World Health Organization

THIRD MEETING OF THE WORKING GROUP ON STRENGTHENING WHO PREPAREDNESS AND RESPONSE TO HEALTH EMERGENCIES **A/WGPR/3/6**
Provisional agenda item 5 **30 September 2021**

Member States Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies (WGPR)

Secretariat analysis for consideration by the Working Group to further identify the incentives for a new instrument on pandemic preparedness and response and the options for strengthening the effectiveness of the International Health Regulations (2005), including a consideration of the benefits, risks and legal implications

1. OVERVIEW

A. Background

1. At the second meeting of the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (the Working Group), the Bureau of the Working Group requested the WHO Secretariat to prepare an analysis for consideration by the Working Group to further identify the incentives for a new instrument in pandemic preparedness and response and the options for strengthening the effectiveness of the International Health Regulations (2005) (hereinafter, the IHR), including a consideration of the benefits, risks, and legal implications.[1]

2. Pursuant to that request, the WHO Secretariat submits this paper for consideration by Member States in order to inform further deliberations by the Working Group in subsequent meetings. In doing so, the Secretariat is mindful of the Working Group's method of work and terms of reference, based on the mandate established by Health Assembly resolution WHA74.7 (2021) and decision WHA74(16) (2021), pursuant to which one of the Working Group's mandated activities is to prioritize the assessment of the benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response, and to submit a report thereon to the Special Session of the Health Assembly in December 2021.

3. Mindful of the depth and importance of this subject matter and of the expedited basis on which this paper was prepared, this paper will benefit from further revisions following discussion in the Working Group, should such revision be deemed appropriate.

[1] See document EBWGPR/2/4.

B. Structure of this paper

4. The remainder of this document is structured as follows:

- Section 2 provides a brief description of the types of instrument available under the WHO Constitution.
- Section 3 addresses legal and structural features relevant to the analysis that follows, including regarding a potential new instrument for pandemic preparedness and response and adjustments to the IHR.
- Section 4 analyses the value of and incentives for (that is, broadly, the benefits of) making adjustments to the IHR to further address pandemic preparedness and response, and related risks.
- Section 5 analyses the value of and incentives for (that is, broadly, the benefits of) a new WHO instrument in pandemic preparedness and response, and related risks.
- Section 6 concludes.

2. WHO CONSTITUTIONAL INSTRUMENTS

A. The three primary instruments under the WHO Constitution

5. The WHO Constitution expressly provides the World Health Assembly with three types of possible instrument:

(a) The Health Assembly may adopt **conventions or agreements**, per Article 19

(b) The Health Assembly may adopt **regulations**, per Article 21

(c) The Health Assembly may make **recommendations**, per Article 23

6. These instrument types differ across a number of important criteria, including the process by which they come into being, their scope, and their legally binding nature on Member States. For ease of reference, a descriptive table of the three types of instrument along key axes is provided in the annex to this paper.

7. The instruments are not exclusive, and the Health Assembly may address a health subject (for example, pandemic preparedness and response) through one or more instruments under one or more of the instrument types, or a combination thereof.

8. A key feature of the WHO Constitution and structure is the principle of transparency and information sharing, and in that regard Member States are, per Article 62, to report annually to the Organization on the action taken with respect to the three types of instrument, namely conventions and agreements, regulations and recommendations.

B. The three primary instruments are not the only means by which WHO acts

9. For completeness' sake it is noted that the three instrument types described above are not the only means by which WHO is able to fulfil its objective, as provided in Article 1 of the Constitution, of the attainment by all peoples of the highest possible level of health.

10. Key additional modalities include: (a) functions of the WHO governing bodies as set out in relevant Articles of the WHO Constitution, including in particular Articles 18 and 28; (b) actions by the WHO Secretariat, for example, Secretariat-issued technical guidelines in a variety of health topics; and (c) special norm-setting arrangements, for example, the Codex Alimentarius Commission, a collaboration between WHO and the Food and Agriculture Organization of the United Nations.

3. STRUCTURAL CONSIDERATIONS REGARDING WHO CONSTITUTIONAL INSTRUMENT(S) ON PANDEMIC PREPAREDNESS AND RESPONSE

11. This section provides a brief summary of structural legal considerations relating to those instruments, including a possible new instrument and possible improvements/amendments to the IHR.

