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SWP Comment

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Lawmaking at the WHO: Amendments to the International Health Regulations and a New Pandemic Treaty After COVID-19

Pedro A. Villarreal

Two concurrent lawmaking processes are currently underway at the World Health Organization (WHO) that could lead to a new pandemic treaty and to amendments to the International Health Regulations (IHR) of 2005. However, two major questions must first be addressed. Firstly, how can global health equity be fostered in the future worldwide distribution of medical supplies during a pandemic? And secondly, how can incentives be put in place so that information on disease outbreaks is exchanged more rapidly and transparently?

The COVID-19 pandemic has highlighted the critical need to ensure that the international community can respond better and faster to the spread of a pathogen like SARS-CoV-2 in the future. However, two interrelated points are particularly open to debate and controversy in this regard. First, how can equitable access to medical countermeasures, such as vaccines, be ensured globally? And second, how should information and data exchange on new disease outbreaks be conducted in the future?

At the heart of the reforms lie the rules of international law in the area of the cross-border spread of disease. To this end, negotiations are underway in Geneva to amend the International Health Regulations (IHR) of 2005 and to create a new WHO convention on pandemic prevention, preparedness, response and recovery (hereafter

referred to as the “pandemic treaty”). At the heart of these efforts is the conviction of some states and groups of states, such as the G7, the European Union (EU) and members of the so-called “Friends of the Pandemic Treaty”, that a rules-based international order offers a more robust alternative to the ad hoc diplomacy that has prevailed to date.

Germany has both a political and a financial interest in the success of these reform processes. Since the West African Ebola crisis of 2014/15, the German government has strived to position itself as a leader in global health. These efforts intensified again during Donald Trump’s presidency, when the U.S.’s general retreat from the multilateral space in global health culminated in the official announcement that it would withdraw from the WHO. While



the Biden administration reversed that decision, the threat of a withdrawal cannot be ruled out especially with the outcome of the 2024 presidential election still very much uncertain.

If Germany wants to maintain its leadership role in global health in general and in the governance of the WHO in particular, it must actively participate in the two aforementioned international lawmaking processes. The window of opportunity for co-designing the legal drafts, which are expected to underpin a more equitable and coherent response to future pandemics, is still open but may close as Germany, the EU, the U.S. and other leading global health actors turn to parallel priorities. Other developments, such as the war in Ukraine and the threat of global economic recession, could further deepen geopolitical fragmentation. Yet Germany can seize upon the current opportunity to prove itself as a reliable long-term partner in global health. Thus, Germany could contribute by approaching the drafting of a pandemic treaty and the IHR (2005) amendments as complementary rather than parallel tasks.

The role of international law in pandemic prevention, preparedness and response

When asking if legally binding international rules are actually needed for dealing with these kind of health threats in the first place, two overarching reasons come to the fore. First, following classic functionalist reasoning, achieving certain goals that are unattainable for a single state requires the active collaboration between different states. This was evident in the emergence of the COVID-19 pandemic. The location of the outbreak, Wuhan, China, was far beyond the legal jurisdiction of authorities in Germany and the EU. Because future pandemics can occur anywhere in the world, it is important to have rules that clearly define what states should and should not do. Second, legal rules can provide more continuity in international cooperation, as opposed to

one that is dependent on a shifting diplomatic calculus. Paralyzing the ability to respond to a pandemic because the political priorities of governments in turn have changed prevents the cycle of “panic and neglect” from being broken.

Pandemic Treaty and International Health Regulations: The Road to Adoption

Under Articles 19 and 21, respectively, of the Constitution of the WHO (“WHO Constitution”), the World Health Assembly may adopt legally binding conventions and regulations. The Assembly, in turn, is composed of representatives of states, often ministers of health, who meet regularly once a year and vote on resolutions and decisions. Therefore, the final decision on what is adopted rests with the Member States themselves.

According to Article 60 of the WHO Constitution, different voting quotas apply to the adoption of regulations or conventions approved by the World Health Assembly (see table 1). For the adoption of treaties or conventions, Article 60 (a) of the Constitution of the WHO requires a two-thirds majority of the Member States present and voting in the Assembly. Regulations can be adopted by a simple majority under Article 60 (b), unless the state representatives classify them as “important issues” on an ad hoc basis, thus requiring the said two-thirds majority. Despite the differences in the provisions regarding the necessary majorities and procedures for entry into force, agreements and regulations are in practice (generally) decided by consensus in the plenary sessions of the World Health Assembly.

