

## A New WHO International Treaty on Pandemic Preparedness and Response: Can It Address the Needs of the Global South?

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### The Idea of a "Pandemic Treaty"

Twenty-five Heads of Government<sup>1</sup> have called for a new international treaty to improve the response to pandemics. On 30 March 2021, these leaders joined the European Council President, Charles Michel, and the World Health Organization (WHO) Director-General, Tedros Adhanom Ghebreyesus, in calling to negotiate an international treaty on pandemics, based on lessons learned during the COVID-19 emergency.<sup>2</sup>

The communiqué notes that there will be other pandemics and major health emergencies and that the question is not whether or not they will happen,

### Abstract

A recent joint communiqué by 25 Heads of Government and the WHO Director-General have called for the negotiation of a pandemic treaty to enable countries around the world to strengthen national, regional and global capacities and resilience to future pandemics. The COVID-19 pandemic has demonstrated the fragility of the mechanisms at the disposal of WHO for preparedness and response to pandemics. The use of binding instruments to promote and protect health in the context of pandemics is needed. If WHO Member States decide that an international treaty to prepare and respond to pandemics is the way forward, it would be important to have clarity from the outset on the elements and areas that will be the subject of negotiation. The first step should be to identify the aspects of pandemic preparedness and response that the current crisis has revealed are not working, and how to build up on the existing instruments, notably the International Health Regulations (IHR). This paper discusses some of the critical issues that should be addressed in such a treaty if negotiations are launched, in view of the needs of countries at different levels of development and with disparate capacities to implement treaty obligations.

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Un reciente comunicado conjunto de 25 Jefes de Gobierno y el Director General de la OMS han pedido que se negocie un tratado sobre pandemias que permita a los países de todo el mundo reforzar las capacidades y resiliencia nacionales, regionales y mundiales ante futuras pandemias. La pandemia del COVID-19 ha demostrado la fragilidad de los mecanismos a disposición de la OMS para la preparación y la respuesta a las pandemias. Es necesario utilizar instrumentos vinculantes para promover y proteger la salud en el contexto de las pandemias, sería importante tener claro desde el principio los elementos y áreas que serán objeto de negociación. El primer paso debe ser identificar los aspectos de la preparación y la respuesta ante una pandemia que la crisis actual ha puesto de manifiesto que no funcionan, y cómo aprovechar los instrumentos existentes, especialmente el Reglamento Sanitario Internacional (RSI). Este documento analiza algunas de las principales cuestiones que deberían abordarse en un tratado de este tipo si se inicia la negociación, teniendo en cuenta las necesidades de países que están en diferentes niveles de desarrollo y con capacidades dispares para aplicar las obligaciones del tratado.

Dans un récent communiqué signé par 25 chefs de gouvernement et le Directeur général de l'OMS, ceux-ci ont appelé à la négociation d'un traité sur les pandémies afin de permettre aux pays du monde entier de renforcer les capacités et la résilience des pays aux niveaux national, régional et mondial face aux futures pandémies. La pandémie de COVID-19 a démontré la fragilité des mécanismes dont dispose l'OMS pour se préparer et réagir aux pandémies. L'utilisation d'instruments contraignants pour promouvoir et protéger la santé dans le contexte des pandémies est nécessaire. Si les États Membres de l'OMS décident que le recours à un traité international de préparation et de riposte aux pandémies est la voie à suivre, il serait important de clarifier dès le départ les éléments et les domaines qui feront l'objet de négociations. La première étape devrait consister à identifier les aspects de la préparation et de la révelé les inefficacités, et à déterminer comment s'appuyer sur les instruments existants, notamment le Règlement sanitaire international (RSI). Ce document examine certaines des questions essentielles qui devraient être abordées dans un tel traité si les négociations sont lancées, en tenant compte des besoins des pays à niveaux de développement différents et des capacités disparates pour mettre en œuvre les obligations découlant du traité.

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but when: "[W]e must be better prepared to predict, prevent, detect, assess and respond effectively to pandemics in a coordinated manner".<sup>3</sup> "To that end", states the communiqué, "... nations should work together towards a new international treaty for pandemic preparedness and response".<sup>4</sup> However, at this stage the objectives, scope and contents of the treaty have not been elaborated upon by its proponents.

