings, to inform the development of the conceptual zero draft to be presented to the third meeting of the INB (document A/INB/3/3). In addition, the Bureau was to provide a summary report of the informal, focused consultations in advance of the third meeting of the INB.

3. The consultations provided a forum for interactive discussion between Member States, relevant stakeholders and experts in the subject to advance the work of the INB. This report describes the details and modalities for the four sessions and provides a brief summary of the substantive issues raised during each consultation.

Modalities for the informal, focused consultation sessions

4. A White Paper summarizing the modalities for the consultations was shared with all Member States and relevant stakeholders, in accordance with the proposed modalities of engagement for relevant stakeholders (document A/INB/1/7 Rev.1) prior to the first informal focused consultation. In addition, a concept note for each session, detailing matters such as, the session topic, sub-topics and participating experts, was prepared and shared with all Member States and relevant stakeholders in advance of each session.

5. The four sessions were conducted virtually (by videoconference), with interpretation in the six WHO official languages. In the interests of transparency, and mindful of the widespread interest in the work of the INB, the Bureau decided that the informal, focused consultation sessions would also be broadcast live. This took place via the WHO Secretariat website for the INB: inb.who.int. As part of the

official INB documentation, each of the four sessions is archived on the website and can be viewed on demand.

6. Participating experts for each session were selected by the INB Bureau, with efforts made to promote diversity, in particular, diversity of scientific viewpoints and perspectives, as well as breadth in subject matter expertise. In addition, as appropriate, WHO Secretariat topic experts were also invited to provide input during the sessions.

7. The informal, focused consultation sessions were chaired by the INB Bureau Co-Chairs, and were moderated by Ms Emma Ross.¹ Each session was structured in two parts: firstly, an interactive, moderated round table of independent experts, during which the moderator asked questions and stimulated input from, and dialogue between, the experts; and secondly, a discussion and reflection session for Member States and relevant stakeholders. Questions and reflections were invited in advance of each session, and many Member States and relevant stakeholders provided advance questions. In addition, Member States and relevant stakeholders were able to pose questions and articulate their reflections during the meeting, for the invited experts to consider in their responses.

8. Mindful of the informal nature of the consultations and the goal of stimulating full and frank discussions, the following modalities applied to all sessions: discussions during sessions, including among participating experts, in no way prejudiced the positions of Member States or any other participants; no comments or questions presented by participants, including Member States, during the informal, focused consultations would imply a view or position of a Member State or other participant; and expert presentations would be provided solely for the consideration of Member States, and would not themselves be sources of input to the conceptual zero draft.

Summaries of the informal, focused consultation sessions

9. The INB Bureau held four informal, focused consultation sessions on the following topics identified by the Bureau: legal matters; operationalizing and achieving equity; intellectual property, production and transfer of technology and know-how; and One Health in the context of strengthening pandemic prevention, preparedness and response, with reference to antimicrobial resistance, climate change and zoonoses.

10. The following section describes each of the four sessions, by first listing the session topic, sub-topics and participating experts, and then providing a summary of certain points made by participants. These non-exclusive summary points are provided to illustrate the rich diversity of views and perspectives presented, bearing in mind that statements made during the informal, focused consultations do not necessarily represent the position of any Member State, any other participant, the INB Bureau or the WHO Secretariat.

Informal, focused consultation 1: legal matters

11. The first session, on the topic of legal matters, was held on 21 September 2022 and addressed the sub-topics of: the relationship between the pandemic agreement and other instruments, notably the International Health Regulations (2005); sovereignty; institutional arrangements and alternatives; and structural and framework considerations of a potential pandemic instrument. The participating experts

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were Dr Ayelet Berman,¹ Professor Gian Luca Burci,² Professor Claudio Grossman,³ Professor Sam Halabi,⁴ Professor Nilüfer Oral,⁵ Professor Matiangai Sirleaf,⁶ Professor Nguyễn Hồng Thao,⁷ Dr Pedro Villarreal,⁸ and Mr Steven Solomon.⁹

12. On the sub-topic of the relationship between the pandemic agreement and other instruments, notably the International Health Regulations (2005), one expert pointed out that the existing benefits inherent in the Regulations (2005) were embedded within the structure of WHO and applied to major events that could constitute a public health emergency of international concern, as well as preparation, detection and prevention measures preceding the declaration of a public health emergency of international concern. There was also recognition that there may be some overlaps between the Regulations and a pandemic agreement.

