

# Mainstreaming Equity in the International Health Regulations and Future WHO Legal Instruments on Pandemic Preparedness and Response

By Nirmalya Syam\*

## Introduction

In the wake of the ongoing COVID-19 pandemic and the constraints to preparedness and response to a pandemic of such global scale, the Member States of the WHO have agreed to undertake parallel processes aimed at strengthening the legal norms relating to pandemic preparedness and response under existing and potentially new international legal instruments under the WHO Constitution, with the objective of enabling

the WHO and its Member States to be better prepared to prevent and respond to future pandemics, learning from the experiences of COVID-19.

In this context, the Special Session of the World Health Assembly had agreed to launch negotiations for a pandemic treaty or other legal instrument under the WHO Constitution and agreed to constitute an Intergovernmental Negotiating Body (INB) to prepare the zero draft text for negotiations.<sup>1</sup> In parallel, a previously constituted

## Abstract

The Member States of the WHO are about to commence the most significant negotiations that could set the paradigm for international legal obligations for preparedness and response to future pandemics. These negotiations focus on amendments to the International Health Regulations (2005) (IHR) as well as the negotiation of a treaty or other legal instrument under the WHO Constitution that will complement the IHR to ensure better preparedness and response to future pandemics, drawing from the experiences of the ongoing COVID-19 pandemic. The most critical consideration for developing countries in these negotiations will be mainstreaming equity concerns, currently missing from the existing rules and mechanisms available globally to enable developing countries to effectively prevent and respond to a pandemic outbreak. In this context, this brief suggests some elements of equity that should be pursued through specific textual proposals by developing countries through amendments to the IHR.

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*Los Estados miembros de la OMS están a punto de iniciar las negociaciones más importantes que podrían establecer el paradigma de las obligaciones jurídicas internacionales en materia de preparación y respuesta a futuras pandemias. Estas negociaciones se centran en las enmiendas al Reglamento Sanitario Internacional (2005) (RSI), así como en la negociación de un tratado u otro instrumento jurídico en el marco de la Constitución de la OMS que complemente el RSI para garantizar una mejor preparación y respuesta ante futuras pandemias, basándose en las experiencias de la actual pandemia de COVID-19. La consideración más crítica para los países en desarrollo en estas negociaciones será la integración de las preocupaciones de equidad, actualmente ausentes de las normas y mecanismos existentes a nivel mundial para permitir a los países en desarrollo prevenir y responder eficazmente a un brote pandémico. En este contexto, este informe sugiere algunos elementos de equidad que deberían perseguirse a través de propuestas textuales específicas de los países en desarrollo mediante enmiendas al RSI.*

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*Les États membres de l'OMS sont sur le point d'entamer les négociations les plus importantes qui pourraient définir le paradigme des obligations juridiques internationales en matière de préparation et de riposte aux futures pandémies. Ces négociations portent sur les amendements au Règlement sanitaire international (2005) (RSI) ainsi que sur la négociation d'un traité ou d'un autre instrument juridique dans le cadre de la Constitution de l'OMS qui complétera le RSI afin d'assurer une meilleure préparation et une meilleure riposte aux futures pandémies, en tirant parti de l'expérience de la pandémie actuelle de COVID-19. La considération la plus critique pour les pays en développement dans ces négociations sera l'intégration des préoccupations d'équité, actuellement absentes des règles et des instruments existants disponibles au niveau mondial pour permettre aux pays en développement de prévenir et de répondre efficacement à une pandémie. Dans ce contexte, ce document suggère quelques éléments d'équité qui devraient être poursuivis par des propositions textuelles spécifiques des pays en développement par le biais des amendements au RSI.*

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WHO Working Group on Pandemic Preparedness and Response (WGPR) has been mandated to undertake discussions on implementation of the recommendations emanating from four separate but related reviews undertaken to assess the preparedness and response to the COVID-19 pandemic (IAOC, IHR Review, IPPR and GPMB).<sup>2</sup> The WHO Executive Board session in February 2021 also agreed that dedicated discussions will take place in the WGPR to consider amendments to the International Health Regulations (2005) to address specific and clearly identified issues and challenges without opening up the entire IHR for renegotiation.<sup>3</sup>