According to the communiqué, "A treaty is a legally binding instrument of international law. An international pandemic treaty adopted within the framework of the World Health Organization (WHO) would enable countries around the world to strengthen national, regional and global capacities and resilience to future pandemics."<sup>5</sup>

This paper discusses some of the critical issues that should be addressed in such a treaty if negotiations are launched, in of view the needs of countries at different levels of development and with different capacities to implement treaty obligations.

## Emergency Preparedness and Response by WHO

In accordance with article 2 (a) of the WHO Constitution, as adopted in 1946, "the Organization act as the directing and coordinating authority on international health work". Its functions include to provide "necessary aid in situations of health emergency upon the request or acceptance of governments", as well as "to stimulate and advance work to eradicate epidemic, endemic and other diseases" (article 2 (d) and (g). Under Articles 21(a) and 22 of the Constitution, the World Health Assembly (WHA) is empowered to adopt regulations "for the prevention of the international spread of disease" which, once adopted by WHA, take effect for all Member States of WHO "except those which expressly reject them within the prescribed period". The management of global action against the international spread of disease has been, hence, a fundamental and historic responsibility of WHO.

The principal normative instrument that WHO currently has to respond to health emergencies is the International Health Regulations (IHR), adopted by WHA in 1969. The purpose of IHR is "... to prevent, protect against, control and provide a public health response to international spread of diseases ...."<sup>6</sup>. All WHO Member States are States Parties to the IHR and none have opted out of the instrument. The IHR was revised in 2005 to overcome the original limitation of the notifiable diseases to yellow fever, plague and cholera. While the type of diseases is not

limited, the IHR 2005 imposes a limitation on the measures that may affect international traffic or trade.

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The International Health Regulations (IHR) set out minimum core capacities that States Parties must put in place to detect, assess, report and respond to potential public health emergencies of international concern (PHEIC).7 However, most States Parties to the IHR have not fully established the required core capacities. Many countries with limited resources have been unable to provide the domestic resources necessary to that end. Only a few rich countries have provided technical or financial cooperation to build core capacities in spite of the obligation under article 44 of the IHR for States Parties to engage in such cooperation.<sup>8</sup> Concerns over adverse economic impact on a country following a declaration of PHEIC (in the form of possible temporary recommendations of travel or trade restrictions by the IHR Emergency Committee) may discourage States Parties from promptly sharing information about a potential PHEIC.9 While in the context of the COVID-19 emergency, the genome sequence information was promptly shared,<sup>10</sup> many countries have acted unilaterally and without coordination regarding the movement of people and traffic of goods.<sup>11</sup>

Indeed, the COVID-19 pandemic demonstrated that no government could address the threat of this or future pandemics on its own. It has shown that there is a need for a collective and organized action to protect the public health at the global level and ensure that the needs of all countries, particularly the developing and least developed countries, are advanced and safeguarded. However, the WHO Member States are still awaiting the findings of the International Health Regulations (IHR) Review<sup>12</sup> and the review by the Independent Panel for Pandemic Preparedness and Response (IPRP) that have been initiated to have an informed view on how existing WHO mechanisms have responded to the pandemic. It would be important for WHO Member States to consider the findings of these reviews, suggestions of Member States13 and of relevant studies to understand the existing gaps in pandemic preparedness and response and how the proposed pandemic treaty would address those gaps.

In the context of such reviews, WHO Member States should, in particular, address the systemic deficiencies that allowed many governments to disregard WHO guidance on how to deal with the spread of the virus, notably regarding travel and trade restrictions and equality in the global distribution of vaccines– practicing, instead, vaccine nationalism<sup>14</sup>–thereby offering lip service to global solidarity.<sup>15</sup>

While addressing such aforementioned systemic deficiencies, it will be important to recognize the efforts made by the WHO Secretariat to respond to the COVID-19 pandemic, inter alia, by issuing more than 400 guidance documents for individuals, communities, schools, businesses, industries, health workers, health facilities and governments related to different aspects of the COVID-19 pandemic in the first six months of 2020,<sup>16</sup> defining priority groups for vaccination in all countries, undertaking efforts to generate funding for the distribution of vaccines in low and middle income countries, coordinating clinical trials, supplying timely information about vaccine candidates, etc. But these initiatives were ostensibly insufficient to articulate a truly global and coherent response to the pandemic and its devastating effects.

The pandemic has been a telling reminder of the fragility of the mechanisms at the disposal of the WHO and reveals that the organization does not have the means to enforce its standards and guidance.<sup>17</sup> Moreover, WHO financing is not sustainable and adequate to respond to the challenge of COVID-19 and future pandemics.