Towards a new pandemic treaty

WHO conventions or agreements (equivalent to international treaties) and WHO regulations (such as the IHR and its amendments) have a different scope in terms of what they can regulate. Conventions or agreements can be adopted “on any matter within the competence of the Organization,” according to Article 19 of the WHO

Table 1

Comparison of WHO Conventions and Regulations

| Type of Instrument | Approval Procedure | Subject | Precedents |
|-------------------------------|---|---|---|
| WHO Conventions or Agreements | <ul style="list-style-type: none"> ■ Qualified majority (2/3) in the World Health Assembly ■ Subsequent approval by national bodies (if so stipulated) and ratification | <ul style="list-style-type: none"> ■ All matters within the competence of WHO under Article 2 of its Constitution | <ul style="list-style-type: none"> ■ Framework Convention on Tobacco Control (2003) |
| WHO Regulations | <ul style="list-style-type: none"> ■ Simple majority in the World Health Assembly, unless otherwise agreed | <ul style="list-style-type: none"> ■ Five thematic areas specifically identified in Article 21 of the WHO Constitution | <ul style="list-style-type: none"> ■ Nomenclature Regulations (1948, revised in 1967) ■ International Sanitary Regulations (1951) ■ International Health Regulations (1969) ■ International Health Regulations (2005) |

Constitution, while Article 2 enumerates 22 functions of the organisation, the first of which is to act as the “governing and coordinating body of international health.” In addition, Article 19 of the WHO Constitution is a provision of broad scope, however in practice certain limits are set, which is particularly evident when the WHO addresses issues that fall within the purview of other regimes of international law. Subjects such as access to medicines (due to intellectual property rights) and environmental health (in connection with the One Health approach) are examples thereof.

After the vote in the World Health Assembly, WHO conventions usually still need to be approved by domestic bodies, such as parliaments. Once this approval has been given, the states submit an instrument of ratification, in which they also declare that they agree to be bound by the provisions of the convention. Thus, these conventions only become binding once they have undergone the entire ratification process, and only for those Member States that have done so.

The idea of concluding a pandemic treaty was first formally put forward by the President of the European Council, Charles

Michel. The proposal was justified under a number of advantages associated with a treaty. For instance, it compels national policymakers to engage in global health policy on a continuous basis; it establishes the principles and objectives of multilateral preparedness; and it can provide more binding equity in the distribution of medical goods and promote the One Health approach. The WHO Director-General later expressed his endorsement of the initiative.

Following the model set by the Framework Convention on Tobacco Control, an Intergovernmental Negotiating Body (INB) was established in December 2021 to develop a new pandemic treaty. It is composed of representatives from Member States and holds regular meetings to provide updates on the status of the lawmaking process. Recently, the INB published a “Conceptual Zero Draft” that will form the basis for the discussion at the next meetings. The document is the result of several rounds of feedback from WHO Member State delegations, non-governmental organisations (NGOs) and individual experts on a range of issues. However, the text does not yet contain the final wording of the provisions, but rather is intended to serve as a basis for negotiations on a number of overarching concerns.

In this context, it should be noted that, in contrast to other policy areas such as international trade, the EU does not have exclusive, but rather only complementary competence in the area of (global) health, so that the entry into force of a pandemic treaty would fall within the competence of each individual EU Member State. However, this does not prevent the EU from actively participating in the negotiations, as its Commission has received a mandate from the Council of the EU to do so. Nevertheless, the positions of Germany and the EU on the pandemic treaty have been in line since the beginning of the process.

Amending the IHR (2005)

Besides conventions, the World Health Assembly may adopt legally binding regulations in five areas: 1) sanitary and quarantine requirements for preventing the international spread of disease; 2) nomenclatures of diseases, causes of death, and public health practices; 3) standards for diagnostic procedures aimed at an international use; d) standards ascertaining the safety, purity and potency of biological, pharmaceutical and similar products in international trade; and (e) advertising and labelling of biological, pharmaceutical and similar products in international trade. The first of these areas sets the legal basis for the International Health Regulations (IHR) of 2005, currently the main legally binding instrument that focuses on the transboundary spread of diseases.

Under Article 21 of the WHO Constitution, the World Health Assembly can adopt regulations that are legally binding on states unless they expressly reject them (“opt out”). Once the period specified in the regulations for rejecting or formulating reservations has elapsed, the rules in question are binding on all states that have not expressed any objections. A salient procedural feature of WHO regulations is that, the participation of national legislatures or other governmental bodies involved in the approval of treaties is not necessary. In addition, the regulations require a lower voting thresh-

old at the World Health Assembly than conventions. This was accepted by WHO Member States when they ratified the organisation’s constitution and is perhaps a testament to the trust that governments place in their delegates to the World Health Assembly.

In January 2022, the US government submitted a proposal to amend 13 provisions of the IHR (2005). However, delegates to the 75th World Health Assembly in May 2022 only approved the suggestion to shorten the period for rejecting amendments under Articles 55 or 59 of the IHR (2005) from 18 to 10 months and the period before such amendments come into force from 24 to 12 months. The other initiatives from the US government included the possibility for the WHO to declare a public health emergency of international concern without first consulting the affected Member States, and the creation of a new mid-level emergency declaration. Here, WHO Member States felt that more time was needed to discuss the scope of such changes.

