insights

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By: Gian Luca Burci, Adam Strobeyko, and Daniela Morich

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Global Health Law Reforms: An Update on the Amended International Health Regulations and the Pandemic Agreement Negotiations

Introduction

The COVID-19 pandemic has been an unprecedented crisis, profoundly impacting health, economies, and societies worldwide. It has also exposed the shortcomings of the global health governance system and its emergency laws, spurring discussions on reform. During the pandemic's early phases, issues such as low compliance with international information-sharing obligations, widespread imposition of disproportionate trade and travel restrictions, and the hoarding of available health products by the richest countries highlighted the urgent need for more robust and equitable global rules.

In November 2021 and May 2022, respectively, World Health Organization (WHO) member states launched two global health law reforms to strengthen pandemic prevention, preparedness, and response (PPPR). They decided to concurrently negotiate targeted amendments to the International Health Regulations (IHR), the only legally binding instrument for preventing and controlling the international spread of diseases, and a new Pandemic Agreement. Both were scheduled for conclusion at the 77th World Health Assembly (WHA) in May 2024. This *Insight* will review the newly-adopted IHR amendments and provide updates on the Pandemic Agreement negotiations, highlighting progress and challenges in these pivotal global health law reforms.

The Goals and Current Status of the Negotiations

Beginning with the IHR, the scope of reform was, in principle, narrow and technical, aiming to adopt targeted amendments grounded in equity and solidarity to strengthen the existing legal framework. This process successfully concluded on June 1, 2024, with the consensus adoption of a number of amendments by the WHA.

In contrast, negotiations on the Pandemic Agreement were more complex and ambitious in scope, aiming at covering the entire spectrum of PPPR measures. Its core provisions address critical issues such as access to health products during emergencies, technology transfer, geographically diversified local production and the global supply chain, PPPR financing, an integrated One Health approach to surveillance, and a Pathogen Access and Benefit-Sharing (PABS) System.

Following two years of highly political and divisive negotiations, member states did not reach a conclusion in May 2024, and the mandate of completing the Pandemic Agreement was extended by one year. Two main factors led to this unfavorable outcome. Firstly, a rushed and dysfunctional process did not allow for an initial discussion of shared common issues and postponed real negotiations to the end. Secondly, the positions on both sides—with developed countries prioritizing “security” measures to reduce the risk of future pandemics, and developing countries prioritizing “equity” concerns and more structural changes—were entrenched and uncompromising.

Amending the IHR

The Regulations, first adopted by the WHA in 1951 and completely revised in 2005, have been criticized as ineffective in past emergencies, notably during the COVID-19 pandemic, but, until 2022, there had not been much appetite for revising them again.

The impetus for reform came from the United States (US), reluctant to embark on uncertain treaty negotiations and preferring to strengthen existing law. The WHA adopted in 2022 an initial set of technical amendments to the IHR’s final clauses proposed by the US and invited member states to propose further amendments by September 2022. This unusual approach to frontloading proposals before negotiations began led to a rather chaotic mass of over 300 amendments proposed by over 100 states. Despite the mandate to focus on “targeted amendments,” several developing countries submitted far-reaching proposals on access to health products, financing, assistance, and other “equity” issues, sometimes overlapping with parallel pandemic agreement proposals. This move showed the determination of developing countries

to transform the IHR from a technical and operational tool into a regulatory and political instrument.

The negotiations resulted in the adoption of a fraction of the initial proposals, reflecting a restrained approach to what could be agreed on politically and what was considered a priority. This outcome implicitly validates the structure and approach of the IHR despite previous criticism. The perception of the Regulations as a technical instrument familiar to operational agencies in states parties also probably played a role in orienting the negotiations towards a focused and limited outcome.