If a new binding instrument were negotiated it should help to address some of those weaknesses and contribute to establish a stronger international health framework, with WHO as the governing authority for global health not only de facto but de jure. Such an instrument should be based on principles of equity, solidarity, inclusiveness and transparency, and allow for a collective and coordinated action that ensures, in particular, universal and equitable access to diagnostics, vaccines and medicines needed to address a pandemic. It would also be important to ensure an adequate balance of legal rights and obligations of countries at different levels of development. To this end, it would be critical to ensure that there is effective participation of all countries in the negotiations.<sup>18</sup>

## Strengthening or Marginalization of WHO

Any discussion on a future framework in WHO<sup>19</sup> on pandemic preparedness and response should be informed by the experience of past initiatives and reforms undertaken in the WHO and avoid the mistakes of the past. In every health crisis, be it HIV/AIDS or now COVID-19, WHO Member States have chosen to allocate funding and the power to act outside WHO, leading to fragmentation of the global health governance with the creation of parallel agencies or mechanisms and the consequent marginalization of the role of WHO. This has weakened rather than strengthened the organization. It would be important not to repeat these mistakes. In 1986, Jonathan Mann, Director of WHO Global Programme on AIDS (GPA), organized a direct action strategy; to provide treatment and conduct/coordinate research by a team of 200 scientists and with an expenditure of US\$ 70 million per year, which led to a confrontation with the then Director-General, Hiroshi Nakajima of Japan. Because of this confrontation, Mann left WHO, and the United States and other countries decided to withdraw the GPA from WHO. After some years of discussion and debate, the Joint United Nations Programme on HIV/AIDS (UNAIDS) was founded in 1994–1995 under the leadership of Peter Piot.

The Global Fund to Fight AIDS, Tuberculosis and Malaria ("the Global Fund") was created in 2002 as an innovative financing mechanism that seeks to raise and rapidly disburse funds for programs to reduce the impact of HIV/AIDS, tuberculosis and malaria in lowand middle-income countries. The idea for the Global Fund came from the Brundtland administration, which envisioned it as an innovative mechanism for financing WHO. In this context, the Brundtland administration called for a "Massive Attack on the Diseases of Poverty" in December 1999. The Global Fund was finally established in January 2002, outside WHO, following negotiations involving donors, country governments, non-governmental organizations (NGOs), the private sector and the United Nations.

The Expanded Programme on Immunization was launched by the World Health Assembly (WHA) in 1974. This immunization program was one of the major functions of the WHO. However, this program was marginalized with the creation of Gavi, a partnership of public and private sector organizations, institutions and governments (including the Bill & Melinda Gates Foundation, the United Nations International Children's Emergency Fund [UNICEF], the World Bank, WHO, vaccine manufacturers, NGOs and technical and health research institutes), that was approved at the Board Meeting of the Gates Foundation in Seattle on 12 July 1999. Since then, Gavi has taken the lead role in global immunization programs, including through initiatives such as COVAX in the current COVID-19 pandemic.

The COVAX mechanism is the vaccine pillar of WHO Access to COVID-19 Tools (ACT) Accelerator, officially known as the "COVID-19 Global Vaccine Access Facility". It was established in April 2020 and is co-led by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI) and WHO. The funding and capacity to act are, once again, outside WHO.

## **The Pandemic Treaty**

The proposal for a pandemic treaty raises many questions that should be clarified before negotiations begin.

If a new international treaty on pandemic preparedness and response is to be negotiated, the mistakes of the past should be avoided and it should be ensured that any new functions remain within WHO and contribute to strengthen the organization's capacity to manage pandemics. A pandemic treaty should not create new parallel agencies or mechanisms outside the effective control of WHO and its Member States, leading to further fragmentation of the multilateral health governance structure and the consequent further marginalization of WHO.

There seems to be a recognition of the failure of the existing global system of health governance, and that WHO has not been able to play the role it was expected to perform. The COVID-19 pandemic has highlighted the need for a strong and independent global health governing body capable of managing a deficiencies in such instruments and mechanisms and what are the possible alternatives to address them; what would be the relationship of a new treaty with the IHR and other international agreements, particularly those in the context of WTO; and how a treaty could ensure effective circulation and access to needed goods, services and technologies during a pandemic.