A. Multiple instruments and modalities are possible under the WHO Constitution

12. A preliminary point to emphasize is that the Health Assembly can establish more than one instrument, using one or more of the three instrument types under the Constitution (described in Section 2 above), to address a health topic, including pandemic preparedness and response. There is no "either/or" requirement, from a governance or legal perspective with respect to the instruments, such as whether to improve (amend or adjust) the IHR or adopt a new instrument: both are legally available. It is noted in that regard that relevant principles of international law, such as *pacta sunt servanda* ("agreements must be kept"), and certain terms of existing instruments, such as Article 57 of the IHR, require such instruments to be coherently implementable in good faith and mutually compatible. There are also practical considerations to be addressed in this regard, such as time and resource constraints.

B. Key features of a framework convention approach

13. During Working Group meetings certain Member States contemplated that a new instrument on pandemic preparedness could take the form of a legally binding framework convention or agreement, under Article 19 of the WHO Constitution. This section provides a brief description of the key features of such a framework convention approach, and WHO's experience in this area.

14. The only other instrument established under Article 19 of the WHO Constitution – the Framework Convention on Tobacco Control (the WHO FCTC) – takes a framework structure approach. The WHO FCTC is the first international convention negotiated under the auspices of WHO, adopted by the World Health Assembly on 21 May 2003 and entered into force on 27 February 2005. It has since become one of the most rapidly and widely embraced treaties in United Nations history.[1] Another well-known example of a framework convention is the Paris Agreement, addressing climate change.

[1] 2018 Global progress report on implementation of the WHO Framework Convention on Tobacco Control. Geneva: World Health Organization; 2018(https://www.who.int/fctc/reporting/WHO-FCTC-2018_global_progress_report.pdf, accessed 29 September 2021).

15. From a purely legal perspective, a framework agreement has no legal difference from a "regular" convention; both are legally binding and generally follow the same mechanisms and practice. Structurally, "regular" conventions often address clearly defined obligations and topics, from inception, and, in comparison, "framework" conventions can provide for a stepwise approach, with (a) the first step of establishment of the convention itself, which usually sets out general terms and principles (which can themselves be drafted as legally binding obligations); and (b) subsequent step(s), implemented and approved by States Parties, which establish future instruments and content to the convention. These additional instruments and content can include protocols, guidelines, processes, best practices, and the like, and can be legally binding, or not, at the decision of States Parties.

16. Should the Working Group so request, the Secretariat would be prepared to provide a further discussion paper outlining the structure and process by which framework conventions are established, finalized and implemented, including experience gained from the WHO FCTC.

C. Adjustments to the IHR: three structural options

17. There are three primary means by which the IHR could be further developed/adjusted: amendments, understandings in practice, and detailed reporting arrangements. Each is discussed in turn in the remainder of this subsection.

18. **Amendments.** The formal process to amend the IHR is set forth in Articles 55 and 59 of the instrument. Amendments may be proposed by any State Party or by the Director-General for the Health Assembly's consideration. If approved by the Health Assembly (per the Constitution, through a simple majority vote, though adoption by consensus has been the practice), amendments enter into force on the same terms that governed the entry into force of the revised IHR themselves: amendments come into force 24 months after the notification of their adoption by the Director-General and States Parties may reject or file reservations to them within 18 months from such notification. As a matter of practice, since their adoption in 2005, the revised IHR were formally amended only once: in 2014, Annex 7 was indeed amended by the Health Assembly, through a resolution adopted by consensus, to extend the temporal validity of the protection resulting from the yellow fever vaccination.[1]

19. **Understandings in practice.** In addition to the formal amendment process described above, a practice that has developed to a limited degree in connection with the application of the IHR suggests that issues concerning the interpretation or application of certain provisions may, in certain contextually specific cases, be addressed through other mechanisms, notably through the adoption by the Health Assembly of technical understandings of the provision(s). For example, on two occasions the Health Assembly addressed itself to the interpretation of Article 15(3) of the IHR concerning the temporal validity of temporary recommendations in regard to declared public health emergencies of international concern for polio and COVID-19. Through decisions adopted by consensus, the Health Assembly interpreted this provision in a manner that allowed for the continued application of those temporary recommendations beyond the second World Health Assembly after the determination of the public health emergency of international concern to which they relate.[2] It may be the case, if deemed acceptable

[1] Annex 7 was amended through resolution WHA67.13 (2014). The amendment entered into force for all States Parties on 11 July 2016.

