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GOVERNING PANDEMICS SNAPSHOT

A SERIES OF PERIODIC BRIEFINGS ON THE STATE OF GLOBAL REFORMS FOR PANDEMIC PREPAREDNESS AND RESPONSE | JANUARY 2023

Welcome to the inaugural issue of the Governing Pandemics Snapshot, a publication aiming to provide a concise, periodic overview on the state of efforts to strengthen global pandemic preparedness and response (PPR). This first issue looks back at 2022 and forward to 2023, examining three topics that will recur with each issue: negotiations towards a Pandemic Treaty (or instrument), amendment of the International Health Regulations; and Financing of PPR. Each issue will also cover a rotating special topic, and we begin here with Pathogen- and Benefit-Sharing (PBS). More frequent updates are available on our timeline at Governing-Pandemics.org. Feedback is welcome at globalhealth@graduateinstitute.ch, and keep an eye out for our next issue in mid-2023.

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PANDEMIC TREATY: TOUGH POLITICAL NEGOTIATIONS AHEAD

Daniela Morich[1]

Following a milestone World Health Assembly decision in late 2021, WHO Member States have been negotiating an international agreement on pandemic prevention, preparedness and response to strengthen global capacities and resilience for future pandemics.

The year 2022 was the year for the advance of these pandemic treaty talks with the establishment of a formal process, a strict timeline, and initial discussions on principles. In 2023, negotiations will shift from broad consultations to tough politics.

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The Covid-19 pandemic brought to the surface the shortcomings of global health governance for emergencies and accelerated discussions to reform it. At a special WHA session in late 2021, the second-ever convened by the World Health Assembly, WHO Member States agreed to establish an intergovernmental negotiating body (INB) to negotiate a new “instrument” to strengthen pandemic prevention, preparedness and response – or, a pandemic treaty.

The INB initiated its work in early 2022 and is to present the outcome of the negotiations to the 77th World Health Assembly (WHA) in May 2024. This is an ambitious timeline for a complex international rule-making process, especially as it will run in parallel to the process to revise the International Health Regulations (IHR), a pre-existing WHO instrument that governs the cross-border spread of infectious disease.

Nonetheless, the INB is moving forward and achieved two mid-term milestones in 2022. In July, at the second INB meeting, Member States agreed that the instrument should be legally binding, which suggests countries are ready to accept new international obligations to improve pandemic prevention and response. In addition, the INB engaged in intensive intersessional consultations to seek input not only from governments or well-established experts – the traditional protagonists of international rulemaking – but also from civil society organizations and the public. Despite these efforts, commentators have argued that the process is still not as inclusive as it should be. As work on the instrument progresses, negotiators should expect more demands to expand meaningful participation of stakeholders beyond governments.

The INB's Bureau (six countries elected to lead the process) released the 'conceptual zero draft' (CZD) ahead of the third meeting of the INB, which took place in December 2022. The CZD –which can be seen as the first rough draft of the accord – brought to the negotiating table a broad set of issues and highlighted a collective willingness to ensure a more equitable response to future threats. It also reflected tough divisions on several issues, in particular, intellectual property (IP), pathogen- and benefit- sharing, One Health, financing and accountability, which will likely become more visible and contentious as negotiations move to the next phase.

At the conclusion of the gathering, Member States directed the INB Bureau to develop the 'zero draft'. Delegates strongly encouraged the Bureau to move away from the vague and aspirational language of the CZD and to present clear legal provisions and definitions, including one for '*pandemic*', for Member States to negotiate in earnest.

The INB Bureau is expected to circulate the zero draft in early February 2023. At this stage, the negotiation process will likely shift from a consultation and information gathering process to become a more politicized, polarized and consequential debate. The time available to negotiators is constrained. The 2023-2024 agenda includes 6 additional INB meetings scheduled over 14 months in addition to meetings of the drafting groups, with the IHR revision process unfolding in parallel. Considering the complexity of the issues on the table, the existing divisions between Member States, and the limited time available to negotiators, achieving meaningful progress in this new highly-political phase is the tall order for 2023.