## Building on Existing WHO Legal Instruments<sup>21</sup>

WHO competence includes proposing conventions, regulations and recommendations with respect to international health matters; the normative activity is considered to be part of its work in directing international health. The World Health Assembly (WHA) has the authority to adopt international conventions or treaties under article 19 of its Constitution (see Box). This competence, however, has been exercised only once for the adoption of the Framework Convention on Tobacco Control (FCTC).

WHO can also adopt, under the "opting-out" technique, regulations on technical issues. Past experience

#### Article 19 of the WHO Constitution

Article 19 of the WHO Constitution states: "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".

global health crisis. As Gostin, Moon and Mason Meier recently noted, "the world is facing an unprecedented global health threat, and the response is highlighting the structural limitations of the capacity of international organizations to coordinate with nation states".<sup>20</sup>

Whether this would need a new treaty to deal with pandemics or reviewing and strengthening the IHR (notably by introducing enforcement mechanisms and binding obligations to share resources including health technologies for preparedness and response to a pandemic by countries at different levels of development) is one of the preliminary issues to be assessed by the member States. In any case, as discussed below, such a treaty should build on the IHR as revised in 2005. A pandemic treaty may address some of the gaps in the global health governance, but would not address other systemic issues in the governance of public health, which would require further coordinated action by WHO Member States.

Before commencing negotiations on a pandemic treaty there is need for Member States to take an informed view of what legal instruments and mechanisms exist in WHO for pandemic preparedness and response. Some questions include what are the shows that in the negotiation of these regulations, given the asymmetric capacity of WHO members to participate, often a small group of countries can decisively influence the outcome. WHA can also make recommendations to members, which are of a voluntary nature and in most cases are not accompanied by mechanisms and strategies for concrete implementation.

Despite the substantial normative powers conferred, such as in Article 19 of the Constitution, in practice WHO has paid little attention to law—especially hard law—as a tool for the protection and promotion of health. On the contrary, it has shown itself to be more in favor of seeking political agreement and assumed a more persuasive rather than a role of enforcing legal obligations. The fact that in seventy years it has adopted only one international regulation on a sensitive issue (the control of infectious diseases) and only one international treaty in a substantive area (tobacco control) suggests that WHO still has a long way to go in promoting health through the law.

The WHO Framework Convention on Tobacco Control (FCTC), called by some the "vaccine" against cancer and cardiovascular disease is, as mentioned, the only binding convention negotiated under Article 19 of the WHO Constitution. In May 2003, after three years of negotiations and six years of work, WHA unanimously adopted FCTC, which has now been signed by 177 countries. This showed that WHO can exercise the power to adopt an international treaty in a substantive area to provide a legal response to a global health threat. This is undoubtedly one of the greatest achievements of WHO in its entire history.

Paradoxically, unlike other organizations such as WTO and FAO, WHO does not use legal means to enforce disciplines that are vital for the protection of global health. This situation can be attributed to the decisive influence of developed countries that are reluctant to adopt binding instruments, and is aggravated by the organization's financial dependence on donors' contributions, as shown by the imbalance between the regular budget (supported by members' mandatory contributions) and the voluntary contributions made by a small group of countries and a few philanthropic entities, which together contribute more than 80 per cent of the budget.

In the current international context brought about by COVID-19 and of the uncoordinated intervention of multiple health actors, WHO could regain its identity and leadership through the effective use of Article 19 of the Constitution in the negotiation and adoption of international conventions that will help member States to comply with their human rights obligations to promote the right to health.

However, reaching these objectives through a new pandemic treaty will depend on whether the treaty contains provisions that effectively advance the public interest in terms of the right to health over commercial interests of the healthcare industries, which are often unconditionally supported by the governments that host them. In this regard, the provision under Article 5.3 of FCTC that requires parties to protect policymaking and their implementation in respect of tobacco control from commercial and other vested interests could be worth emulating in a future pandemic treaty, if adopted, to safeguard health policymaking for pandemic preparedness and response from such interests.

It is also noteworthy that in a recent statement the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) which represents the multinational pharmaceutical industry, has expressed the desire that "... the biopharmaceutical industry should play a role in shaping an international pandemic treaty."<sup>22</sup> The negotiations on the pandemic treaty, however, should only take place among member States and be exclusively a member State driven process.