A major concern for developing countries and least developed countries (LDCs) in view of the experience of the COVID-19 pandemic is that calls and pledges for solidarity and equity-based actions to enable such countries to respond to the pandemic promptly, effectively and on an equal footing with developed countries have been ignored in practice. This has resulted in delayed and inadequate access to medical countermeasures such as diagnostics, vaccines and therapeutics and the sharing of technologies (including know-how) and the components for scaling up local production and supply of such products in developing countries and LDCs. This happened even though the medical countermeasures such as vaccines and therapeutics were developed with unprecedented speed and pathogen sequences were rapidly shared by all countries to facilitate their rapid development. Hence, addressing these issues should be a priority for WHO Member States, particularly developing countries and LDCs, in any negotiation over revision of existing WHO legal instruments or negotiation of any new treaty or other legal instrument under the WHO Constitution. As described below, these are part of a broad theme of issues that have been categorized under an umbrella term – “equity” – as agreed to by the Member States in the WGPR, and subsequently endorsed in relevant decisions of the Health Assembly and the Executive Board.

### **Meaning of “Equity” in the Context of the Member State Discussions in the WHO**

At the second session of the WGPR held in September 2021, WHO Member States considered a report by the WHO Secretariat which had proposed to categorize the various COVID-19 related recommendations from official WHO reviews (the IHR Review, the IPPR Report and the IOAC report), documents from external inter-governmental platforms (such as the G-20, G-7 and the Global Health Summit), recommendations from independent expert parties (such as the Global Preparedness and Monitoring Board, the Panel for a Global Health Convention, and the Pan-European Commission on Health and Sustainable Development). In this context, the WGPR requested the Secretariat to add “equity” as a specific category to “... include recommendations, ranging from issue of timely access to pandemic countermeasure resources including through research and development, voluntary licenses, technol-

ogy transfer, and capacity building for manufacturing of medical products and commodities as well as those related to social protection and universal health coverage”.<sup>4</sup> Thus, the term equity was agreed upon among WHO Member States as an umbrella term to encompass issues relating to access to medical countermeasures, as well as social protection issues.<sup>5</sup> At the third meeting of the WGPR in October 2021, the WHO Secretariat updated its report on COVID-19 related recommendations introducing the category of equity, which included recommendations relating to four broad themes identified by the Secretariat – economic and social protection including human rights, equitable access to healthcare goods and services including vaccines and/or non-pharmaceutical measures, and equitable representation and participation (gender, geographic and socioeconomic status).<sup>6</sup>

The issues related to equitable access to medical countermeasures were further detailed in the report of the WGPR to the Special Session of the WHA as including research and development, intellectual property, technology transfer, empowering or scaling up local and regional manufacturing capacities during emergencies to discover, develop and deliver effective medical countermeasures and other tools and technologies. In this context, the report stated that these issues could be meaningfully addressed under the umbrella of a potential new instrument and through discussions in several other relevant global forums.<sup>7</sup> The decision of the WHA Special Session establishing the INB recognized the commitment of Member States to develop a new instrument prioritizing the need for equity.

After the conclusion of the WHA Special Session, the US had submitted an informal proposal suggesting certain targeted amendments to the IHR.<sup>8</sup> Following informal consultations on the proposal Member States agreed to recommend the Executive Board of the WHO to adopt a decision that noted that that the WGPR will include dedicated time for discussion on strengthening the IHR through implementation, compliance and potential amendments. The decision also urged Member States to take all appropriate measures and consider potential amendments to the IHR, which

“... should be limited in scope and address clearly identified issues, challenges, including equity, technological or other developments, or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation and compliance of the International Health Regulations (2005), and their universal application for the protection of all people of the world from the international spread of disease in an equitable manner....”<sup>9</sup>

