

## Assessing the State of Play in the WHO Pandemic Instrument Negotiations

By Viviana Muñoz Tellez \*

Members of the World Health Organization set the ambitious target to negotiate and conclude a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (hereafter 'the pandemic instrument'), by 2024. It has been agreed that the instrument should be legally binding, while elements of the text may vary between legally binding and non-legally binding. The instrument will be adopted under Article 19 or 21<sup>1</sup> of the WHO Constitution. In parallel to this process, conducted by the Intergovernmental Negotiating Body (INB) established in December 2021, negotiations are on-going to make targeted amendments to the International Health Regulations (IHR) as last revised in 2005. The IHR (2005) is currently the only binding instrument related to pandemic preparedness and response; however, it does not regulate the development and distribution of medical products necessary to address pandemics. The IHR (2005) negotiations, which are conducted through the Working Group on Amendments to the International Health Regulations (2005) (WGIHR), also aim to conclude by 2024.<sup>2</sup>

This Policy Brief focuses on the negotiations of the pandemic instrument by the INB, which has met in five sessions in Geneva, the latest held on 12-16 June 2023.<sup>3</sup>

The Plenary of the INB at times accepts participation of non-state actors, but formal negotiations in the Drafting Group are closed, and there is no public record of its deliberations.<sup>4</sup> The Bureau<sup>5</sup> of the INB was entrusted to develop with support from the WHO Secretariat, a "conceptual zero draft" of the pandemic instrument (WHO CA+), as a basis for commencing negotiations at the 4<sup>th</sup> session of the INB.<sup>6</sup> Moving into the fifth INB session (INB5), the Zero Draft was extensively commented on by Member States, which took the form of a "Consolidated text" reflecting the proposals submitted by them.<sup>7</sup> For the INB5 session that was held on 12-16 June 2023, the Bureau prepared a second version of the Zero Draft WHO CA+.<sup>8</sup>

In the run up to the INB5, it was unclear what would be the textual basis for the work of the INB and the Drafting Group, whether the Bureau WHO CA+ or the Consolidated Text. The second version of the Bureau's Zero Draft

### Abstract

This Policy Brief discusses the state of play of the negotiations of the pandemic instrument at the World Health Organization. The Intergovernmental Negotiating Body (INB) is increasing its meetings as the target deadline for completion in the first half of 2024 draws closer. To advance, the political will needs to be scaled up in the next months. The expectations should not be lowered to focus on the lowest common denominator. Real progress needs to be made in priority areas of concern for developing countries to keep momentum.

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*Ce rapport sur les politiques examine l'état d'avancement des négociations sur l'instrument relatif aux pandémies à l'Organisation mondiale de la Santé. L'Organe intergouvernemental de négociation (OIN) multiplie les réunions à mesure que se rapproche l'échéance fixée pour l'achèvement de l'instrument au premier semestre 2024. Pour avancer, la volonté politique doit être renforcée dans les prochains mois. Les attentes ne doivent pas être réduites pour se concentrer sur le plus petit dénominateur commun. De réels progrès doivent être réalisés dans les domaines prioritaires pour les pays en développement afin de maintenir l'élan.*

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*Este informe sobre políticas analiza la situación de las negociaciones del instrumento sobre pandemias en la Organización Mundial de la Salud. El Órgano Intergubernamental de Negociación (ONI) está aumentando sus reuniones a medida que se acerca el plazo previsto para su finalización en el primer semestre de 2024. Para avanzar, es necesario aumentar la voluntad política en los próximos meses. No deben rebajarse las expectativas para centrarse en el mínimo común denominador. Es necesario lograr avances reales en las áreas prioritarias que preocupan a los países en desarrollo para mantener el impulso generado.*

\* Viviana Muñoz Tellez is Coordinator of the Health, Intellectual Property and Biodiversity Programme (HIPB) of the South Centre.

WHO CA+ received mixed reactions, with Member States generally welcoming the text as a basis for further negotiations but some pointing to many omissions of proposals that were previously incorporated in the Consolidated text or shared prior to the reconvened INB5 session. Member States also had different suggestions for how to organise the work, such as to start with the selection of a limited set of articles that deal with issues of most importance or contention.