## Complementing and Strengthening the International Health Regulations ("IHR Plus")

As noted above, one important issue to be considered by Member States in discussing about a new pandemic treaty is whether the same proposed objectives (once clarified) could be reached through a revision and strengthening of the IHR (particularly by introducing enforcement mechanisms) or a new instrument would be necessary. The IHR Review report that will be considered by WHO Member States in the upcoming World Health Assembly of 2021 observes that, a future pandemic treaty should not only be compatible with the IHR, but must also have the effect of strengthening it.23 In this regard, the report states "... clarity is required with regard to the triggers for global coordination and response actions in the case of a pandemic, which may go beyond what the IHR provides for (i.e. issuing of temporary recommendations when a public health emergency of international concern is determined). Such triggers and actions could be related to coordination of global supply chains, or sharing of pathogens and benefits arising from it, or coordination of research and development for developing medical countermeasures."24 The IHR Review also states that "... sustainable national health systems, accessible to all, are an essential basis for global health emergency preparedness and response." 25 Indeed, these considerations should be taken into account in order to strengthen and complement IHR. In the past, however, initiatives to develop instruments to deal with some of these elements did not obtain the support or were opposed by some WHO Member States.

## **Opposition to a R&D Treaty**

Apart from FCTC, the only other attempt in WHO to negotiate a treaty on a specific health matter – a treaty for public funding of biomedical research and development (R&D) for diseases that disproportionately affect developing countries<sup>26</sup> – was frustrated by the opposition from developed countries. A number of expert reports pointed out that market-based incentives such as intellectual property (IP) protection did not incentivize private investments into R&D for diseases that predominantly affect the poor and did not offer attractive profitable returns. Thus, the WHO Consultative Expert Working Group (CEWG) on R&D recommended the launch of negotiations for a treaty to build up an alternative R&D model based on public investment and free from intellectual property ownership.<sup>27</sup>

In May 2012, the World Health Assembly adopted resolution WHA 65.22 that welcomed the report of CEWG and urged Member States to develop concrete proposals and actions based on the recommendations of CEWG. However, no proposals were made in subsequent discussions to address the CEWG recommendation to introduce an alternative model to pharmaceuticals R&D by calling for negotiations to begin on a binding international treaty.

A binding global treaty negotiated within WHO could have enabled the definition of priorities, and enhanced the coordination and the sustainable financing of R&D of useful and safe biomedical products at affordable prices for the public and social security systems. The adoption of such a treaty within WHO, based on Article 19 of its constitution, could have also allowed for a review of the way WHO functions in a broader sense.

The recommendation to start negotiations on a R&D treaty did not move forward due to the lack of broad support among WHO members and as noted, the opposition from industrialized countries where the major pharmaceutical industry is located. The crisis triggered by COVID-19 is a new and historic opportunity to revisit the role of WHO in prioritizing, coordinating and funding biomedical R&D and help enhance the organization's capacity to effectively manage global challenges.

The fact that the pandemic treaty is proposed by a number of developed countries suggests that its eventual negotiation would be made in a different scenario, as such countries will be driving the efforts to adopt the proposed instrument. Now would be the time for developing countries to assess the extent to which such a treaty may advance global public health and take their special needs into account. In this regard, it will be logical to think that a pandemic treaty, if negotiated, would need to include disciplines on R&D, including clinical trials, and ensure that the outcomes of R&D will be accessible and affordable to all. It is hoped that developing a new model of R&D will now obtain the support of all members States.

# Opposition to a Temporary Waiver of TRIPS Obligations

While the proponents of the idea of a pandemic treaty have stated that the treaty would also ostensibly address the actions needed for effective response to a pandemic in all countries, it is noteworthy that several of these proponents oppose the proposal for a waiver of obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) regarding intellectual property rights in respect of technologies required for responding to COVID-19,28 as advanced by India and South Africa and supported by more than 100 countries in WTO.29 The suspension of such obligations in times of pandemics should certainly be a component in any framework that promotes the expansion of production and equal access to products needed for prevention or treatment. If we are talking about a global emergency, why not start by approving a temporary

waiver regarding the TRIPS obligations during the current pandemic? Recently, the US expressed support for undertaking text-based negotiations on the proposed waiver. However, it is still uncertain whether the textbased negotiations will result in a waiver that is sufficiently broad in scope.<sup>30</sup> Notably, even after the US statement, some EU members such as Germany have continued to oppose the proposed waiver.<sup>31</sup>