It should be noted here that the EB decision does not refer to the possible amendments to the IHR as “targeted amendments.” Instead, the decision allows for consideration of any amendment with the condition that the scope of the amendments should be limited, and address clearly identified issues and challenges including equity, insofar as they are critical to supporting effective implementation

and compliance with the IHR and their universal application for protection of all people all over the world from international spread of disease in an equitable manner. It is noteworthy that the reference to the need for the amendments to be limited in the relevant sentence of the EB decision is followed by the words "... and address clearly identified issues and challenges **including** equity..." without any comma after the words "limited in scope". This suggests that "equity" as such is a clearly identified issue and member States may propose any amendment to advance equity issues in the IHR. In other words, amendments relating to equity will be within the scope of a limited IHR amendment exercise. This decision should not be misinterpreted to suggest that only limited equity issues could be addressed in the IHR.

A harmonious reading of the decision of the WHA Special Session establishing the INB and the EB decision on strengthening IHR clearly demonstrates that both decisions recognize that equity is a central and cross-cutting issue that should be addressed both in a new instrument negotiated in the INB as well as in the amendments to the IHR. Thus, it will be critical for WHO Member States, particularly developing countries and LDCs, to advance proposals to mainstream equity in both instruments.

The issue of equity should not be left for consideration only in a future instrument such as a pandemic treaty to be negotiated under the INB but should also be addressed in the context of the WGPR discussions, particularly concerning amendments to the IHR. An approach of mainstreaming and addressing equity issues both in any future instrument and the IHR would also safeguard against any State Party not ratifying a future instrument and hence absolving itself from the scope of obligations relating to equity, as similar obligations under the IHR would still apply given the nature of the IHR as an instrument under article 21 of the WHO Constitution that applies to all WHO Member States, unless opted out within 18 months of notification of amendment of the Regulations.<sup>10</sup> In this context, it is noteworthy that in the recently concluded session of the WGPR in February 2022, the African Group had stated that "We recommend that Equity should be addressed both the within the potential IHR (2005) amendments well as the new international instrument. Therefore, equity provisions proposed in the IHR (2005) should be complemented in zero draft prepared by the INB with cross referencing to relevant IHR provisions."<sup>11</sup>

It is also important to note that the IHR as an instrument under article 21 and any future instrument under article 19 of the WHO Constitution addressing pandemic preparedness and response, will both have the same status as a treaty under the Vienna Convention on the Law of Treaties (VCLT). The VCLT defines a treaty as an international agreement in written form between States which is governed under international law, whatever be its designation or form.<sup>12</sup> Indeed, the IHR

used to be referred to as the International Sanitary Convention before the establishment of the WHO, and it is also deposited with the UN Secretary-General as a treaty like other international treaty instruments. Hence, following the adoption of a new instrument from the INB negotiations WHO and its Member States will have to implement harmoniously provisions of two related treaty instruments – the IHR and a new instrument. Therefore, it will be critical to address the issue of access to medical countermeasures as global public goods and related issues as elements of equity in both instruments to ensure mutual supportiveness and complementarity between them.<sup>13</sup> Provisions should be included in the text of the IHR and any other future instrument to address specific equity challenges faced by developing countries and LDCs, e.g., relating to availability and affordable access to medical countermeasures, and corresponding responsibilities and legal obligations of the WHO Secretariat and its Member States, particularly developed countries.

The following sections address elements of equity that could be considered by developing countries as possible amendments to the IHR to be discussed by the WGPR.<sup>14</sup>

### **Equity in the Scope of the Instruments**

In mainstreaming equity issues in the IHR, equity should be specifically mentioned as a principle in the provisions relating to definitions, object, purpose, and scope. Given the critical need to ensure that the IHR specifically addresses the need for equitable access to medical countermeasures for all States Parties to enable a public health response to the international spread of disease, a specific definition of the term "medical countermeasures" could be introduced under Article 1 of the IHR to clarify that medical countermeasures include diagnostics, vaccines, drugs, medical therapies and other health products, technologies and know-how. Subsequent provisions could spell out the elements of an equitable approach to ensure access to medical countermeasures.