13. Suggestions were put forward about the different elements a pandemic agreement could focus on so as to avoid duplication of elements already covered in the Regulations. Emphasis was placed on the fact that the pandemic agreement might focus on special issues with an impact on a pandemic. One expert suggested that the Regulations included steps leading to the declaration of a public health emergency of international concern, and therefore a pandemic agreement could expand their scope by considering aspects of pandemic definition and the implications of the declaration of a pandemic.

14. On the sub-topic of sovereignty, one expert pointed out that whereas there was a need to respect the sovereignty of States, it was also important to balance sovereignty against their other obligations, including avoiding the violation of rights and cooperating in protecting the rights of persons. In that regard, an expert emphasized that respect for human rights was essential in the new instrument, along with a reflection of the optimal means of ensuring the participation of civil society and the needs of persons in vulnerable situations, especially in the event of disasters.

15. On the sub-topic of institutional arrangements and alternatives, the experts stressed the importance of collaboration with other relevant international organizations through the new instrument and other modalities. Similarly, there was a need for harmonization of the processes of the Working Group on Amendments to the International Health Regulations (2005) and the INB as mandated by Member States.

16. On the sub-topic of structural and framework considerations, the experts noted that Member States could develop creative and innovative solutions in the drafting of the new instrument. One expert was of the view that the drafting process presented an opportunity to create a new stakeholder engagement strategy. Another made the following proposals: the drawing up of a framework instrument that could be implemented through different protocols; reliance on science-based evidence to advance

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policy formulation, as well as governance and compliance mechanisms; and the development of meaningful indicators for assessing and measuring implementation of the new instrument and its impact.

Informal, focused consultation 2: operationalizing and achieving equity

17. The second session, on the topic of operationalizing and achieving equity, was held on 5 October 2022 and addressed the sub-topics of: access to pandemic response products and delivery/distribution; access and benefit sharing, including genetic sequence data; and strengthening health systems, including the importance of universal health coverage and primary health care. The participating experts were Dr Ayoade Olatunbosun-Alakija,¹ Professor Didier Houssin,² Mr Rajinder Kumar Suri,³ Professor Patricia Garcia,⁴ Dr Mohga Kamal-Yanni,⁵ Dr Yuanqiong Hu,⁶ and Dr Ahmed Al-Mandhari.⁷

18. On the sub-topic of access to pandemic response products and delivery/distribution, the experts noted the importance of ensuring timely and equitable access to pandemic response products, and the fair allocation of these products based on public health need and risk. One expert noted that it was essential for the new instrument to define the concept of equity enshrined in the idea of “leaving no one behind”, and that equality was not equity (and vice versa). It was also suggested that “global public goods” would need to be defined in the new instrument.

19. The experts also referred to existing instruments, institutions and modalities and their potential relevance for addressing equity in future pandemics through the new instrument, for example, the Pandemic Influenza Preparedness (PIP) Framework, Unitaaid, the Access to Covid-19 Tools (ACT) Accelerator, and the WHO equitable access to essential medicines framework, taking into account their effectiveness. While noting that temporary mechanisms played a central role in the response to the COVID-19 pandemic, any future pandemic would require a more durable mechanism. A major contribution of the new instrument would be to provide just such a sustainable solution in the period between pandemics that could be activated when one developed.