## Pathogen and Benefit-Sharing

An issue that has been highlighted in the public statements<sup>32</sup> made by the proponents of the pandemic treaty is that it would address the need for expedited sharing of pathogens and their genetic sequence information to respond to a pandemic. Access and benefit sharing relating to pathogens—as well as to other genetic resources—are subject to the provisions of 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. The Nagoya Protocol allows for the adoption of specialized instruments for specific categories of genetic resources, such as pathogens, to the extent that they are consistent with Protocol's objectives.<sup>33</sup>

In a pandemic situation the pathogen and its genome information should be shared immediately for research and development of medical countermeasures. However, this should be without prejudice to subsequent benefit-sharing, for example, by making available the resulting vaccines and know-how to scale up manufacturing and secure affordable access to those products. Thus, WHO Member States can develop, as part of the proposed treaty, a framework for expedited sharing of pathogen samples with benefit-sharing on an equal footing.<sup>34</sup>

### **Final Remarks**

Not surprisingly, the health, economic and social crisis brought on by COVID-19 has led to a call for an international treaty on pandemic preparedness and response to address this and future pandemics. The limitations of the current global health governance have become evident. However, before launching negotiations for a pandemic treaty, the first step should be to identify the aspects of pandemic preparedness and response that the current crisis has revealed are not working and how to build up on the existing instruments, notably the IHR. In other words, what are the major issues or elements on which a possible treaty negotiation should be focused?

COVID-19 has revealed insufficiencies and the need for new approaches and action in many areas in order to ensure a rapid and coordinated response to the spread of the disease across countries and regions,<sup>35</sup> such as:

- Increasing laboratory and surveillance capacity to identify diseases of zoonotic origin in all countries.
- Improving alerts, independent, reliable and accurate scientific communication.
- Developing mechanisms for an expedited sharing of pathogens, including biological samples and genomic data, without prejudice to the equitable sharing of the benefits derived from their utilization.
- Expanding the use of digital technologies for data collection and sharing while respecting the sovereign rights of States over their health data and its use.
- Prioritizing R&D efforts and developing mechanisms for collaboration in funding and carrying out scientific and translational research as well as transparent and independent clinical trials.
- Transparency in R&D costs and prices.
- Making available pandemic-related health supplies as global public goods (without limitations imposed by the enforcement of intellectual property rights).
- Establishing mechanisms to enable open access to technologies, including know-how, for scaling up of local manufacturing of pandemic-related health supplies.
- Coordinating the supply of vaccines and other health products to all countries, including to developing and least developed countries, on the basis of equality and health needs.
- Lifting unnecessary regulatory barriers for the market entry of generic manufacturers, by establishing abbreviated regulatory approval pathways for faster marketing approvals and promoting inter-agencies cooperation.
- Adopting measures to ensure the continued availability and affordability of vital medical supplies and equipment and other essential goods and services to meet basic needs, consistent with national requirements.
- Regulating the scope of legal immunities and guarantees against liability for negligence, flaws in manufacturing practices, or adverse events associated with vaccines.

Many of these elements cannot function on the basis of solidarity or goodwill cooperation alone. The use of binding instruments to promote and protect health in the context of pandemics is needed. If WHO Member States decide that an international treaty to prepare and respond to pandemics is the way forward, it would be important to have clarity from the outset on the elements and areas that will be the subject of negotiation. A treaty would imply obligations as well as enforcement tools to implement them. Yet it is an open question how such a treaty can address some or all of the above issues having in view the needs of countries at different levels of development and, consequently, with different capacities to implement the obligations it may impose.

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## **Endnotes:**

<sup>1</sup> Standing with the World Health Organization Director-General Tedros Adhanom Ghebreyesus, the leaders signing on so far represent Albania, Chile, Costa Rica, the European Council, Fiji, France, Germany, Greece, Indonesia, Italy, Kenya, the Netherlands, Norway, Portugal, the Republic of Korea, Romania, Rwanda, Senegal, Serbia, South Africa, Spain, Thailand, Trinidad and Tobago, Tunisia, the United Kingdom and Ukraine. See WHO, "COVID-19 shows why united action is needed for more robust international health architecture", 30 March 2021. Available from <u>https://www.who.int/news-room/commentaries/ detail/op-ed---covid-19-shows-why-united-action-isneeded-for-more-robust-international-health-architecture.</u>

<sup>2</sup> European Council, "An international treaty on pandemic prevention and preparedness". Available from <u>https://</u> <u>www.consilium.europa.eu/en/policies/coronavirus/</u> <u>pandemic-treaty/</u>.

