#### ADVANCE, UNEDITED ONSCREEN VERSION



FOURTH MEETING OF THE WORKING GROUP ON STRENGTHENING WHO PREPAREDNESS AND RESPONSE TO HEALTH EMERGENCIES Provisional agenda item 2

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### Report of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies to the special session of the World Health Assembly

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#### **BACKGROUND**

- 1. The Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR) was established with a mandate derived from resolution WHA74.7 (2021), which requested the WGPR:
  - (a) to consider the findings and recommendations of the Independent Panel for Pandemic Preparedness and Response, the Review Committee on the functioning of the International Health Regulations (2005) during the COVID-19 response and the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme, taking into account relevant work of WHO, including that stemming from resolution WHA73.1 (2020) and decision EB148(12) (2021), as well as the work of other relevant bodies, organizations, non-State actors and any other relevant information; and
  - (b) to submit a report with proposed actions for the WHO Secretariat, Member States and non-State actors, as appropriate, for consideration by the Seventy-fifth World Health Assembly through the Executive Board at its 150th session.
- 2. In a separate but related decision (WHA74(16)), the WGPR was also requested "to prioritize the assessment of the benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response and to provide a report to be considered at the special session of the Health Assembly."
- 3. Recognizing and acknowledging the two inter-linked mandates with regard to their required reporting timelines, the WGPR will submit two reports: the first report to the special session of the World Health Assembly (WHASS), to be held on 29 November–1 December 2021; and the second to

the Executive Board at its 150th session, to be held on 24–29 January 2022. Both reports will complement each other to bring forth the synergies and benefits to take forward both mandates in a holistic manner.

- 4. The current report refers to the decision WHA74(16) on assessing the benefits of developing a WHO convention, agreement or other international instrument ("the new instrument") on pandemic preparedness and response with a view towards the establishment of an intergovernmental process to draft and negotiate such a convention agreement, or other international instrument. The WGPR will continue its work on its second report as directed by resolution WHA74.7 to consider all the recommendations and the different actions and tools to implement them, including the new instrument and targeted amendments to the International Health Regulations (2005) (hereafter referred to as IHR (2005)), that will be proposed for consideration by the WHO governing bodies for further action by the WHO Secretariat, Member States and non-State actors, as appropriate.
- 5. The WGPR agreed that its work needs to be conducted in an efficient, effective, inclusive, consensus-based and transparent manner to ensure the meaningful engagement of all Member States. The WGPR also agreed that given its focus to strengthen WHO preparedness and response to health emergencies, subgroup meetings during intersessional periods, if any, should be sequential and no more than two, to enable maximum participation by Member States.
- 6. The WGPR has convened four meetings during the period July to November 2021. The WGPR also conducted several intersessional informal consultations on specific themes, such as IHR (2005) strengthening, equity, health architecture and benefits of a new instrument, and two dialogues with non-State actors. To facilitate better dissemination of information and Member State engagement, the Bureau briefed five<sup>1</sup> of the six WHO regional committees to provide opportunities for the exchange of views among regional stakeholders, encourage participation in the WGPR's deliberations and seek input on regional experience.
- 7. At the first meeting of the WGPR, on 15–16 July 2021, it elected the officers of the Bureau<sup>2</sup> and adopted its terms of reference and methods of work, including the modalities of engagement of relevant key stakeholders as well as the timeline and deliverables of the WGPR. The WGPR meeting summaries prepared by the Bureau are available online.<sup>3</sup>

 $<sup>^{1}</sup>$  The regional committees for Africa, the Americas, South-East Asia, the Eastern Mediterranean and the Western Pacific.

<sup>&</sup>lt;sup>2</sup> Co-Chairs – H.E. Ms Grata Endah Werdaningtyas of Indonesia and Mr Colin McIff of the United States of America; Vice-Chairs – Dr Malebogo Kebabonye of Botswana; H.E. Mr François Rivasseau of France; Dr Ala Alwan of Iraq; Dr Lyn James of Singapore.

<sup>&</sup>lt;sup>3</sup> https://apps.who.int/gb/wgpr/.