AN EXISTENTIAL MOMENT FOR THE INTERNATIONAL HEALTH REGULATIONS

Gian Luca Burci[2]

While negotiations on a new pandemic instrument continue in 2023-24, the International Health Regulations (IHR) remain the sole global legally-binding instrument devoted to the prevention and control of the international spread of disease - and revisions to those are already underway. Can the two parallel processes complement each other or will they add new layers of confusion? That is the challenge negotiators and member states will face.

Although considered an essential component of the global health security toolbox, the IHR attracted severe criticism and allegedly low compliance during the COVID-19 pandemic. The momentum towards a new "pandemic treaty", beginning in late 2020, was in part a reaction to the perceived weaknesses and limitations of the IHR.

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The difficult and sometimes confusing discussions in the Working Group on strengthening WHO preparedness and response to health emergencies created by the 74th World Health Assembly in 2021 to discuss reforms, ultimately led to a WHA decision in December 2021 to launch negotiations on a new legal instrument ("pandemic treaty") to be adopted by 2024.

Then, in 2022, attention turned back to the IHR as member states sought faster solutions for the most burning issues that had surfaced during the pandemic - particularly around outbreak reporting and IHR compliance. As a result, a complex IHR amendment process is also now underway. The two processes (IHR revisions and pandemic accord) are thus now proceeding in parallel, with hard decisions still to be made on the issues that the revised IHR will tackle - as compared to the new pandemic accord.

Negotiations to amend the IHR in 2023/2024 raise an existential question about their *raison d'etre*: should they retain their technical, operational character, or expand significantly to address highly political questions such as those on international assistance, equity and access to technologies for disease outbreaks?

The US broke the ice by proposing its own substantial set of amendments in January 2022, and successfully winning agreement at the 75th WHA in May 2022, to both adopt a set of limited technical IHR amendments and to open up a broader process for further amendments. The WHA thus launched negotiations towards "targeted amendments" of the IHR with the same 2024 deadline for WHA adoption as the new pandemic accord. Member States submitted their proposed amendments by 30 September 2022 and an expert "review committee" analyzed them and presented its recommendations to the Director-General in January 2023.

A Working Group open to all Member States will work from February 2023 towards a negotiated package. The process is unusual compared to other intergovernmental negotiations, in that states hardly ever place on the table all their proposed amendments at the outset; the initial US disclosure of all its amendments, however, required a similar treatment for other states and made that approach inevitable.

Wildly diverse amendments but a few trends emerge

The outcome of the first phase of this process is a massive aggregation of wildly diverse amendments (available here) proposed or supported by almost 100 states. They range from focused technical amendments to far-reaching changes. Despite their diversity, a few trends emerge dividing Global South and Global North countries. The most political proposals, coming in particular from the African Region, Bangladesh and India, aim at ensuring equitable access to vaccines, distributed manufacturing capacities, technology transfer, limitations on patenting and sustainable financing of national capacities.

These proposals reflect the North-South divide that we have been witnessing in the recent treaty conferences on climate change and biodiversity and are clearly also a consequence of the inequities in access to life-saving medical countermeasures displayed during the COVID-19 pandemic.

Other proposals, in particular from the European Union, the Eurasian Economic Union (submitted by the Russian Federation) and the United States, aim at strengthening the IHR within their current approach, e.g. by tightening compliance and accountability for information sharing, encouraging the sharing of genetic sequence data and through the use of digital technologies.

Two negotiating processes unfolding at the same time

The challenge in reaching an agreed package in time for the 2024 WHA is increased by the unprecedented parallel unfolding of two negotiating processes with the same timeline, where countries will probably submit the same types of proposals for both instruments to secure an overall favorable outcome. An important point in this respect that is often overlooked is that amendments to the IHR will in principle enter into force at the same time for all its 196 parties, whereas the pandemic instrument - since it will likely be an international treaty - will enter into force once a critical mass of countries has ratified it and only for them, with new countries joining once they ratify.

The broad range of proposals for the pandemic instrument and the likelihood that the US will eventually not ratify it may actually lead Global South countries to prioritize the IHR for some of the most ambitious proposals. This possibility raises one final issue. Currently, the IHR is essentially an operational instrument to coordinate outbreak prevention and control and depoliticize WHO's role in managing them. There is no emphasis on equity, assistance or international cooperation. Amendments proposed by Global South countries would transform it into a regulatory and transactional instrument with a more political role for WHO and differential treatment for developing countries to improve equity in the availability of health technologies. Fundamentally, negotiators will have to decide what they want the IHR to be - and if the IHR is expanded to encompass the issues of health equity then what role would the new pandemic instrument play?