[2] See decisions WHA68(9) (2015) and WHA74(15) (2021).

by the Health Assembly, and in the absence of objection by any State Party, that further, similarly limited, technical understandings may be adopted in the future through the same process.

20. **Reporting arrangements.** While technically an application of the existing terms of the IHR, it is worthwhile noting the provisions of Article 54(1) of the IHR, which provides that "States Parties and the Director-General shall report to the Health Assembly on the implementation of [the IHR] as decided by the Health Assembly". This provision could be utilized by the Health Assembly to adjust the reporting obligations of IHR States Parties; for example, by establishing an IHR reporting conference.[1]

4. VALUE AND INCENTIVES RELATING TO ADJUSTMENTS TO THE IHR, AND ATTENDANT RISKS AND POSSIBLE MITIGATION MEASURES

A. Consideration of benefits

21. Key benefits from adjusting the IHR as a means to addressing and revising the pandemic preparedness response architecture are detailed as follows.

22. **Familiarity of IHR.** Health ministries of Member States are familiar with the IHR, and focusing on their strengthening builds on this familiarity. IHR states parties have established, generally within their health ministries, IHR focal points, and in some cases, IHR competent authorities as well. Such structures provide a basis for institutional (as opposed to individual) understanding and awareness of IHR terms. This reservoir of understanding can serve to advance both development and implementation of steps to strengthen the IHR.

23. **"Revisability" of the IHR.** Weaknesses within the IHR that have been identified can be addressed. The IHR Review Committee has identified a number of weaknesses in the IHR that may be amenable to strengthening, either through formal amendment, or, perhaps other steps as identified above. The amendment of Annex 7 to the IHR by the Health Assembly in May 2014 provides a useful precedent. Moreover, amendment of the amendment provisions of the IHR, as has been raised, so that amendments can enter into force more quickly, could further strengthen the "revisability" of the IHR.

24. **Focus on existing commitments for preparedness and response.** A benefit of focusing attention to technical level revisions on the IHR at this time could be anchoring discussions in existing technical considerations, instead of focusing on "political" matters that may be addressed in a new instrument. That said, as detailed in paragraph 12 above, it is not an "either/or" situation, and IHR revisions could be addressed along with a new instrument – for example, in a stepwise approach, or parallel processes.

25. **Entry into force globally and at a "time certain".** Because IHR approval operates through an "opt-out" mechanism where countries are presumed to agree their applicability unless they formally object, a more streamlined approval process than traditional "opt-in" approval is possible. This offers the important benefit of formal IHR amendments being broadly, if not universally, subscribed. From a procedural perspective, as detailed in paragraph 18 above, amendments to the IHR (which are regulations, under Article 21 of the WHO Constitution) come into force 24 months after the notification of their adoption by the Director-General and States Parties may reject or file reservations to them within 18 months from such notification. This could be viewed as a process-based benefit, when compared to

[1] The reporting modalities of the WHO Universal Health and Preparedness Review (UHPR) may also be relevant in this regard. The UHPR is a new mechanism proposed by WHO as means to increase accountability and transparency among Member States in gap identification and capacity-building for better health emergency preparedness.

the entry into force of a new instrument (under Article 19 of the Constitution), which as detailed in the annex to this paper, must be accepted by each Member State in accordance with its constitutional processes before coming into force. This could also, in principle, economize on time and process as a matter of domestic law of Member States, depending on the terms of their national processes. However, the fact that a new instrument (based in Article 19) requires domestic acceptance could also be viewed as a benefit for principles of transparency, involvement across sectors, and engagement – all factors which could support and galvanize the global response to pandemic preparedness and response.

B. Consideration of risks

26. Similar to the discussion of benefits above regarding adjustments to the IHR, risks and mitigation measures discussed below generally focus on the structural considerations between only adjusting the IHR, as compared to adjusting the IHR and also establishing a new instrument on pandemic preparedness and response under the WHO Constitution.

27. **A possible "slippery slope" for strengthening the IHR.** The IHR are rooted in 20th century sanitary regulations which focused on containing the spread of disease, in decades prior to digital technologies. Further, they do not define pandemics, and therefore treat all public health emergencies of international concern, whether pandemic or non-pandemic, equally. There is a risk that by opening certain provisions of the IHR to address modern pandemics in today's highly-digitized and globalized world, other parts of the IHR may lose relevance or coherence, at least relative to amended provisions, to 21st century pandemic threats. This risk could be mitigated, for example by a detailed review of any cross-impacting provisions in the IHR, or by agreement of States Parties to a broad-scope amendment to the IHR to appropriately address the issue.