# ASSESSMENT OF THE BENEFITS OF DEVELOPING A NEW WHO CONVENTION, AGREEMENT OR OTHER INTERNATIONAL INSTRUMENT ON PANDEMIC PREPAREDNESS AND RESPONSE

- 8. There is general consensus that several key aspects of health emergency preparedness and response may not be addressed solely within the scope of the IHR (2005) and may be best addressed either through a potential new instrument or through another normative, policy or programmatic tool available through WHO. In addition, some recommendations and key areas will require effective coordination between WHO and other institutions that may have relevant mandates for those issues and recommendations. Member States raised the following topics.
  - (a) Equity. Member States agree that equity is critically important for global health both as a principle and an outcome. Member States emphasized that equity, including capacity building and equitable and timely access to and distribution of medical countermeasures and addressing barriers to timely access to and distribution of medical countermeasures, and related issues such as research and development, intellectual property, technology transfer and empowering/scaling up local and regional manufacturing capacity during emergencies to discover, develop and deliver effective medical countermeasures and other tools and technologies, is essential, in particular in prevention, preparedness and response to health emergencies. While each of these areas are complex, equity is at the core of the breakdown in the current system. Despite unprecedented developments of medical countermeasures, the challenge remains to ensure their universal and equitable access and distribution, with a view to achieving UHC. This is an issue that could be meaningfully addressed under the umbrella of a potential new instrument and through discussions in several other relevant global fora.
  - (b) One Health approach. This is an area where there is strong prioritized interest, but where further elaboration and collaboration is needed, particularly as the One Health concept reaches beyond pandemic preparedness and response. Many aspects may be beyond the scope of the IHR (2005), and complex. This complexity is reflected through the involvement of multiple actors at global and national levels, but application of a One Health approach also would yield significant benefits for the international community to reduce the risks posed by emerging diseases of zoonotic origin in the future.
  - (c) Prevention, rapid risk assessment ,detection and response. Some aspects of this could be handled under the discussions on strengthening the IHR (2005) implementation, compliance, and potential targeted amendments, while others could be incorporated under a new instrument. There is wide support among Member States to strengthen collective efforts necessary to prevent, rapidly detect and share information to respond effectively to outbreaks of disease with pandemic potential.
  - (d) Compliance and accountability with IHR obligations. While IHR (2005) has a dispute resolution provision, it remains unused to date. Many Member States expressed a desire to prioritize strengthening compliance, and recognized the importance of providing incentives for implementation and assistance to respond, but there remains divergence on how best to do that: as part of strengthening the IHR (2005) or as part of a new instrument.
  - (e) Finance. Member States recognized the need to provide the organization with adequate and sustainable financing, so WHO can play a leading and coordinating role in global health as enshrined in the WHO Constitution. Member States also recognize the need for national investments and leadership from other actors including the international financial institutions and existing global health institutions.

- (f) Resilient and rapid response to pandemics, by enhancing surge capacity, through striving to achieve universal health coverage and health system strengthening, which includes enhancement of primary health care, health workforce and social protection.
- (g) Sample sharing by enhancing and expanding networks, mechanisms and incentives for sharing pathogens, genetic information, biological samples and the benefits derived therefrom. Member States see sample sharing as important, as well as the need to develop proper incentives and benefits to support more equitable health emergency preparedness and response. There is openness to explore a more comprehensive mechanism under the auspices of WHO.
- (h) Structural solutions to promote a whole-of-government and whole-of-society approach to pandemic prevention, preparedness and response, including other health emergencies, are a priority for Member States.
- (i) Misinformation and disinformation. Member States recognize the need for national and global coordinated actions to address misinformation, disinformation and stigmatization that undermine public health.

