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

By Dr. Germán Velásquez* and Nirmalya Syam **

The Idea of a “Pandemic Treaty”

Twenty-five Heads of Government 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.

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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but when: “[W]e must be better prepared to predict, prevent, detect, assess and respond effectively to pandemics in a coordinated manner”.3 “To that end”, states the communiqué, “… nations should work together towards a new international treaty for pandemic preparedness and response”.4 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.”5

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 ….”. 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.

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.8 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,10 many countries have acted unilaterally and without coordination regarding the movement of people and traffic of goods.11

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) Review12 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 nationalism14—thereby offering lip service to global solidarity.15

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, 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. 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.

Strengthening or Marginalization of WHO

Any discussion on a future framework in WHO 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 low- and 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 cre-
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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.”22 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—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.26

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, as advanced by India and South Africa and supported by more than 100 countries in WTO. 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 text-based negotiations will result in a waiver that is sufficiently broad in scope. Notably, even after the US statement, some EU members such as Germany have continued to oppose the proposed waiver.

Pathogen and Benefit-Sharing

An issue that has been highlighted in the public statements 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.

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.

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, 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.

References


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Endnotes:

1 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 https://www.who.int/news-room/commentaries/detail/op-ed-covid-19-shows-why-united-action-is-needed-for-more-robust-international-health-architecture.


3 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.

5 Ibid.


8 Ibid.

9 Ibid.


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


18 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.


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23 WHO document, supra note 11, p. 50.

24 Ibid., p. 39.

25 Ibid., p. 63.


31 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.


33 Nagoya Protocol, Article 4.4.

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POLICY BRIEF

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