Similarly, new language could be proposed to amend Article 2 of IHR to specify that the purpose of the IHR is to provide a public health response to the international spread of disease in ways that are equitable. The current text of Article 2 does not require such response to be equitable but only requires such response to be commensurate with public health risks. Following such amendment, Article 2 would clarify that the purpose and scope of the IHR is to prevent, protect against, control and provide a public health response in ways that are commensurate with and restricted to public health risks, ensure equitable access to medical countermeasures for all States Parties, and avoid unnecessary interference with international traffic and trade.

Equity as a principle should also be reflected in article 3 of the IHR which lays down the principles guiding its implementation. These principles currently do not include any reference to equity and cooperation, nor does it recognize the need for considering and addressing the differences in technical and financial capacities of States Parties,

though many developing countries lack the necessary technical and financial capacities for implementation of the obligations under IHR. Hence, developing countries should consider amending article 3 of the IHR to introduce a new principle that implementation of the IHR must be based on equity and cooperation towards all States Parties while considering and addressing differences in technological and economic capacities and levels of development of States Parties.

### **Equity in Provisions Relating to Prevention, Detection and Control of Pandemic Threats**

In the context of the IHR, the US had submitted informal textual proposals for introducing new obligations under the IHR for implementing a preventive and precautionary approach.<sup>15</sup>

While these issues require further discussion, equity should be at the centre of any provision laying down obligations to take preventive measures. These would include the supply of technological, financial and training of human resources for developing countries with less resources and weak health systems (see below). Equity should also be mainstreamed in the design of any early warning system or issuance of intermediate or regional alerts by the WHO under the IHR in terms of the consequences of such alerts, to ensure that needs of developing countries, such as with regard to medical countermeasures, are adequately safeguarded through corresponding obligations on the WHO and other States Parties.

### **Developing Country Obligations Subject to Provision of Finance and Technology**

A key issue for developing countries with regard to prevention, detection and response to pandemic threats is the need for financial and technological support for establishing, maintaining and strengthening core capacities for the same, as they can be constrained from taking effective pandemic prevention and response measures due to limited resources and weak health systems. All States do not have similar capacities to deal with the problem of international spread of disease. Therefore, the obligations that States must comply with must take these capacity challenges into account and ensure that true cooperation is extended to such countries to build the required capacities to enable them to respond to a pandemic or international spread of disease on an equal footing with other countries. Therefore, international cooperation, including official development assistance, should be directed towards building capacities for prevention and response in low-income countries to ensure a truly global response to future pandemics. Such a provision could be a core element to be included through appropriate amendments under Article 5.1 (core capacities for detection) and article 13.1 (core capacities for prompt response) of the IHR.

Consideration could also be given to establishing a dedicated financing and technology transfer mecha-

nism within WHO to facilitate a rapid response to a pandemic through scaled up local production of medical countermeasures including diagnostics, vaccines and therapeutics.<sup>16</sup>

### **Ensuring all WHO Actions in Response to a Pandemic are Consistent with the IHR**

Currently, the WHO response to a pandemic after declaration of a PHEIC can also include many other initiatives which are outside the scope of IHR (e.g., initiatives like ACT-A and mechanisms relating to vaccines – COVAX –, diagnostics and therapeutics under it, other initiatives like the BioHub, etc.). These include initiatives based on partnership with corporations, philanthropies, etc. However, such initiatives may have impactful consequences for equitable access to medical countermeasures. Therefore, it will be pertinent to introduce a new provision in the IHR to the effect that upon a declaration of PHEIC, all actions of the WHO must be consistent with the IHR.

### **Obligation to Provide Support to WHO Coordinated Response**

Article 13.5 of the IHR exhorts all States Parties to provide support to the WHO coordinated response activities. Language could be added to this provision to make it mandatory and not optional for States Parties to provide support to the WHO coordinated response, taking into account different levels of development and capacity of parties to contribute, and specifying that these activities would include supply of health products and technologies including diagnostics, therapeutics and vaccines for effective response to a PHEIC. Moreover, additional language could be included requiring any State Party that is unable to provide the support requested by WHO to provide reasons for the same to the Director-General, which should be reported under the IHR reporting mechanisms to the WHA. Corresponding mandatory obligations could also be included in the text of any future instrument complementing the IHR.