<sup>3</sup> WHO, *supra* note 1. Article 2 (1) (a) of the Vienna Convention on the Law of Treaties defines a treaty as "an international agreement concluded between States in written form and governed by international law, whether embodied in a single instrument or in two or more related instruments and whatever its particular designation.

4 Ibid.

<sup>5</sup> Ibid.

<sup>6</sup> WHO, International Health Regulations (2005), Article 2.

<sup>7</sup> L. O. Gostin and R. Katz, "The International Health Regulations: The Governing Framework for Global Health Security", *The Milbank Quarterly*, vol. 94, no. 2 (2016). Available from

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC49117 20/#milq12186-bib-0044.

<sup>8</sup> Ibid.

9 Ibid.

<sup>10</sup> "Full genome sequences of the new virus were shared with WHO and the international community immediately

after the pathogen was identified on 7 January" (WHO, Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19), 16–24 February 2020, p. 31. Available from <u>https://www.who.int/docs/default-source/coronaviruse/who-china-joint-mission-on-covid-19-final-report.pdf</u>).

<sup>11</sup> See e.g., R. Habibi, et al., "Do not violate the International Health Regulations during the COVID-19 outbreak", *The Lancet*, vol. 395, 29 February 2020, pp. 664–66. Available from <u>https://www.thelancet.com/action/showPdf?pii=S0140-</u> <u>6736%2820%2930373-1</u>; C. Foster, "Justified Border Closures do not violate the International Health Regulations 2005", EJIL:Talk! (11 June 2020). Available from <u>https://www.ejiltalk.org/justified-border-closures-do-not-</u> <u>violate-the-international-health-regulations-2005/</u>.

<sup>12</sup> The report of the IHR Review to be discussed in the upcoming 74th session of the World Health Assembly of 2021 has been recently posted on the WHO website. See WHO document A79/4 Add.1. Available from ,

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<sup>13</sup> This is referring to suggestions or proposals that member States could make in the light of the findings of the IHR review, IPRP review and IAOC review.

<sup>14</sup> See M.Z. Abbas, *Practical Implications of 'Vaccine Nationalism': A Short-Sighted and Risky Approach in Response to COVID-19*, Research Paper No. 124 (Geneva, South Centre, November 2020). Available from <u>https://www.southcentre.int/wp-</u> <u>content/uploads/2020/11/RP-124.pdf</u>.

<sup>15</sup> See C. Wenham, "A global pandemic treaty won't work until leaders realize the benefits of solidarity", *The Guardian*, 1 April 2021. Available from

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<sup>16</sup> WHO Director-General's opening remarks at Executive Board Meeting. Special Session on the COVID-19 Response, 5 October 2020,

https://www.who.int/dg/speeches/detail/who-directorgeneral-s-opening-remarks-at-executive-board-meeting.

<sup>17</sup> J.H. Duff, et al., "A global public health convention for the 21st century", *The Lancet Public Health*, 5 May 2021. Available from

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<sup>18</sup> A virtual format for conducting negotiations may not be conducive to an effective participation of delegations from countries with limited access to high-speed Internet. In this context, it is a matter of concern that the EU has expressed that it is keen to conclude the negotiations for adoption of a new treaty by early 2022. This would imply that the negotiations will take place virtually due to the ongoing pandemic situation.

<sup>19</sup> See G. Velásquez, *The World Health Organization Reforms in the Time of COVID-19*, Research Paper, No. 121 (Geneva, South Centre, November 2020). Available from

https://www.southcentre.int/research-paper-121november-2020/.

<sup>20</sup> L. Gostin, S. Moon, and B. Mason Meier, "Reimagining Global Health Governance in the Age of COVID-19", *American Journal of Public Health* 110(11):1615–1619, (November 2020). DOI: 10.2105/AJPH.2020.305933.

<sup>21</sup> See G. Velasquez and X. Seuba, *Rethinking Global Health: A Binding Convention for R&D for Pharmaceutical Products,* Research Paper, No. 42 (Geneva, South Centre, December 2011). Available from

https://www.southcentre.int/research-paper-42december-2011/.

<sup>22</sup> IFPMA, Statement: COVID-19 vaccine and treatment innovators response to global leaders urgent call for international pandemic treaty, 30 March 2021. Available from <u>https://www.ifpma.org/wp-</u>

<u>con-</u>

tent/uploads/2021/03/IFPMA\_Statement\_International\_ Pandemic\_Treaty\_30March2021.pdf.