28. **A growing complexity of the IHR, beyond its already complicated structure.** Many provisions of the IHR include cross references both within the instrument itself, and to external "applicable international agreements". For example, the regulations regarding *free pratique* are subject both to the terms of Article 43 of the IHR, as well as to, as applicable, the United Nations Convention on the Law of the Sea and the 1923 Convention on the international Regime of Maritime Ports. There are numerous other examples of areas within the IHR involving similar cross-referencing. Further, from a substantive perspective, if the IHR were revised to create an intermediate level of alert, a system for declaring such a level would have to be established, as would, presumably, a system setting out the implications of declaration of such an intermediate level. The Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response considered that confusion about declarations of public health emergencies of international concern and about the implications of such declarations is already a weakness of the IHR. Adding another level of alert would risk adding to existing uncertainty within the instrument, in addition to the complexity of the instrument's relation to other external international agreements. A possible mitigation measure for these risks is careful, attentive drafting to any revisions to the IHR, including both for internal coherence and the instruments' relation to other international agreements.

29. **The Constitutionally-limited scope of the IHR under Article 21 of the WHO Constitution.** The technical nature of the IHR follows from the WHO Constitution and the nature of the three types of WHO Constitutional instrument described in Section 2 above. Article 21 of the WHO Constitution provides a narrow scope for regulations such as the IHR; in contrast, an Article 19 convention or agreement could address pandemics within the broader framework of the "competency of the Organization" as a whole, including its expansive definition of health and its foundational principles as set out in the preamble of the WHO Constitution. This potential breadth can be legally understood as both encompassing (by way of supporting), and going beyond, the Article 21 scope of "sanitary and

quarantine requirements and other procedures designed to prevent the international spread of disease". Mindful that the risk presented here is a structural one, the limitations of the IHR and Article 21 of the WHO Constitution, the risk could be mitigated by one or more additional instruments.

30. **The IHR's internal limitation of scope, under IHR Article 2.** Article 2 of the IHR expressly states its purpose and scope: "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade". Member States may conclude, based on the text of the IHR and its use in practice, that this purpose and scope sets out approaches to pandemics based on a balancing test principle, as opposed to a precautionary principle. Whether preventing and responding to pandemics is appropriately managed with a precautionary approach or a balancing test approach, or a combination that is situationally determined, is a question for Member States. However, if Member States were to prefer a precautionary approach, or a situationally determined approach, Article 2 would require amendment. This risk could be addressed by expanding the scope of Article 2 of the IHR, by adding appropriate new provisions, articles, sections, and perhaps protocols or annexes to the instrument, utilizing the formal amendment process established in Article 55 of the IHR.[1] This would entail a larger scale, rather than a "targeted" approach.

31. **Challenges of creating an IHR compliance mechanism.** Revising the IHR may not appropriately ensure appropriate global pandemic preparedness and response, if States Parties do not comply with the revised instrument. A criticism expressed of the IHR is that the compliance of States Parties with the Regulations is not robust, including, importantly, in the context of a public health emergency of international concern, including in the recent COVID-19 context. This risk could be mitigated and addressed from a structural perspective by revising the architecture of the IHR, for example to emphasize States Parties' substantive and/or compliance obligations, or to establish a consequences or benefit arrangement, or other mechanisms, to promote compliance. If done within the IHR, such an effort would likely involve more than targeted amendments. This risk could be mitigated by establishing external compliance systems for the IHR, but such "adjuncts" (for example, free-standing compliance bodies) would be unlikely to carry legally binding force.

5. VALUE AND INCENTIVES RELATING TO A NEW INSTRUMENT ON PANDEMIC PREPAREDNESS AND RESPONSE, AND RISKS

32. As requested by the Bureau of the Working Group, this section discusses the benefits of adopting a new instrument pandemic preparedness and response. The evaluation generally assumes that the instrument is legally binding. a convention or agreement under Article 19 of the WHO Constitution, although it could be otherwise, for example the new instrument could be a recommendation of the Health Assembly under Article 23.