### **Obligations to Facilitate Production, Availability and Access to Medical Countermeasures**

Currently there is no binding legal obligation on the part of the WHO Secretariat<sup>17</sup> or States Parties to address issues relating to facilitation of access to medical countermeasures. Hence it would be pertinent to introduce new provisions in the IHR relating to access to medical countermeasures, technologies and know-how for public health response to specify actions that must be taken relating to this aspect of the public health response on the part of the WHO and States Parties, following the declaration of a PHEIC, or any potential early alert agreed upon. Such provisions could introduce the following obligations:

- 1) Obligation on the part of the WHO Secretariat to undertake an immediate assessment following the declaration of a PHEIC or an early alert about the availability and affordability of medical countermeasures for an effective global response to the disease.

- 2) Obligation on the part of the WHO Secretariat to identify medical countermeasures that are necessary to respond to the spread of the disease promptly, adequately and effectively.
- 3) Obligation on the part of the WHO Secretariat to issue temporary or standing recommendations under articles 15 and 16 of IHR for global equitable allocation of available medical countermeasures.
- 4) Obligation on States Parties to cooperate with each other and the WHO in the implementation of such recommendations.
- 5) Obligation on States Parties to provide exemptions under applicable laws and regulations for third parties' use of intellectual property rights as needed to ensure the timely supply of the medical countermeasures concerned, including their materials and components.
- 6) Obligation on States Parties to require recipients of public subsidies to develop or produce medical countermeasures identified by WHO as necessary for a public health response to a PHEIC, to make them available at marginal costs.
- 7) Obligation on States Parties to rapidly share with the WHO all relevant regulatory dossiers submitted by manufacturers of medical countermeasures for responding to a PHEIC. This can be complemented by corresponding obligation on the WHO Secretariat to share the same immediately upon request by any State Party for scaling up manufacturing process and expediting regulatory approvals.
- 8) Obligation on the WHO Secretariat to facilitate local manufacturing and scaling up of medical countermeasures in all States Parties upon the declaration of a PHEIC or issuance of an early alert (if introduced under the IHR) by making available specifications, developing regulatory guidelines for the rapid approval of new products, establishing a database on required raw materials and potential suppliers and a repository of cell lines to speed up the development of biologicals, including vaccines.
- 9) Obligation on States Parties to ensure that all actors within their territories (e.g., manufacturers, suppliers, regulatory authorities, IP offices) act consistently with the IHR obligations and WHO recommendations thereunder.

### **Pathogens, Sequence Information and Benefit-Sharing**

In the informal textual proposal on targeted amendments to the IHR,<sup>18</sup> the US had suggested language under article 6 of the IHR obligating States Parties where an event occurs to promptly share information relating to the genome sequence of the pathogen causing the

disease. Currently the IHR does not obligate States Parties to specifically share sequence information. However, one major demand from developed countries in both the IHR and the text of a future instrument will concern the issue of rapid sharing of pathogens, particularly their sequence information. While rapid sharing of pathogens and sequence information is indeed necessary, for developing countries equitable access to the medical countermeasures developed through such shared material or information is also of primary interest. Therefore, any proposal for a provision imposing obligations to share pathogens and their sequence information must be in accordance with the provisions of the Convention on Biological Diversity (CBD) and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (hereinafter the Nagoya Protocol) or any special agreement developed thereunder. It should treat obligations on rapid access to pathogen samples and sequence information on an equal footing with rapid, equitable and adequate access to all States Parties through a WHO allocation mechanism to the medical countermeasures derived or developed from such material or information, as well as sharing of the technology and knowhow for the same with all States Parties.