The INB5 agreed to focus discussion of the Drafting Group on the second Bureau text of the Zero Draft WHO CA+. It was also agreed that the INB could continue to refer to the Consolidated text. The Drafting Group took up the Bureau's text Chapter II, addressing Articles 9 (Research and development), 10 (Liability risk management), 11 (Co-development and transfer of technology and know-how), 12 (Access and benefit-sharing), 13 (Supply chain and logistics), and 14 (Regulatory strengthening).

The Drafting Group during INB5 mostly engaged in exchange of views. It broke into an informal meeting for article 9 on "research and development" to keep dialogue going and help build trust, given the wariness showed by Member States in entering into textual negotiations. The agreed working principle for the negotiations is that "nothing is agreed until everything is agreed".

Informal meetings of the Drafting Group continued in June and July, in the run up to the 6<sup>th</sup> session of the INB (INB6) that will be held from 17–21 July 2023.<sup>9</sup> This session will address Article 9 (Research and development), Article 12 (Access and benefit-sharing) and Article 13 (Supply chain and logistics). During INB6, the Drafting Group will work in plenary on these articles based on the second version of the Bureau's text, followed by the remaining articles of Chapter II and thereafter Chapters III and I, as time permits.<sup>10</sup>

The future of the INB process is still clouded by deep uncertainty. The Bureau's second Zero Draft WHO CA+ will be the basis for discussion but it does not constitute a formal negotiation document. A new revised Bureau text is likely to be produced in the next months. The fate of negotiations in the formal Drafting Group will depend on progress in informal meetings ("informals"). These are, however, in a "trial" phase, as it is clear that not all delegations are able to participate fully and actively in these meetings and have a double burden of back-to-back meetings of the WGIHR and the INB.

The procedures up to the next INB6 also need to be further finetuned and agreed upon. At the closing of the INB5 Member States requested the Bureau to provide greater predictability on the modalities for the intersessional informals and INB6; to provide information in a timely manner on articles to be taken up so delegations are adequately prepared; to make available interpretation facilities during informals; and to keep the formal Drafting Group meeting as the platform for

negotiations.<sup>11</sup>

A joint plenary session of the INB and the WGIHR<sup>12</sup> will be held on 21 July and 24 July 2023. The next session of the WGIHR will be held from 24 to 28 July. Discussions in the WGIHR are directly relevant to that of the INB, as the IHR (2005) underpins the future pandemic instrument. The two global health instruments must be mutually supportive and will need to be implemented concurrently by WHO Member States. Some of the issues proposed for IHR amendments in the WGIHR are also under discussion in the INB. This includes new obligations to expand the scope of information that countries must share under the IHR to include biological material and genomic data, conditioned to sharing of benefits, and introducing new obligations aimed at ensuring equitable access and distribution of medical products including building national capacities for research and development (R&D) and manufacturing.

## **Coalitions**

The need for a pandemic treaty was first advanced by the Council of the European Union, and subsequently supported by a select group of leaders from various countries as well as from the WHO Director General. This group evolved into the "Group of Friends of the Treaty" that were the main advocates for a new international instrument. Once the decision to negotiate was adopted by the World Health Assembly, the coalition broke away given the different interests in the substantive elements of the possible instrument.

Coalitions in the INB for the most part take the form of regional groupings. The African Group has remarkably kept a united stance among the 47 countries in advancing proposals and in discussions in a coordinated manner in the INB and WGIHR. During INB5, countries of the Caribbean and Latin American made group interventions, which is infrequent in the WHO, more so as they are part of the regional Pan American Health Organization (PAHO) that also includes the United States.

A new inter-regional coalition was announced during the reconvened INB5 session as the "Group for Equity" uniting numerous developing countries from Africa, Latin America and the Caribbean and Asia<sup>13</sup> around the vision that the INB process should result in a WHO CA+ that is just, fair and cognisant of the circumstances of developing countries, which can only be achieved through concrete provisions in the text that effectively operationalize equity. The Group of 77 and China has also increased its coordination with regards to the WHO INB process.