#### Benefits of a new WHO convention, agreement or other international instrument

- 9. Based on the discussions of the WGPR, a number of potential benefits of a new instrument for strengthening pandemic preparedness and response have been identified, inter alia:
  - (a) High-level political commitment, and whole-of-government and whole-of-society approach which could strengthen cross-sectoral coherence and mobilization. This could maintain focus and drive continued momentum to ensure pandemic preparedness and response remains a regular feature on the agenda of world leaders.
  - (b) An opportunity to enhance, update and strengthen the leading and coordinating role of WHO and its function to act as the directing and coordinating authority on international health work in light of the 21st century global health landscape, including in improving engagement with civil society and the private sector. Doing so could provide a clear pathway for policy-makers and leaders in pandemic preparedness and response, supporting coherence and avoiding fragmentation at both the national and global levels. The WHO Constitution expressly provides for the possibility of a new instrument, and WHO has experience managing whole-of-society and whole-of-government instruments, including for example the WHO FCTC.
  - (c) Create constituency support for the new instrument and its goals for pandemic preparedness and response, for example a conference of Parties.
  - (d) Fostering confidence by States Parties to mutual high-level commitments to pandemic preparedness and response.
  - (e) Anchoring all the principles found in the WHO Constitution (Preamble), including the principle of non-discrimination and the right to the enjoyment of the highest attainable standard of health. These are important in advancing equity and universal health coverage, ensuring equitable access to medical countermeasures and health services, both now and in the future.
  - (f) Addressing equitable access to countermeasures such as vaccines, therapeutics and diagnostics. A framework could facilitate concrete measures and long-term mechanisms to develop, manufacture and scale up countermeasures through increasing local production, sharing of technology and know-how for broadening manufacturing capacity, and strengthening regulatory systems.

- (g) Sharing of data, samples, technology and benefits in the context of pandemic preparedness and response. There are some legally binding agreements relating to pathogen sharing, but no comprehensive framework within WHO, either for sharing of pathogens or for sharing of the benefits derived therefrom, which takes into account the reality and needs of pandemic preparedness and response.
- (h) Reducing the risks posed by emerging diseases of zoonotic origin in the future, recognizing that diseases of zoonotic origin are among the most likely sources of future pandemics. This could include strengthening existing platforms and surveillance, furthering multisectoral partnerships (human, animal and environmental health sectors), and promoting specific countermeasures in line with the One Health approach.
- (i) Supporting the strengthening of strong, resilient and inclusive health systems which are foundational for effective and efficient pandemic preparedness, prevention, detection and response systems, through strengthening primary health care service, healthcare workers and achieving universal health coverage.
- 10. Many Member States emphasized that developing a new instrument on pandemic preparedness and response under Article 19 of the WHO constitution could offer a number of benefits. An Article 19 instrument under the WHO constitution would be legally binding on State Parties that opt to ratify it, and this legally binding status offers the potential for greater sustained attention, both political and normative, to the critical issue of a pandemic preparedness and response, than a non-binding act.
- 11. Member States noted the recommendation by the IPPPR on the need for a pandemic treaty to strengthen global coordination and response actions in the case of a pandemic, which was also noted by the IOAC as well as the IHR Review Committee.

#### WHO instruments available for Member States and their potential use

- 12. The WHO Constitution provides the Health Assembly with three types of possible instrument:<sup>1</sup>
  - (a) The Health Assembly may adopt conventions or agreements, per Article 19 (opt-in).
  - (b) The Health Assembly may adopt regulations, per Article 21 (opt-out).
  - (c) The Health Assembly may make recommendations, per Article 23 (non-binding).
- 13. The WGPR established that the Health Assembly can take forward the WGPR's linked mandates through multiple means, to address any given health topic within WHO's mandate, including pandemic preparedness and response. There is no "either/or" requirement, from a governance or legal perspective with respect to the instruments, as to whether to strengthen the IHR (2005), including through potential targeted amendments, or adopt a new instrument: both options are legally available, as well as complementary resolutions and decisions to address related issues such as WHO governance and to move forward with recommendations within existing WHO technical work.
- 14. There were no proposals and no support from Member States to renegotiate or reopen the entire IHR (2005). Member States will need to consider all the above options when discussing the proposals for strengthening IHR and a new instrument, and provide clear direction for the next phase of the work.
- 15. There is also the possibility of strengthening compliance through existing terms and provisions. In this regard, Article 54(1) of the IHR (2005) provides that "States Parties and the Director-General

<sup>&</sup>lt;sup>1</sup> https://apps.who.int/gb/wgpr/pdf\_files/wgpr3/A\_WGPR3\_6-en.pdf.

shall report to the Health Assembly on the implementation of these Regulations as decided by the Health Assembly"; this provision could be utilized by the Health Assembly to adjust the reporting obligations of States Parties, for example, by establishing an IHR (2005) reporting conference.