Currently, there is no legal framework within the WHO on sharing of pathogen samples or sequence information other than the PIP Framework which is limited in scope to influenza pathogens of pandemic potential. However, the WHO Secretariat has launched initiatives such as the Bio-Hub<sup>19</sup> with some Member States though these currently are not governed by a legal framework for pathogen and benefit-sharing agreed to by all WHO Member States. The issue of pathogen and benefit-sharing remains unaddressed in the WHO and it is possible that a legal framework specific to pathogen and benefit-sharing within the WHO could be developed.

### **Conclusion**

The COVID-19 pandemic has glaringly exposed the lack of equity and solidarity towards developing countries to enable them to be prepared for and respond effectively to the pandemic. As the WHO Member States undertake the most important reforms laying down binding legal obligations on the part of States to prevent and respond better to future pandemics, it will be imperative to ensure that equity does not remain an empty rhetoric but is transposed into concrete and specific legal obligations under the IHR as well as any complementary future treaty or other legal instrument under the WHO Constitution. To that end, developing countries in the WHO must advance proposals to mainstream equity in every facet of the legal architecture in the WHO about pandemic preparedness and response. Noting that the IHR is an existing instrument that will continue to apply to future pandemics with possible amendments and a complementary treaty or other legal instrument, equity issues should be addressed in the relevant provisions of the IHR which could be cross-referenced into the provisions of a complementary future instrument.

This would ensure that even WHO members that do not ratify a convention developed under Article 19 of the WHO Constitution or who do not endorse any other instrument, as adopted by the WHO membership, are subject to equity obligations specified through IHR amendments that mainstream equity therein.

#### Endnotes:

<sup>1</sup> World Health Assembly Second Special Session Decision, SSA2(5). Available from [https://apps.who.int/gb/ebwha/pdf\\_files/WHASSA2/SSA2\(5\)-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHASSA2/SSA2(5)-en.pdf).

<sup>2</sup> World Health Assembly Resolution, WHA 74.7. Available from [https://apps.who.int/gb/ebwha/pdf\\_files/WHA74-REC1/A74\\_REC1-en.pdf#page=27](https://apps.who.int/gb/ebwha/pdf_files/WHA74-REC1/A74_REC1-en.pdf#page=27).

<sup>3</sup> WHO Executive Board Decision, EB150(3). Available from [https://apps.who.int/gb/ebwha/pdf\\_files/EB150/B150\(3\)-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/EB150/B150(3)-en.pdf).

<sup>4</sup> WHO document A/WGPR/2/4. Available from [https://apps.who.int/gb/wgpr/pdf\\_files/wgpr2/A\\_WGPR2\\_4-en.pdf](https://apps.who.int/gb/wgpr/pdf_files/wgpr2/A_WGPR2_4-en.pdf). The promise of equity was a key driver for developing countries to support the negotiations of the treaty. See Nicoletta Dentico et. al., "The politics of a WHO pandemic treaty in a disenchanted world", G2H2 Report, Geneva, December 2021, p.35. Available from <https://g2h2.org/wp-content/uploads/2021/11/The-Politics-of-a-WHO-Pandemic-Treaty-final.pdf>.

<sup>5</sup> The WHO Secretariat applies a working definition of "health equity" in the context of its work on "social determinants of health" – "Health equity is defined as the absence of unfair and avoidable or remedial differences in health among population groups defined socially, economically, demographically and geographically." See WHO, Social determinants of health. Available from [https://www.who.int/health-topics/social-determinants-of-health#tab=tab\\_3](https://www.who.int/health-topics/social-determinants-of-health#tab=tab_3).

<sup>6</sup> WHO document A/WGPR/3/5. Available from [https://apps.who.int/gb/wgpr/pdf\\_files/wgpr3/A\\_WGPR3\\_5-en.pdf](https://apps.who.int/gb/wgpr/pdf_files/wgpr3/A_WGPR3_5-en.pdf).

<sup>7</sup> WHO document A/WGPR/5/2. Available from [https://apps.who.int/gb/wgpr/pdf\\_files/wgpr5/A\\_WGPR5\\_2-en.pdf](https://apps.who.int/gb/wgpr/pdf_files/wgpr5/A_WGPR5_2-en.pdf).