## **Façade of engagement?**

The value of a new pandemic instrument will essentially depend on its ability to enhance effective coordination of State policies and actions, increase cooperation among States on an equitable basis and enhance all countries capacities, including through adequate financial and technological support for developing countries. Indeed, the purported motivating factor for the pandemic instrument

negotiations is the “catastrophic failure of the international community in showing solidarity and equity in response to the Covid-19 pandemic.”<sup>14</sup>

This calls for negotiating binding rules that institutionalise solidarity and equity, helping to build more just systems that increase global preparedness and response to pandemics. The current state of negotiations brings into question whether there is real political will from powerful countries to build new international rules to avoid repeating the past mistakes. A question may be posed as to whether the fanfare for a new international instrument focused on strengthening multilateral cooperation was merely a distraction to deflate and respond to criticism of vaccine inequity and public discontent expressed through strong activism from citizens demanding greater government accountability.

The WHO INB is proceeding in parallel to discussions in other fora regarding pandemics, such as the G-7 and G-20, which could help build consensus towards specific commitments and rules in the INB to support development, timely equitable access and distribution of vaccines, therapeutics and diagnostics globally, but this is not the case so far. The G-7 vision is “a strengthened sustainable, equitable, effective and efficient “end-to-end” medical countermeasures global ecosystem that is based on voluntary cooperation”,<sup>15</sup> which echoes the pharmaceutical industry approach.<sup>16</sup> The G-20 efforts in 2021-22 focused on reaching agreement on the establishment of a Pandemic Fund housed at the World Bank, to support building developing country capacities.<sup>17</sup> The Pandemic Fund is distinct from the financing mechanism and provisions that are being discussed as part of the Pandemic Instrument. This year, the G-20 has committed to support the work of the INB and emphasised the need to work to promote equitable access to timely, safe, quality and affordable medical countermeasures for all, but no new commitments have been agreed.<sup>18</sup> India has proposed the establishment of a global research and development network as part of a future global medical countermeasures platform to support pandemic preparedness and response.<sup>19</sup>

In parallel to the INB discussing rules and mechanisms to help ensure timely access to medical products for all countries, the WHO with external partners is continuing to advance a medical countermeasures platform built on the experience of the ACT-A accelerator including the COVAX vaccine initiative, that may roll out by September 2023.<sup>20</sup> This could undermine the INB process, if the INB does not accelerate its discussion on the ground rules for the platform, together with provisions for increasing developing countries self-sufficiency to produce and procure medical products needed to address pandemics. The WHO should brief the INB in plenary on the initiative, as part of the INB discussion on relevant provisions of the pandemic instrument.

In the current context, the real purpose of the WHO INB process may be brought into question, unless there

is a shift in political momentum in developed countries to show real willingness to negotiate new multilateral rules and inclusive governance for equitable access to medical products during pandemics and providing means for enhancing the strained capacities of developing countries to prepare and respond to pandemics. The recent agreement of the European Commission with Pfizer and several European drugmakers to reserve capacity to make up to 325 million vaccines for a future pandemic<sup>21</sup> seems to indicate, however, an entirely different direction. If negotiations in the INB do not advance, the focus will likely shift towards an enhanced IHR amendment process.

The political will for the pandemic instrument needs to be scaled up in the next months. The General Assembly of the United Nations is hosting a High-Level Meeting on Pandemic, Preparedness and Response in September 2023 that is meant to enhance the political momentum towards mobilizing political will for pandemic prevention, preparedness and response. It does not bode well that the current draft is underwhelming. Co-chairs of the former Independent Panel for Pandemic Preparedness and Response observe that “the current draft of the political declaration does not express the commitments required of Heads of State and Government to transform the international system of pandemic preparedness and response. Instead, it reads as a health resolution.”<sup>22</sup>

There is little time left to change course. For the INB negotiations to succeed, the objective of the pandemic instrument should remain ambitious to deliver binding rules that, as noted, institutionalise solidarity and equity among States and in countries, helping to build more just systems that increase global preparedness and response to pandemics.