20. Lessons were also drawn from the experience of the COVID-19 pandemic, in which the timely development and deployment of pandemic response products was affected by a number of challenges. One expert noted that to address these challenges, the world needed to: (a) develop, agree and implement a system to ensure timely, fair and equitable access to safe and effective pandemic response products; (b) establish a mechanism to ensure that all the pandemic response products secured through an access and benefit sharing system were fairly and equitably allocated to countries based on public health risk and need; and (c) develop national plans that identified priority populations and addressed the timely distribution of pandemic response products to them.

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21. Several experts shared the view that the new instrument provided an opportunity to enshrine rules and procedures to ensure that all lives were treated equally through binding arrangements. Examples of possible areas where binding obligations on Member States might apply included: regulating manufacturers of pandemic response products, pathogens and/or genetic sequence data and benefit sharing; cooperating during a pandemic; provisions to incentivize and gradually increase public funding for research and development; and technology transfer and the waiver of intellectual property rights.
22. On the sub-topic of access and benefit sharing, including of genetic sequence data, the experts noted its importance in the new instrument, taking into account existing international instruments, such as the Convention on Biological Diversity and its Nagoya Protocol. Some experts also referred to the Pandemic Influenza Preparedness (PIP) Framework as an illustration of a public-private partnership that incorporated non-State actors, including civil society. The Framework also provided for annual financial Partnership Contributions to WHO from certain manufacturers, for, among others, capacity strengthening and future “real-time” access by WHO to pandemic response products through legally binding advance supply contracts with many of the same manufacturers. Such response products would be allocated by WHO to Member States based on public health risk and need.
23. On the sub-topic of strengthening health systems, one expert noted that the value of health workers should be emphasized, as well as the commitment of Member States to increasing investment in health systems, with the prioritization of biomedical research and public funding for health systems.

Informal, focused consultation 3: intellectual property, production and transfer of technology and know-how

24. The third informal, focused consultation session, on the topic of intellectual property, production and transfer of technology and know-how, was held on 7 October 2022 and addressed the sub-topics of: research and development; patents and access to technology, including related know-how; the role of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement), compulsory licensing and intellectual property waivers; production capacity and supply chain considerations; and regulatory approvals during emergencies. The participating experts were Dr Richard Hatchett,¹ Ms Emma Wheatley,² Dr Carlos María Correa,³ Dr Padmashree Gehl Sampath,⁴ Ms Ellen ‘t Hoen,⁵ Ms Komal Kalha,⁶ Professor Mojisola Adeyeye,⁷ Mr Martin Harvey Allchurch,⁸ Dr Soumya Swaminathan,⁹ and Dr Mariângela Simão.¹⁰

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⁷ Director-General, National Agency for Food and Drug Administration and Control in Nigeria (NAFDAC), Nigeria.

⁸ Head of International Affairs, European Medicines Agency.

⁹ Chief Scientist, WHO.

¹⁰ WHO Assistant Director-General, Access to Medicines and Health Products.

25. On the sub-topic of research and development, the experts proposed an increase in financing and funding at the national level, as well as the development of global coordinating mechanisms in pandemic prevention, preparedness and response. One expert also noted existing mechanisms, such as WHO's R&D Blueprint, and the mRNA vaccine technology transfer hub, and suggested that reliance on existing mechanisms might be considered appropriate so as to avoid duplication.

26. A number of experts further emphasized the need to incorporate equity access provisions or conditionalities within contracts relating to pandemic response products, especially where research was supported by taxpayer funding. It was also emphasized that countries should agree on principles of data sharing, with genomic data sharing becoming the norm. The need to fortify research and development activities was re-echoed throughout the submissions. One expert noted the aspirational goal that vaccines should be ready within 100 days of the designation of a pandemic pathogen.

27. On the sub-topic of patents and access to technology, including related know-how, it was acknowledged that a pandemic agreement provided a good opportunity for overcoming major fragmentation of the international legal system, through the inclusion of human rights considerations. An example was given of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, which contained provisions on countries' commitment to not seek intellectual property protections. One expert also encouraged governments to carry out rigorous analyses and assessments of patent applications, and to strictly apply patent requirements.