<sup>8</sup> See Submission of the United States of America, Proposed Amendments to the International Health Regulations (2005), Articles 5, 6, 9, 10, 11, 12, 13, 15, 18, 48, 49, 53, 59, 20 January 2022. Available from <https://healthpolicy-watch.news/wp-content/uploads/2022/02/C.L.2.2022-IHR-amendments-English.pdf>.

<sup>9</sup> WHO Executive Board Decision, *supra* note 3.

<sup>10</sup> Article 22 of the WHO Constitution states that "Regulations adopted pursuant to Article 21 shall come into force after due notice has been given of their adoption by the Health Assembly except for such Members as may notify the Director-General of rejection or reservations within the period stated in the notice." Accordingly, Article 59.1 of the IHR states that the period for rejection of or reservation to any amendment to the Regulations is 18 months from the date of notification by the Director-General of the adoption of the amendments by the Health Assembly.

<sup>11</sup> Priti Patnaik, "Game on at WHO: International Health Regulations vs. the Pandemic Treaty", Geneva Health Files, 3 March 2022. Available from <https://genevahealthfiles.substack.com/p/game-on-at-who-international-health?s=r>.

<sup>12</sup> Article 2 (1), Vienna Convention on the Law of Treaties.

<sup>13</sup> See generally, 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 No.147 (Geneva, South Centre, February 2022). Available from [https://www.southcentre.int/wp-content/uploads/2022/02/RP-147\\_Can-Negotiations-at-WHO-Lead-to-a-Just-Framework-for-the-Prevention-Preparedness-and-Response-to-Pandemics-as-Global-Public-Goods\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2022/02/RP-147_Can-Negotiations-at-WHO-Lead-to-a-Just-Framework-for-the-Prevention-Preparedness-and-Response-to-Pandemics-as-Global-Public-Goods_EN.pdf).

<sup>14</sup> While the WHO Executive Board decision has given the mandate to the WGPR to consider possible amendments to the IHR, the IHR itself allows States Parties to submit proposals for amendment of IHR at any time. According to article 55.1 of the IHR, any State Party or the Director-General may propose amendments to the IHR for the consideration of the Assembly. The only procedural requirement in this regard as stated in article 55.2 is that text of the proposed amendment shall be communicated to all States Parties by the Director-General four months before the Assembly that will consider the proposed amendments.

<sup>15</sup> See Submission of the United States of America, *supra* note 8. These include proposals for developing early warning criteria for assessing and progressively updating the risk posed by an event of unknown cause, notifying FAO, OIE and UNEP if a notification of an event that could constitute a public health emergency of international concern (PHEIC), empowering the WHO DG to issue an intermediate alert for an event, empowering the Regional Director to notify an event as a public health event of regional concern, and provide related guidance to States Parties in the region.

<sup>16</sup> The experience of the WHO mRNA Hub that was established in June 2021 to share technology and technical know-how with local producers for the production of mRNA vaccines could be explored in this context. See World Health Organization, The mRNA vaccine technology transfer hub. Available from <https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub>. Also see David Richard Walwyn, "How drug companies are sidestepping WHO's technology transfer hub in Africa", DowntoEarth, 14 March 2022. Available from <https://www.downtoearth.org.in/blog/world/how-drug-companies-are-sidestepping-the-who-s-technology-transfer-hub-in-africa-81938>.

<sup>17</sup> It should be noted that several provisions of the IHR (2005) place specific obligations on the WHO secretariat, e.g., article 10.1 states that the "WHO shall request, ... verification ..." of event reported. Article 11 places obligation on the WHO to share specific information.

<sup>18</sup> *Ibid*.

<sup>19</sup> The WHO BioHub is a voluntary mechanism for WHO Member States to share biological materials with epidemic or pandemic potential through laboratories designated as a WHO BioHub Facility. See World Health Organization, WHO BioHub. Available from <https://www.who.int/initiatives/who-biohub>.

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