16. Promoting compliance with Member State obligations through improved transparency and reporting commitments is further supported by Articles 61–65 of the WHO Constitution, which address overall reporting obligations by Member States to WHO, including with respect to conventions, agreements, and regulations established under the WHO Constitution.

## Risks of launching a process to develop a possible new instrument to address pandemic preparedness and response

- 17. The risks include lengthy timeframes for negotiating new instruments or deadlock due to negotiation, and insufficient resource and time commitments resulting from intergovernmental negotiations. There may also be a perception of WHO as not having the mandate or leverage for all areas that could be included in the instrument or to enforce its compliance.
- 18. There are also structural risk considerations, for example incorrect drafting of the instrument, including due to the current lack of information and incomplete assessment of the pandemic response, possible overlap or inconsistencies in obligations of State Parties to the IHR (2005) and the new instrument. Some Member States have posed questions for consideration on how to ensure maximum efficiency and effectiveness of current tools while assessing the benefits of a new instrument, as well the sustainable resourcing, including financing of the instrument. Member States also expressed concern over how the "opt-in" nature of an Article 19 convention might reduce the effectiveness of the instrument due to the insufficient signatories. As a result, a number of Member States have expressed openness to launching a negotiating process for a potential new instrument, while seeking to preserve flexibility in the type of instrument to be finalized as well as the potential for "quick wins" if some elements are ready to be agreed before a final agreement is adopted, making full use of the legal flexibilities outlined above under the WHO Constitution.
- 19. Fragmentation of resources for negotiation is also a concern. Keeping in mind the goals of a clear, efficient, effective, Member State led, transparent and inclusive process, and striving to achieve consensus among all Member States and taking into account the limited time and resources in the face of the continuing pandemic.

#### Key issues for further deliberation

- 20. In the second and third meetings, Member States began to discuss the recommendations from the independent review panels/committees, focusing on the inputs from the Independent Panel on Pandemic Preparedness and Response, Review Committee on the functioning of the International Health Regulations (2005) during the COVID-19 Response, Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme, taking into account the work of other relevant bodies such as the Global Preparedness Monitoring Board, with a view to understanding more clearly how recommendations could be grouped to show convergences, divergences, the timeframes given for implementation, and where implementation is under way.
- 21. Member States have reiterated three key points in the discussions: first, the centrality of a strengthened World Health Organization in the global health architecture; second, the status quo is unacceptable; and third, the WGPR must be willing to move forward in a flexible way that advances both of its linked mandates. Building on the preliminary mapping of recommendations, the WGPR began discussing the Secretariat's assessment of recommendations and possible mechanisms to implement priority recommendations and their current status of implementation (See the WGPR/3/5).