## **Substantive issues**

The wording of the provisions in the Bureau’s text of the WHO CA+ of June 2023 (second version of the Zero Draft) varies substantially as compared to the first Zero Draft in the nature of the provisions (i.e. legally binding and not legally binding) and, particularly, in respect of the extent to which the provisions define concrete legally binding obligations on critical issues for a pandemic instrument to be effective. A few of the provisions drafted as “shall” provide concrete mandates; most of them just aim to “promote”, “encourage”, “incentivize”, “urge”, “make all possible efforts” “endeavour to”, “consider implementing.” Overall, the WHO CA+ now resembles more a declaration, a statement of intention and loose commitments, rather than a legally binding instrument.

The second version of the Bureau text of the WHO CA+ does include provisions concerning areas for which currently there is a dire need for rules and enhanced coordination, such as leveraging public financing for research and development to enhance access to medical products by defining contractual terms, facilitating access to technology and know-how, building regional production capacities and emergency stockpiles, capacity building and financing. However, these priorities of developing coun-

tries are not well articulated in terms of concrete legal obligations, for the most part described as objectives. The Consolidated text of Member State proposals from February 2023 provided ample options for inclusion of concrete legal provisions in these areas. Also missing from the WHO CA+ are rules for the set up and operation of any multilateral procurement mechanism following the ACT-A, and rules for State contracts for funding research and development and purchase of vaccines and other medical products.<sup>23</sup> The failure of COVAX to ensure timely and equitable access to and delivery of vaccines during the Covid-19 pandemic in developing countries remains as a major problem without focused discussions for a concrete solution in the INB.

Developed countries do not seem to want to commit to obligations in these areas beyond voluntary measures, while appearing to engage substantially in the negotiations. The most substantive proposal on equity arises from the European Union for Parties which are high income countries to “make all possible efforts” set out the availability and affordability commitments which will apply to the countermeasure manufacturer in any purchase agreement that they conclude with such manufacturer. In case the countermeasure is in short supply, the Parties would “make all possible efforts” to ensure that countermeasure manufacturers reserve a percent of production (to be determined) for sale to low-income countries and for middle-income countries where most of the world population lives (presumably a lesser percentage than for the former) and tiered pricing.<sup>24</sup>

The expression of willingness to negotiate conditions for access in State purchase contracts with manufacturers is welcome. However, this is a limited proposal. The EU proposal on access to medical products is also undermined by its recent agreement, mentioned above, to unilaterally secure vaccine doses in case of future public health emergencies that do not include requirements for manufacturers to reserve doses for developing countries.

Developing countries are asking developed countries to substantially engage with their proposals in the INB to set commitments to coordinate their supply contracts with manufacturers based on an international fair allocation framework guided by WHO; to facilitate access to technology and know-how and avoid patent and trade-secret barriers in order to facilitate a rapid increase in manufacturing capacity across regions; to increase transparency of contractual terms with manufacturers including prices; to establish mechanisms to strengthen regional supply chains and keep stockpiles of vaccines and other medical products to be quickly deployed in case of a pandemic, and to provide financial means to increase capacities for overall pandemic prevention, preparedness and response.

In the view of the INB Bureau, “although the INB shares the same goal of equity, there are divergent

views on the pathways and legal texts that support achievement of equity.”<sup>25</sup> In other areas, however, such as surveillance, monitoring, reporting and rapid sharing of certain data and information, in which developed countries are pressing for binding commitments, the text under negotiation of the WHO CA+ includes well-crafted binding obligations. In contrast, a carve out to a whole existing international legal regime for access and benefit sharing from genetic resources, derivatives and digital sequence information is being proposed in exchange for purported benefits that would derive from being Party to the new instrument.