While many amendments aim at strengthening or fine-tuning existing provisions, some are innovative and aim at injecting equity into the fabric of the IHR or improving their governance:

- Introducing the concept of a "pandemic emergency" (Articles 1 and 12) to be declared by WHO as a particularly acute and diffuse public health emergency of international concern. The declaration by WHO of a pandemic emergency under the IHR may trigger legal consequences under the future Pandemic Agreement, hence the need for synergy between the two;
- The requirement for states parties to establish or designate a "National IHR Authority" (Article 4) with the responsibility of coordinating national implementation to overcome the confinement of that responsibility to the sole national health agency;
- Facilitating equitable access to health products during a pandemic emergency (Article 13), though with the active role played by WHO rather than states parties, which bear only supporting obligations qualified by references to applicable law and available resources. From this perspective, the amendment does not add much to what WHO is already doing as a form of technical assistance;
- Strengthening collaboration and assistance obligations (Article 44) through a commitment to promote and facilitate sustainable financing of national capacities mostly for the benefit of developing countries, once again qualified by references to applicable law and available resources;
- Establishment (new Article 44 *bis*) of a coordinating financial mechanism under the authority of the WHA to identify and mobilize financial resources, but short of establishing a new fund as originally demanded by developing countries;
- Establishment of an intergovernmental implementation committee (new Article 54 *bis*) to strengthen IHR implementation through learning and cooperation with a facilitative and consultative approach. This new organ is clearly not meant as a compliance and accountability mechanism, but at the same time, it fills a yawning

governance gap in the IHR, which did not have any dedicated implementation review body.

Even with the qualifications just noted, these amendments introduce some important innovations in the political, normative, and institutional structure of the IHR. While positive, there is a risk is that the "equity and solidarity" provisions may lead to a further politicization of the IHR and affect their operational functions, both with regard to the role of WHO that is becoming quasi-regulatory and in terms of increased expectations from developing countries in return for their cooperation. A lot will therefore depend on the implementation of the amendments that will enter into force 12 months after their notification by WHO.

Key Unresolved Issues in the Pandemic Agreement

While it is not possible to predict the outcome of the Pandemic Agreement negotiations, below we analyze the text of the most recent draft of the agreement (hereinafter WHA77 Text). We focus on progress regarding unresolved issues: research and development (R&D), sustainable and geographically diversified production of pandemic-related products (e.g., diagnostics, vaccines, and therapeutics), intellectual property rights, and technology transfer.

In Article 9 of the WHA77 Text, WHO member states largely agree on the need to promote capacity building, scientific collaborations, and sustainable investment in research institutions for pandemic products R&D. Some developed countries oppose new obligations on R&D, including requirements for population-representative clinical trials, publication of clinical and other research results, and tying global access to pandemic products to publicly funded R&D agreements with pharmaceutical corporations. However, a convergence would mark the first time R&D for pandemic products is addressed through an international agreement, as a previous attempt by WHO to develop an R&D treaty failed in 2012.[1]

Article 10 aims to address concerns about the concentration of pandemic products manufacturing in a few countries. It would require parties to identify and support geographically diverse production facilities, prepare to scale up production, and promote transparency across the value chain, including relevant technology, skills, and knowledge transfers. While the draft text includes caveats (requiring parties to take measures "as appropriate"), it would represent the first directive on local production of pandemic products in a binding international agreement.

Article 11.4 largely reaffirms the flexibilities under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Many delegations view the World Trade Organization as the appropriate forum for addressing intellectual property rights issues, including the use of TRIPS flexibilities to access pandemic products. Some developing countries, which have in the past faced economic and diplomatic pressure when pursuing access to health products, have proposed that parties be obliged not to exert pressure on others when TRIPS flexibilities are employed.[2]

Article 11, depending on its final wording, could oblige parties to grant non-exclusive licenses for government-owned intellectual property rights on pandemic-related products and require private patent holders to charge reasonable royalties to developing country manufacturers during a pandemic. However, given the contentious nature of these discussions, it remains uncertain whether parties will be obliged to take such actions or merely encouraged to do so.