- 22. A further analysis of the recommendations was initiated to identify convergences and divergences among them. Member States agreed to consider the recommendations in four broad categories: (1) leadership and governance; (2) systems and tools; (3) finance; and (4) equity
- 23. Based on Member State discussions in the WGPR thus far, emerging consensus has evolved that Member States will need to continue their discussions on the feasibility of implementing the recommendations, particularly how to implement through:
  - (a) Developing a new international instrument
  - (b) Strengthening the IHR (2005); and
  - (c) Exploring use of existing tools and mechanisms available to WHO.
- 24. The WGPR has repeatedly reaffirmed the need to work in an efficient, effective, inclusive, consensus-based and transparent manner. The WGPR further expressed consensus on the importance of strengthening the role of WHO in health emergencies and a shared commitment to strengthen global, regional and national pandemic preparedness and response. While the second report to the Executive Board will provide a deeper review of the WGPR's discussions on all the recommendations and their applicability for strengthening WHO as well as global preparedness and response to pandemics, several items warrant mentioning including as they relate to assessing the benefits of developing a potential new instrument under WHO.
  - (a) Strengthening governance. Member States expressed an interest in strengthening WHO governance and oversight, and in this regard, there is general consensus around the need to increase Member State involvement in, and direction of, WHO governance.
  - (b) Strengthening the International Health Regulations (2005). Member States have reiterated their support for the IHR (2005) as a key component of the global health architecture. Many Member States also expressed their support to strengthen the IHR (2005) including through implementation, compliance and potential targeted amendments without re-opening the entire instrument for negotiations; however, there is a need to agree on a process for how these would be identified and what would be addressed. Some of the issues identified for consideration could include inter alia:
    - (i) building and strengthening core capacities, including funding and financing for core capacities for the implementation of and compliance with the IHR (2005) at national and subnational levels, and strengthening mutual accountability, for example through regular country reviews and potential mechanisms like the Universal Health Preparedness Review. The Member States acknowledged the ongoing pilot of the UHPR and requested updates on the process.
    - (ii) enabling the transparent timely sharing of information on outbreaks as proposed by the Review Committee on the functioning of the International Health Regulations (2005) during the COVID-19 response;
    - (iii) strengthening WHO's ability to provide technical assistance, including for rapid access to outbreak sites with due regard to and respect for the sovereignty of states; and
    - (iv) clear guidance for action in the event of a public health emergency of international concern with potential to establish intermediate alerts
    - (v) Revising the IHR amendments process so that it is more agile in responding to future developments and advances.

- 25. A number of risks were raised about amending the IHR (2005), including:
  - (a) Lengthy timeframes for negotiating amendments or deadlock due to negotiation, and insufficient resource and time commitments resulting from intergovernmental negotiations
  - (b) Possible unintended consequences should amendments lead to the reopening of the entire IHR for negotiation; loss of relevance or coherence; and potentially weakening the instrument overall:
  - (c) Fragmentation of resources for negotiation is also a concern. Keeping in mind the goals of a clear, efficient, effective, Member State led, transparent and inclusive process, and striving to achieve consensus among all Member States and taking into account the limited time and resources in the face of the continuing pandemic.
  - (d) It could lead to increasing complexity of the IHR (2005);
  - (e) potential limitations of ambition resulting from the need for consensual reform of the IHR (2005); and
  - (f) time delays in integrating new amendments in national legislation.

#### CONCLUSIONS AND WAY FORWARD

- 26. Member States agree that there are benefits to developing a new instrument, while also acknowledging that the IHR currently remains the key legally binding instrument for pandemic preparedness. The WGPR has confirmed the importance of a number of topics, as identified in subparagraphs 8 a i that might be better addressed by a new instrument under the auspices of WHO.
- 27. The WGPR assesses, for consideration by WHASS, that the way forward should include as part of a comprehensive and coherent approach a process or processes for: i) developing a WHO Convention, Agreement or other international instrument on pandemic preparedness and response, and ii) strengthening the IHR (2005) including implementation, compliance, support for IHR core capacities, and potential targeted amendments to the IHR.
- 28. The WGPR intends to continue to maintain a coherent, flexible, predictable, and inclusive approach to cover all aspects of the WGPR mandate. Given the interrelated nature of all these discussions, this approach will allow the WGPR to maintain and strengthen overall coherence, for WHO, and relevant partners.
- 29. The WGPR proposes for consideration of the WHASS the following:
  - a) Establish an inter-governmental negotiating body in charge of developing a WHO Convention, Agreement or other international instrument on pandemic preparedness and response;
  - b) Outline a clear, efficient, effective, Member State led, transparent and inclusive process for how to identify and develop the substantive elements and a zero draft of a new instrument, the modalities of negotiation of the instrument, and on what timelines;
  - c) To support the WGPR to continue its work under resolution WHA 74.7, including to identify the tools to implement the recommendations that fall under the technical work of WHO

and further develop proposals to strengthen the IHR (2005), including potential targeted IHR (2005) amendments, and elements that may most effectively be addressed in other venues