## Outlook

Significant resources are being placed in the success of the INB negotiations. The INB is meant to deliver an international instrument that reduces systemic inequities, to allow all countries to be better prepared, respond to and recover from pandemics. The expectations should not be lowered to focus on the lowest common denominator. Real progress needs to be made in the next months in priority areas of concern for developing countries before momentum is lost. The negotiations on amendments to the IHR (2005) should be given as much priority as those in the INB, given the relationship between both processes, and the uncertainty of the INB outcomes in light of the frail political will for binding commitments needed to ensure that the proposed pandemic instrument effectively prevents a new catastrophic failure of the international community in addressing future pandemics.

## Endnotes:

<sup>1</sup> Article 19 of the WHO Constitution states that “the Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. A two-thirds vote of the Health Assembly shall be required for the adoption of such conventions or agreements, which shall come into force for each Member when accepted by it in accordance with its constitutional processes.” Article 21 of the WHO Constitution states that “The Health Assembly shall have authority to adopt regulations concerning: (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”. The IHR were negotiated under Article 21. The WHO Framework Convention on Tobacco Control is the sole instrument to date negotiated under article 19.

<sup>2</sup> The IHR (2005) were adopted at the 58th World Health Assembly on 23 May 2005 and entered into force on 15 June 2007. The regulations are legally binding on all WHO Member States. Their purpose is “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”, Article 2, World Health Organization, 2008. *International health regulations (2005)*. World Health Organization.