<sup>23</sup> WHO document, *supra* note 11, p. 50.

<sup>24</sup> Ibid., p. 39.

<sup>25</sup> Ibid., p. 63.

<sup>26</sup> See World Health Assembly, "Global strategy and plan of action on public health, innovation and intellectualproperty", Resolution 61.21, 24 May 2008. Available from <u>http://www.wpro.who.int/health\_research/wha61\_21\_gl</u> <u>obal\_strategy\_poa\_health\_innovation\_may2008.pdf.</u>

<sup>27</sup> See G. Velasquez, *Medicines and Intellectual Property:* 10 Years of the WHO Global Strategy, Research Paper, No. 100 (Geneva, South Centre, 2019). Available from <u>https://www.southcentre.int/wp-</u>

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 $^{\rm 28}$  WTO document IP/C/W/669, 2 October 2020. Available from

https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?fi lename=q:/IP/C/W669.pdf&Open=True.

<sup>29</sup> See H. Z. de Menezes, *The TRIPS Waiver Proposal: An Urgent Measure to Expand Access to COVID-19 Vaccines,* Research Paper No. 129 (Geneva, South Centre, March 2021). Available from <u>https://www.southcentre.int/wp-content/uploads/2021/03/RP-129.pdf</u>. Also see, C.M. Correa, "Expanding the production of COVID-19 vaccines to reach developing countries: Lift the barriers to fight the pandemic in the Global South", Policy Brief No.92, South Centre, April 2021. Available

from <u>https://www.southcentre.int/wp-</u> content/uploads/2021/04/PB-92.pdf.

<sup>30</sup> G. Velasquez, "What's wrong with Biden's promise to waive vaccine patents: The US's move on intellectual property is in the right direction, but where will it go from here?", *Politico*, 6 May 2021. Available from https://www.politico.eu/article/jo-biden-coronavirusvaccine-patents/.

<sup>31</sup> G. Chazan *et al.*, "Angela Merkel rejects US move to waive patents on vaccines", *Financial Times*, 6 May 2021.

#### Available from https://www.ft.com/content/76a05a85-b83c-4e36-b04d-7f44f63e57b0.

<sup>32</sup> See European Council, An international treaty on pandemic prevention and preparedness. Available from https://www.consilium.europa.eu/en/policies/coronavirus /pandemic-treaty/. See also statement to the press by WHO Director-General Tedros Adhanom Ghebreyesus on the pandemic treaty. WHO, Press briefing on pandemic treaty with Dr Tedros and Charles Michel. Available from https://www.youtube.com/watch?v=XINZ9xpQmv8.

<sup>33</sup> Nagoya Protocol, Article 4.4.

<sup>34</sup> A. Rizk, *et al.*, "Governing Pathogen – and Benefit-Sharing (PBS)", Global Health Center Working Paper No. 23, Graduate Institute of International and Development Studies, Geneva, 2020, pp.67,74. Available from

https://www.graduateinstitute.ch/sites/internet/files/2020 -12/GHC\_WorkingPaper\_No\_23\_Web.pdf.

<sup>35</sup> The following elements focus on pandemic response; the proposed treaty, however, should also include measures necessary to enhance the global preparedness for a pandemic.

<sup>36</sup> In some reported cases, Western vaccines producers have been reported to demand national assets as guarantees and overly broad exemptions from liability. See M. Davies, et al., " 'Held to Ransom': Pfizer Demands Governments Gamble with State Assets to Secure Vaccine Deal", The Bureau of Investigative Journalism, 23 February 2021. Available from https://www.thebureauinvestigates.com/stories/2021-02-23/held-to-ransom-pfizer-demands-governments-gamblewith-state-assets-to-secure-vaccine-deal. The WHO has also entered into an agreement with a company to secure insurance coverage for a no-fault compensation program against individuals making liability claims for adverse effects of any vaccine provided through the COVAX Facility. This insurance scheme effectively shifts the burden of liability for adverse effects away from vaccine manufacturers. See WHO, "No-fault compensation programme for COVID-19 vaccines is a world first", News Release, 22 February 2021. Available from https://www.who.int/news/item/22-02-2021-no-faultcompensation-programme-for-covid-19-vaccines-is-a-worldfirst.

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