So far, 16 States Parties – including the U.S. – have submitted proposals for amending the IHR (2005), both on their own behalf and in association with regional groupings, including the EU, the WHO African Region, the Eurasian Economic Union and MERCOSUR. The proposed amendments are publicly available in full on the WHO website, and are also depicted in a compilation showing the wording that would change. Currently, a so-called Review Committee is busy summarising these amendment proposals and is preparing its report, due by mid-January 2023. The Review Committee’s report will serve as the basis for the final proposal prepared by a Working Group on Amendments to the International Health Regulations (2005), composed of selected delegates from States Parties. The latter body will draft the legal text and, eventually, submit the final amendment proposal to the WHO Director-General, who should then circulate it to all States Parties at least four months before the 2024 World Health Assembly.

Minding pitfalls ahead

Particular pitfalls lurk in both lawmaking processes. Compared with the amendments to the IHR (2005), the negotiations on a completely new pandemic treaty are mired in heated arguments. This is because there is not yet a clear framing for some of the issues it addresses, and their discussion is correspondingly open-ended. For example, the One Health approach includes aspects of environmental protection, food safety and animal health, where direct overlaps with other norms of international law must be taken into account. So far, it is not clear how these overlaps will be addressed. Furthermore, even if a future pandemic treaty were to be adopted by the World Health Assembly, its success would depend to a large extent on the respective domestic political constellations in the 194 Member States because of the ratification process required. In other words, it could take a very long time for a significant number of countries to complete their respective national procedures.

At the same time, the comparatively streamlined procedure for entry into force of amendments to the IHR (2005) does not mean that consensus is self-evident. Both the International Sanitary Regulations of 1951 and the IHR (1969) were opposed or were met with reservations and rejections by a number of WHO Member States. By contrast, when the current IHR was adopted in 2005, only India and the United States expressed reservations. However, neither of these states wished to alter the primary obligations found in the provisions. Throughout the history of the WHO, proposed amendments have never been as intensively debated as the revisions proposed by the United States in 2022. This is likely related to the fact that the stakes are high given the catastrophic scale of the COVID-19 pandemic.

The equity debacle in pandemics

Perhaps the most contentious issue for many delegations at the WHO, particularly

from the Global South, is the challenge of ensuring equitable access to medical countermeasures during a pandemic. The rampant “vaccine nationalism” witnessed in the context of COVID-19 will likely be fresh in the minds of the governments of those regions of the world in particular, as many struggled to procure enough vaccine doses for their own populations. Comprehensive rules on this point would have to deal with various aspects, such as the issue of intellectual property in medical goods and the establishment of financing and procurement mechanisms for their distribution. Thus, the notion of “equity” in pandemics currently represents the centrepiece of negotiations from several Global South countries. In the aforementioned conceptual zero draft for the pandemic treaty, the goal of equity is described as the following: “fair, equitable and timely access to affordable, safe and efficacious pandemic response products, among and within countries, including between groups of people irrespective of their social or economic status.”

To ensure that this provision remains more than wishful thinking, a new pandemic treaty should take into account the lessons learned from the limited effectiveness of the ACT Accelerator in general and the COVAX initiative in particular. These mechanisms were designed to promote the global distribution of medical interventions against COVID-19. However, neither has met its goals, which in the case of COVAX was to distribute 2 billion vaccine doses by the end of 2021, with only 50 percent of that amount actually being distributed. Meanwhile, in the case of the other pillars of the ACT Accelerator, which were intended to promote the distribution of diagnostic and therapeutic products, they fell even further short of expectations. Several studies have already attempted to explain such failures. Some analyses point to the greed of Global North countries in stockpiling medical supplies to protect their own populations. An evaluation commissioned by the WHO and published by Open Consultants in October 2022 cites, among other things, the overambitious design of COVAX as one

of the key reasons for the initiative's limited success. The report recommends instead that other programs with a more focused scope be developed. These should cater to countries that are unable to self-procure critical medical supplies during an emergency. Legally binding rules for such an eventuality could ensure that countries commit to financial contributions on a permanent basis, regardless of shifting political circumstances.

Remove political barriers to pandemic-related data collection

One of the perennial problems in pandemic preparedness and response is the early reporting of disease-related events that have the potential for cross-border spread. This is a classic challenge for public health authorities, as such events can occur in locations far outside their territorial jurisdiction.

The issue is particularly strategic for Germany, because the WHO Hub for Pandemic and Epidemic Intelligence, or "Pandemic Hub" for short, is located in Berlin. Prompt and reliable information on disease outbreaks can be considered a global public good, thus international rules are the best means to give clarity on the normative expectation for countries to report such information in a timely and transparent manner.