- <sup>3</sup> With regard to the negotiations on the IHR (2005) see Nirmalya Syam, Mainstreaming Equity in the International Health Regulations and Future WHO Legal Instruments on Pandemic Preparedness and Response, Policy Brief 108, South Centre, [https://www.southcentre.int/wp-content/uploads/2022/03/PB108\\_Mainstreaming-Equity-in-the-IHR-and-Future-WHO-Legal-Instruments-on-Pandemics\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2022/03/PB108_Mainstreaming-Equity-in-the-IHR-and-Future-WHO-Legal-Instruments-on-Pandemics_EN.pdf).
- <sup>4</sup> This procedure has drawn criticism, see Priti Patnaik and Shoa Moosavi, 'Pandemic Accord Negotiations: Away from Public Glare, but Center of Attention', Geneva Health Files Newsletter Edition 17, <https://genevahealthfiles.substack.com/p/pandemic-accord-negotiations-away>.
- <sup>5</sup> The Bureau for the INB is composed of co-chairs, Ms. Precious Matsoso of South Africa and Mr. Roland Driecé of the Netherlands, and vice-chairs, Ambassador Tovar da Silva of Brazil, Mr. Ahmed Soliman of Egypt, Mr. Kazubo Taguchi of Japan and Dr. Viroj Tangcharoensathien of Thailand.
- <sup>6</sup> Document A/INB/4/3, available at [Zero draft of the WHO CA+ for the consideration of the Intergovernmental Negotiating Body at its fourth meeting](#).
- <sup>7</sup> The Consolidated Text with the annotated textual proposals by Member States was not published.
- <sup>8</sup> Document A/INB/5/6, available at [https://apps.who.int/gb/inb/pdf\\_files/inb5/A\\_INB5\\_6-en.pdf](https://apps.who.int/gb/inb/pdf_files/inb5/A_INB5_6-en.pdf).
- <sup>9</sup> The Draft Programme of Work for INB6 is available at [Draft programme of work \(who.int\)](#).
- <sup>10</sup> See WHO News Release, 17 June 2023, [Countries set out way forward for continued negotiations on global agreement on pandemic prevention, preparedness, and response \(who.int\)](#).
- <sup>11</sup> See closing statement by Ethiopia on behalf of the African Group and by India on behalf of the Friends of Equity group to the INB5 on 16 June 2023.
- <sup>12</sup> The report of the WGHIR is available at [Report of the third meeting of the Working Group on Amendments to the International Health Regulations \(2005\) \(who.int\)](#).
- <sup>13</sup> The group includes, as of 16 June 2023, Argentina, Bangladesh, Botswana, Brazil, China, Colombia, Dominican Republic, India, Indonesia, Fiji, Kenya, Malaysia, Mexico, Pakistan, Paraguay, Peru, Philippines, South Africa, Tanzania, Thailand. India, delivering the statement at the closing session of INB5, invited all Members that share the vision to join the group.
- <sup>14</sup> INB Bureau Zero Draft text, p.1., A/INB/5/3, 2 June 2023.
- <sup>15</sup> G7 Hiroshima Vision for Equitable Access to Medical Countermeasures, May 2023, [https://www.g7hiroshima.go.jp/documents/pdf/session3\\_01\\_en.pdf](https://www.g7hiroshima.go.jp/documents/pdf/session3_01_en.pdf).
- <sup>16</sup> Berlin Declaration, Biopharmaceutical Industry Vision For Equitable Access In Pandemics, [i2023\\_IFPMA\\_Berlin-Declaration\\_Biopharmaceutical-industry-vision-for-equitable-access-in-pandemics-1.pdf](#).
- <sup>17</sup> G20 Bali Declaration, para 20. [G20 Bali Leaders' Declaration, 15-16 November 2022.pdf](#).
- <sup>18</sup> G20 Foreign Ministers Meeting, Chairs Summary and Outcome, 1-2 March 2023, [FMM\\_OUTCOME\\_DOC.pdf \(g20.org\)](#).
- <sup>19</sup> Press Release: G-20 India Presidency, Third Health Working Group Meeting, 6 June 2023, Hyderabad, [G20 India Presidency: 3rd HWG Meeting](#).
- <sup>20</sup> WHO Concept Note, Developing a New Platform for Access to Equitable Access to Medical Countermeasures in Pandemics, 2 February 2023, [countermeasures-platform\\_who-consultative-process---concept.pdf](#).
- <sup>21</sup> The deal, announced on 30 June 2023 by the European Union's Health Emergency Preparedness and Response Authority (HERA) was reached with four contractors including Pfizer for mRNA vaccines. See [Framework contract signed under EU4Health to guarantee a fast response to future health crises \(europa.eu\)](#).
- <sup>22</sup> Ellen Johnson Sirleaf and Helen Clark, Open letter to leaders and decision-makers responsible for the Political Declaration to be agreed for the 20 September UNGA High-Level Meeting on Pandemic Prevention, Preparedness and Response, 9 July 2023, <https://theindependentpanel.org/ellen-johnson-sirleaf-and-helen-clark-open-letter-to-leaders-and-decision-makers-responsible-for-the-political-declaration-to-be-agreed-for-the-20-september-unga-high-level-meeting-on-pandemic-prevent/>.
- <sup>23</sup> For more discussion on these substantive areas, see Viviana Munoz Tellez, Can Negotiations at the World Health Organization Lead to a Just Framework for the Prevention, Preparedness and Response to Pandemics as Global Public Goods?, Research Paper 147, February 2022, South Centre, [The South Centre | Research Paper 147, 28 February 2022](#); and Katrina Pehudoff et al, A pandemic treaty for equitable global access to medical countermeasures: seven recommendations for sharing intellectual property, know-how and technology, *BMJ Glob Health*, 2022 Jul;7(7):e009709, [PubMed \(nih.gov\)](#).
- <sup>24</sup> See European Union initial textual proposals for an agreement on pandemic prevention, preparedness and response, 28 March 2023, article G.1.6 Benefit Sharing Through Equitable Access to Countermeasures, and G.2.1, Availability of countermeasures, available at [EU proposals integrated into the ZD 28 March.pdf \(europa.eu\)](#).
- <sup>25</sup> Tovar da Silva Nunes, Ahmed Soliman, Kazuho Taguchi, Precious Matsoso, Roland Alexander Driecé, Viroj Tangcharoensathien, Addressing inequity: the world needs an ambitious Pandemic Accord, Comment, *The Lancet*, July 05, 2023, [https://doi.org/10.1016/S0140-6736\(23\)01369-7](https://doi.org/10.1016/S0140-6736(23)01369-7).

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The South Centre  
International Environment House 2  
Chemin de Balexert 7-9  
PO Box 228, 1211 Geneva 19  
Switzerland  
Tel.: +41 22 791 8050  
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