28. On the sub-topic of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement), compulsory licensing and intellectual property waivers, Article 8 of the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health were cited for their role in strengthening government public health interventions, including the possibility of compulsory licensing. There were also divergent views on which of the two options, voluntary collaboration on the one hand and compulsory licensing on the other, was ideal in a pandemic response. Several experts supported the idea that compulsory measures were required, with one expert expressing the view that voluntary collaboration was preferable in order to encourage flexibility. One expert articulated the need to consider additional modalities, such as patent buyouts.

29. On the sub-topic of production capacity and supply chain considerations, the experts acknowledged the importance of training, including awareness of training gaps in some countries and regions. Regional agreements were also considered essential for facilitating pooled arrangements for pandemic response products.

30. In connection with the sub-topic of regulatory approvals during emergencies, the strengthening of national and regional capacity, including clinical and regulatory capabilities, was seen as essential for harmonizing regulatory compliance across countries. The possibility of mutual support between multilateral, regional and national initiatives for technology transfer was also acknowledged. The coordination of clinical trials was seen as essential to developing robust and actionable data, including to allow regulatory bodies to rely on the data to make decisions.

Informal, focused consultation 4: One Health in the context of strengthening pandemic prevention, preparedness and response, with reference to antimicrobial resistance, climate change and zoonoses

31. The fourth and final session, on the topic of One Health in the context of strengthening pandemic prevention, preparedness and response, with reference to antimicrobial resistance, climate change, and zoonoses, was held on 14 October 2022 and addressed the sub-topics of: framing One Health in the

context of pandemic prevention, preparedness and response; multisectoral collaboration for animal, human and environmental health; integrated surveillance, monitoring and interoperable data sharing systems for One Health; and drivers for pandemics, including at the human–animal–environment interface. The participating experts were Dr Osman Dar,¹ Dr Monique Eloit,² Dr Jean-Philippe Dop,³ Professor Wanda Markotter,⁴ Professor David Hayman,⁵ Professor Dame Sally Davies,⁶ Ms Doreen Robinson,⁷ and Dr Chikwe Ihekweazu.⁸

32. On the sub-topic of framing One Health in the context of pandemic prevention, preparedness and response, reference was made to the definition developed by the One Health High-Level Expert Panel (OHHLEP), which emphasized the linkage between the health of humans, animals and ecosystems. Several experts put forward the recommendation that the new instrument should promote prevention as a primary means of addressing potential pandemics.

33. On the sub-topic of multisectoral collaboration on animal, human and environmental health, the experts proposed that reference should be made to the One Health Joint Plan of Action (2020–2026) as a potential source of guidance for the provisions on One Health in the future instrument. Several experts emphasized that multisectoral collaboration and coordination, backed by a regulatory framework, were key to the prevention of, and response to, pandemics.

34. On the sub-topic of integrated surveillance, monitoring and interoperable data sharing systems for One Health, the experts acknowledged the need to apply an approach of collaborative surveillance, noting the significant gaps in human surveillance and even greater gaps in the animal and environmental sectors. One expert proposed that monitoring the causes of excess mortality for both human and animal populations was essential in assisting countries to make investment decisions as part of their pandemic response. Several experts also emphasized the importance of investing in integrated and interoperable surveillance systems at the local level, while noting that the sustainability of systems depended on local priorities, interest and need.

35. On the sub-topic of the drivers of pandemics, including at the human–animal–environment interface, the experts mentioned the following root causes of pandemics: climate change on account of its ability to shift geographical risk over time; land use change, for which health impact assessments should be included as a legal obligation; the wildlife trade, which required regulation and the monitoring of relevant markets; and migration. One expert noted that since antimicrobial resistance was now itself an insidious pandemic, antibiotics should be regarded as global public goods; antimicrobial resistance and the human–animal interface needed to be addressed through a One Health approach in order to mitigate future pandemics.

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