The existing IHR (2005) do not provide balanced incentives for states to report information to the international community. On the one hand, Article 6 of the IHR (2005) requires States Parties to notify the WHO within 24 hours of the discovery of "of all events which may constitute a public health emergency of international concern within its territory in accordance with the decision instrument". Moreover, Article 43 of the IHR (2005) seeks to incentivise such notifications by requiring states not to impose unnecessary travel and trade restrictions on other Member States, and to notify the WHO and provide a public health justification whenever restrictions are adopted. In practice, however, these provisions have long been a source of concern because

states have wide latitude in determining the "necessity" of such travel and trade restrictions. A glaring example of this was South Africa's notification of the discovery of the Omicron variant on its territory, which immediately led to a barrage of travel bans from and into the country. These measures discourage states from readily informing the WHO, and in turn the international community, of health threats on their territory that could have a cross-border dimension.

On this very point, the director of the Pandemic Hub in Berlin explained that the biggest challenge in collecting and processing data is political, namely the unwillingness of authorities in affected countries to share them. The desirable exchange of information could be pushed both through a new pandemic treaty or other legal instruments, and through changes to the IHR (2005). At the same time, efforts would need to be made to avoid the overlap and duplication of reporting requirements. A streamlined reporting of disease-related events would benefit the functioning of the Pandemic Hub in Berlin. This could then act as a true "node" for processing data reported by WHO Member States. At the same time, the Pandemic Hub could provide additional incentives for states to report information if legally binding rules ensured their proper use and respected the sovereign interests of states.

After COVID-19: Making the most out of international law

The World Health Assembly has set a deadline of May 2024 for putting both a draft pandemic treaty and the proposed amendments to the IHR (2005) to a vote. In the latest versions of both documents, the focus on equity runs through several sections. A major obstacle at this present moment is the lack of stable funding commitments for future initiatives that could build on the lessons learned from the ACT Accelerator. Both the current conceptual zero draft and the proposed amendments to the IHR (2005)

include sections on international financial mechanisms established to promote, among other things, “equitable and timely access” to medical supplies needed for pandemic response. Future commitments on this matter could be made more concrete by referring to mandatory or “assessed” pro rata contributions by Member States.

The World Bank recently developed a financial assistance mechanism that extends beyond the WHO, the Financial Intermediary Fund (FIF) for Pandemic Prevention, Preparedness and Response (Pandemic Fund). With a contribution of 68.5 million euros, Germany is one of the founding members of the Pandemic Fund, and has one representative with a seat on its Board. So far, however, the World Bank member states’ contributions to this Fund have been voluntary. A pandemic treaty or amendments to the IHR (2005) imposing corresponding cooperation obligations could ensure a stable funding stream in the future. Ultimately, it is in the interest of both Germany and the EU to ensure that their investments bear fruit in the long term. To this end, fixing international norms in the treaty or IHR (2005) amendments could provide more stability in combating pandemics. Since the federal government is already a major donor to several global health initiatives, it could use its position to negotiate longer-term financial commitments with other countries that match their respective capacities. The legal design of these commitments could be similar to that of the United Nations Framework Convention on Climate Change (UNFCCC) and related instruments and protocols.

The issue of information and data sharing related to disease outbreaks in a region will still fall largely within the scope of Articles 6 and 7 of the IHR (2005). Given that the amended IHR will most likely have a larger number of states parties than the pandemic treaty, at least initially, the primary exchange of information will continue to be based thereupon. Consequently, it must be a priority to better monitor compliance with information-sharing obliga-

tions. The proposed amendments to the IHR (2005) foresee the creation of an Implementation and/or a Compliance Committee which could take over those functions currently performed almost entirely by the WHO Secretariat. Ensuring the operability of these new committees or legally enhancing the current work of the Secretariat would benefit the functioning of the WHO Hub in Berlin as well. At the same time, the conceptual zero draft includes a statement that it intends to promote “solidarity with countries” that report public health emergencies, without specifying how such solidarity could be shaped and maintained. This is precisely the aspect that could be considered in the context of the notification requirements of the IHR (2005), namely with regard to those cases in which notifying states face disproportionate responses from other countries.

Outlook

Germany should press for greater synergies between the two ongoing pandemic law-making processes at the WHO with the following elements at the forefront of this effort:

- Linking the concept of “equity” in the pandemic treaty to lessons learned during the COVID-19 pandemic about the shortcomings of the ACT Accelerator in general, and the COVAX initiative in particular.
- Using both the IHR (2005) and the pandemic treaty to ensure the exchange of data for the Berlin-based Pandemic Hub. New and reformed legally binding international rules can help deal with the political barriers impeding a more transparent sharing of pandemic-related information. Incentives should be put in place to increase the willingness of states to transfer data; for example, by granting immediate access to funding mechanisms when countries face disproportionate responses after they report outbreaks in their territories.

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