Agreement has been elusive on Article 12 dealing with the proposal to establish the WHO PABS System. Rapid and reliable sharing of pathogens and their genetic sequence data is crucial for the risk assessment and development of health products. The widespread sharing of SARS-CoV-2 sequences and its variants has enabled an unprecedentedly fast response to the COVID-19 pandemic.[3]

In line with the approach of the UN Convention on Biological Diversity (CBD) and its Nagoya Protocol, there is an overall agreement on reaffirming the principle of national sovereignty over biological resources (pathogen samples). There is also a large consensus that sharing of pathogen samples and genetic sequence data should be linked to equitable benefit-sharing, which could incentivize states to participate in a multilateral system. However, achieving balance between different demands and deciding on how to operationalize them has been the biggest point of contention in the negotiations. Countries with developed scientific infrastructure and pharmaceutical manufacturers prefer rapid and unconditional access to pathogens and genetic sequence data, favoring non-monetary benefit-sharing like open access to information, scientific acknowledgment and collaboration. Meanwhile, developing countries view the PABS System as a way to achieve equity through mandatory, comprehensive benefit-sharing, including monetary or in-kind contributions.

Finding consensus on designing a functional PABS System has been elusive, particularly on setting a percentage for offering pandemic-related products free or at cost during emergencies. Additionally, there is lack of agreement on key features of the system, such

as the use of standardized contracts to legally bind pharmaceutical companies, and the registration requirements and terms of use for other participants (including scientists) wishing to use the System. Issues concerning the relation of the PABS System to other international instruments, in particular the Nagoya Protocol to the CBD, must also be addressed to ensure legal certainty, proper functioning, and rapid, reliable access to pathogens alongside equitable benefit-sharing.

In light of these difficulties, the WHA77 Text contains only a set of principles to guide the future PABS System, with details to be agreed on in a separate instrument. If adopted, it would be the first legally binding agreement on access and benefit-sharing for public health, the other extant instrument being a non-binding WHO framework adopted in 2011 on sharing pandemic influenza virus samples and related benefits. The risks and opportunities in creating this instrument are monumental; it remains to be seen if a functional PABS System that contributes to global PPPR can be established.

Conclusion

International pandemic law-making is still a work in progress, with many uncertainties about its outcome and the effectiveness of the instruments emerging from difficult and divisive negotiations. The amendments to the IHR confirm that it is easier to fit and adapt political claims into an existing legal frame than to develop new law in the absence of a sufficiently robust common ground. Still, despite the current divisions, the negotiation of the pandemic agreement is revealing a remarkable degree of convergence within the international community towards the essential elements of a credible legal regime for the prevention and control of a global disaster such as COVID-19. This is a cause for some optimism.

About the Authors:

Gian Luca Burci is Senior Visiting Professor of International Law and Academic Adviser of the Global Health Centre at the Graduate Institute of International and Development Studies, Geneva.

Adam Strobeyko is a Swiss National Science Foundation Postdoctoral Researcher in International Law at the Graduate Institute of International and Development Studies, Geneva

Daniela Morich is Manager and Adviser at the Global Health Centre, Graduate Institute of International and Development Studies, Geneva.

[1] Kiddell-Monroe, Rachel, Johanne Iversen, and Unni Gopinathan, *Medical R&D Convention Derailed: Implications for the Global Health System*, J. HEALTH DIPLOMACY (2013), https://www.researchgate.net/publication/273316846_Medical_RD_Convention_Derailed_Implications_for_the_Global_Health_System.

[2] For an examination of the use of TRIPS flexibilities to secure access to health products, and the cases of pressure exerted upon countries engaged in compulsory licensing, *see*: Ellen F.M. 't Hoen et al., *Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001-2016*, BULLETIN W.H.O., 96(3), 185–193 (2018), https://doi.org/10.2471/BLT.17.199364.

[3] WHO, *Global genomic surveillance strategy for pathogens with pandemic and epidemic potential, 2022–2032* (2022), https://www.who.int/publications/i/item/9789240046979.