A. Consideration of benefits

33. As a preliminary point, we note that the discussions of Member States and the recommendations of different panels regarding a new instrument have focused on four overarching substantive categories

[1] It may be considered, or viewed, that Article 44 of the IHR (dealing with collaboration and assistance) could be a means to expand the substantive scope of the instrument, without entering into the Article 55 formal amendment process, thereby by-passing those constraints, including on timing. However, questions may arise regarding whether this view is consistent with the wording or the drafting history of Article 44, which relates to modalities for cooperation on implementation of the IHR (thus the repeated reference to "under these Regulations"). It is therefore unclear if this view could form an appropriate basis for expanding the substantive scope of the IHR as an instrument or rendering unnecessary the IHR's amendment process as set forth in Article 55.

related to pandemic preparedness and response, namely (1) governance, (2) financing, (3) systems and tools, and (4) equity. While other substantive categories for a new instrument have also been discussed, this analysis will focus on these four.

34. Further, the evaluation of benefits is an exercise in relativity, in that benefits of one approach must be compared with others. As such, the following discussion evaluates certain steps or ideas that have been raised under each of the four substantive areas just referred to.

35. **Governance.** A new instrument could provide authoritative structure and cohesion to the global governance of pandemic preparedness. The current governance structure is complex and fragmented and has not achieved generally desired levels of effective collective action and equitable access to countermeasures, both of which are essential for pandemic preparedness and response. Member States could take further voluntary steps in this regard as well, but such steps in the past have not led to levels of commitment and action generally regarded as sufficient by all States. In contrast, a legally binding instrument, negotiated by all WHO Member States (indeed open to all countries) could establish a global consensus on the governance architecture of pandemic preparedness and response, devoid of the ambiguity that potentially competing voluntary arrangements might create.

36. **Financing.** A new instrument could address the topic of sustained, predictable funding for health emergency preparedness and response, including from domestic budgets. Currently there is insufficient investment in country, regional and global preparedness and response capacities for pandemics and other health emergencies. Funding currently cycles between extremes of panic and neglect. Moreover, existing response financing mechanisms and streams are variable and fragmented, and dedicated preparedness financing on the global level is virtually non-existent. There is a need for coordinated, predictable, transparent, broad-based, sustainable and flexible funding to ensure the world is prepared for, and can respond to, pandemics, including high-risk pathogens. While voluntary mechanisms have been established, and are being proposed to address these problems, a binding instrument could frame and/or complement such mechanisms and reinforce them, inter alia, through application of the international legal principle of *pacta sunt servanda*, the obligation to implement undertakings in good faith.

37. **Systems and tools.** A new instrument could include the following:

- Enhancing the global early warning, alert and emergency response system under WHO's leadership, to predict and detect emergencies, to communicate real-time risk assessments and to protect the planet from prospective disease outbreaks and mitigate the impact of future emergence of novel zoonotic virus.

- Ensuring a global health emergency end-to-end supply chain and logistics system able to specify, quality assure, prioritize and deliver vital commodities rapidly to those who need them most.

- Mobilizing a global health emergency workforce that is rapidly deployable nationally, regionally and internationally, to detect and respond to health emergencies.

- Accelerating research and innovation for health emergencies around a transparent and coordinated global process to pursue research and innovation priorities for collective action and ensure that sustainable global platforms are pre-prepared for the next epidemic.

- Enhancing and expanding networks, mechanisms and incentives for the sharing of pathogens and biological samples, genomic data to facilitate and accelerate the development of diagnostic tests and evaluation for diseases of epidemic potential.

- Establishing an access and benefit sharing mechanism to ensure the timely, predictable, fair and equitable access to products arising from the use of such pathogens, biological samples and genomic data.

- Managing misinformation and disinformation needs a coordinated response to manage the infodemic phenomenon that has escalated during the COVID-19 pandemic.

- Coordinating a global platform to foster the safe development and implementation of innovative pandemic tools, mindful of the need for international collaboration to accelerate innovation while ensuring the maximum benefit of all such new tools.

38. Such a broad set of initiatives could be concluded through a Health Assembly resolution or a patchwork of political initiatives. Indeed, Health Assembly resolutions often do encompass a complex set of recommendations. Examples of this include the Pandemic Influenza Preparedness (PIP) Framework and the various "Codes" adopted through resolutions of the Health Assembly. Doing so offers, in particular, the advantage of speed of applicability. But such non-binding instruments are not necessarily faster to negotiate than binding ones. The PIP Framework took roughly as many years to elaborate as the WHO FCTC. And once agreed, such non-binding instruments do not benefit from the kind of, and level of, dedicated and higher-level regular review that binding instruments generally establish.

39. **Equity.** A new instrument could address the topic of equity in pandemic preparedness and response, which could include ensuring economic and social protection and advancing respect for human rights, providing for equitable access to healthcare services and medical countermeasures, including vaccines, and ensuring equitable representation and participation (including considering gender, geographic and socioeconomic status) in global pandemic preparedness and response activities and work conducted pursuant to the instrument. Such measures, again, could be elaborated in a non-binding format. In the past, such "soft law" framing has resulted in terms that skew towards the aspirational, rather than operational. While a binding framework may not necessarily reduce this risk, the increased visibility of negotiations on legally-binding terms and conditions could drive expectations, ambitions and results for concrete and operational steps.

40. In addition to the benefits described above, there could be other benefits of a binding instrument, as follows.

41. **Potentially higher confidence among parties that commitments will be implemented in good faith.** As noted above, when States establish legally binding commitments the principle of *pacta sunt servanda* applies to them. This has both normative and political implications, raising the respective stakes on observance.

42. **Anchoring pandemic preparedness and response in key principles.** A legally binding agreement on pandemics under Article 19 of the WHO Constitution would be grounded in the equitable and human right principles set out in the Constitution's preamble.

43. **Constituency creation.** Governance structures established by legally binding agreements generally operate to elevate public attention to the subject of the agreement in ways that non-binding

instruments do not. As is clear from the operation of the WHO FCTC in this regard, it is reasonable to anticipate that a binding agreement on pandemic preparedness and response would create a broad and sustained stakeholder constituency

B. Consideration of risks

44. Undertaking a new legally binding instrument of international law is a significant matter, and one which therefore comes with attendant risks. Certain risks, and possible mitigation measures, are outlined below.

45. **A requirement for a legally binding form could result in protracted negotiations or deadlock, with a result of delayed or no action by Member States on pandemic preparedness and response.** Member States could fail to achieve consensus, or discussions could take an extensive amount of time. This creates both reputational risk for all involved, as well as substantive risk that time is lost in securing progress. This risk can be mitigated by effective leadership and management of the negotiating process.

46. **Negotiation of a legally binding instrument can take time and resources, which could, in the near term, detract resources from Member States' COVID-19 response activities.** During Working Group meetings to date, certain Member States commented that their health experts are currently fighting the COVID-19 pandemic in country, and mindful of this critical mission do not have the time or resources to devote to a detailed intergovernmental negotiation process for a legally binding instrument. That said, this risk could be addressed, at least in part, by the structure of the legally binding instrument. In particular, a framework convention approach, as detailed in Section 0, may enable Member States to lock in binding commitments at the Head-of-State level at an early stage and address practical and detailed components of the instrument in due course as resources permit, through protocols, rules, guidelines, processes, and best practices.

47. **WHO may not be the appropriate venue for a global agreement for worldwide attention and action, whether because of its mandate or because of policy or political considerations.** A potential risk is that WHO, as an organization, is not seen as having the mandate, or political leverage, to engage all relevant stakeholders and parties to undertake and manage a new international instrument which focuses on health but is also cross-cutting, for example in addressing subjects relating to trade and intellectual property rights.

48. As a structural matter, this risk is inapposite: WHO, a United Nations specialized agency, has the Constitutional mandate to address the substantive areas raised in discussions by Member States to date. The Organization's broad scope was intentional, as evidenced by the broad definition of health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". Furthermore, under the WHO Constitution it is the Health Assembly which has the final decision on the Organization's mandate, permitting it to resolve questions of interpretive scope.

49. From the political and practical lenses, WHO has experience in managing all-of-government and whole-of-society international instruments, in particular as illustrated by its leadership in elaborating the WHO FCTC, and its protocol on illicit trade in tobacco products. If Member States decide to pursue a new instrument under Article 19, including all relevant parties and stakeholders in both the negotiation process and the long-term implementation work would presumably be a key consideration.

50. **The instrument could be too rigid, or too broad, and fail to meet global expectations.** In particular, negotiations on a binding instrument could be side-tracked by protracted discussions on one

or more important issues for which Member States may have differing fundamental perspectives. Further, an overly "rigid" legal instrument might not be able to appropriately address the multi-faceted and dynamic nature of pandemic preparedness and response. These risks can be mitigated by the instrument choice itself; in particular, the use of a framework convention instrument (as discussed in paragraph 12) could enable the over-arching framework to be established, and subsequent negotiations and instruments (for example protocols) on specific subsequent areas could be tailored to specific circumstances, allowing a multitude of instrument choices based on the needs and nature of each subject area, including for example legally binding protocols or "softer" more flexible commitments, such as guidelines. The is the approach parties to the WHO FCTC have taken.

51. **The arrangements could create gaps between instruments and/or varying obligations between Member States.** If the structural arrangement selected is one of a framework convention on pandemic preparedness, coherence with other related instruments such as the IHR could present issues if they appear to, or do in fact, conflict. Also, if not universally subscribed, a framework convention could present obligations for parties to it that vary from obligations under the IHR.

52. These concerns could be mitigated by careful drafting and preparation of the instrument. Further, it is notable that international instruments with multiple "layers" and interoperability requirements with other instruments occurs in other fields and instruments of international law.[1]

6. CONCLUSION

53. As requested by the Working Group, this paper has described the types of global health instrument available under the WHO Constitution (summarized in the annex for reference), described certain modalities and instruments proposed by Member States during Working Group discussions to date, and summarized the benefits and risks of adjustments to the IHR and a potential new instrument for pandemic preparedness and response, including ones rooted in the WHO Constitution. A key point of emphasis in this regard is that from a structural and legal perspective Member States are free to select from none, all, or a mix, of instrument types; it is not "either/or".

54. In balancing the risks, benefits and desired outcomes, Member States may find that a "blended" approach, leveraging all three types of WHO instruments, as well as other Constitutional and political options, may result in an optimal means to ensure that the global pandemic preparedness and response architecture, viewed from an integrated and holistic perspective, is both effective and comprehensive in advancing global solidarity and cooperation. Based on Member State interventions to date, such a "blended" and integrated approach could comprise (a) a new instrument – a legally binding framework convention – as the "parent" instrument for pandemic preparedness and response; (b) the IHR, with improvements (amendments, or otherwise) to ensure they are fit-for-purpose, and remain a cornerstone of the new architecture; and (c) as necessary (now or in due course), additional measures adopted by the Health Assembly, or other appropriate forums, synergizing with the new instrument and the IHR.

55. The Secretariat hopes that this paper may prove helpful to Member States in their consideration and discussion of this subject, and is available to provide further information and analysis to the Working Group on request.

[1] The agreements of the World Trade Organization and the United Nations Convention on the Law of the Sea were noted by a Member State as relevant possible examples of international legal instruments which consolidate one or more existing arrangements and may prove to be relevant examples for Member States' further consideration.

ANNEX

SUMMARY OF HEALTH INSTRUMENTS UNDER THE WHO CONSTITUTION

Instrument (and legal basis)	**Process for establishment/ entry into force**	**Material scope**	**Legally binding or non-binding character**	**Amendments**	**Example(s)**
Conventions or agreements (Articles 19, 20)	Adopted by the Health Assembly through a two thirds vote (though adoption by consensus is possible); Come into force for each Member State when accepted by it in accordance with its constitutional processes	Any matter within the competence of the Organization	Legally binding on States Parties	Formal amendment process	WHO Framework Convention on Tobacco Control
Regulations (Articles 21, 22)	Adopted by the Health Assembly through a simple majority (though adoption by consensus is possible); Come into force for all Member States after due notice has been given of their adoption by the Health Assembly, except for such Member States as may notify the Director-General of rejection or reservations within the period stated in the notice	(a) sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease; (b) nomenclatures with respect to diseases, causes of death and public health practices; (c) standards with respect to diagnostic procedures for international use; (d) standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce; (e) advertising and labelling of biological, pharmaceutical and similar products moving in international commerce	Legally binding on States Parties	Formal amendment process	International Health Regulations (2005) WHO Nomenclature Regulations
Recommendations (Article 23)	Adopted by the Health Assembly through a simple majority (but well-established practice is adoption by consensus)	Any matter within the competence of the Organization	Not legally binding on Member States, however political effects of expected implementation and compliance; binding on the WHO Secretariat	Adoption of a new resolution or decision	Pandemic Influenza Preparedness (PIP) Framework (WHA64.5) Global Code of Practice on the International Recruitment of Health Personnel (WHA63.16) International Code of Marketing of Breast-milk Substitutes (WHA34.22)