FINANCING PANDEMICS: NECESSARY BUT INSUFFICIENT PROGRESS TO DATE

Seyed-Moeen Hosseinalipour & Suerie Moon[3]

Since the pandemic's outset, financing PPR has been consistently ranked as a major challenge. There is a major gap between financial needs and investment in global PPR, estimated at 10.5 billion USD per year.

2022 witnessed two important developments on the PPR financing front: a new commitment from Member States to increase WHO assessed contributions, and the launch of the Pandemic Fund. The previous year had seen strong consensus among the various international reviews: the Independent Panel for PPR, the Global Preparedness Monitoring Board, and the G20 High-Level Independent Panel agreed that pandemic financing was in urgent need of reform.

WHO relied too heavily on donations and voluntary contributions to run the organization, including its emergency programme. Additionally, there was a substantial gap between available financial resources and needs. The G20 estimated that an additional US$10.5 billion per year for financing PPR was needed.

The WHO Working Group on Sustainable Financing, established by the Executive Board, met seven times during the course of 12 months to develop recommendations for sustainable WHO financing. As a result, the WHA 2022 adopted the historic decision to increase assessed contributions to 50% of the WHO's

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program budget by 2030. In addition to the overall strengthening of WHO, this budget increase aims to improve the financing of its emergency programme including the internal Contingency Fund for Emergencies (CFE). It is hoped that this change will expand the level and scope of WHO's emergency support to Member States, allowing for better and faster response in the early stages of potential pandemics. Although only a portion of the increased funding will go to PPR, this is a solid step forward in solidifying WHO's role and guarding against further fragmentation of the PPR system.

The other notable change is the launch of the Pandemic Fund by the G20 in November 2022, with the World Bank serving as both Trustee and Secretariat. Currently chaired by Indonesia, the Fund aims to provide a dedicated stream of additional, long-term financing to strengthen PPR capabilities at the country level. The governing board is comprised of an equal distribution of seats between donors and beneficiaries with 9 seats for each. The Bill and Melinda Gates Foundation (BMGF) occupies the board seat for philanthropic contributors, and Amref Health Africa and the Global Health Council hold the two seats for civil society organizations from the Global South and North, respectively. Eligible countries may only apply to the Fund by partnering with one of the designated "implementing agencies" including WHO, Unicef, the Global Fund, Gavi, and a group of regional Development Banks.

Limiting eligible grantees to such a small number is unusual, and may pose challenges to finding and funding the best proposals. However, it may address critiques that a new fund would further fragment the global architecture. For similar reasons, WHO chairs the Technical Advisory Panel (TAP) of the Fund, which aims to provide technical guidance to identify funding priorities and critical gaps.

The Fund now has US$1.6 billion to work with, far short of targets but perhaps far more than some skeptics would have predicted a year ago. Most of the funding commitments come from the usual suspects: the majority from traditional donor governments (i.e. OECD Development Assistance Committee members), with sizeable contributions also from the European Commission, BMGF, Rockefeller Foundation, and Wellcome Trust. However, notably, the Fund has also attracted contributions from some less traditional sources, such as China, India, Indonesia, Saudi Arabia, Singapore, South Africa, and the UAE, perhaps indicating an expanding commitment to investing in global PPR among non-Western emerging powers.

As Covid-19 gradually slips out of the headlines and down the global agenda, it is unclear whether the Fund will ever be able to raise enough, an indicator of the gap between ambitions and political realities. Despite measures to assuage concerns about fragmentation, it remains to be seen how and how well the Fund will integrate into the existing architecture. Finally, the lion's share of PPR financing does and will come from the national (not international) level, and so a key question for 2023 is whether governments will increase their PPR financing commitments and/or commit to do so through legally-binding instruments such as the pandemic treaty or IHR.

PATHOGEN AND BENEFIT SHARING (PBS) – FROM PATCHWORK TO SYSTEM?

Adam Strobeyko[4]

The sharing of pathogen samples and their genomic sequencing data (GSD) between laboratories, governments and pharmaceutical companies enables surveillance and the research & development of vaccines, diagnostics and treatments for pandemics. However, how to ensure both the reliable international flow of samples & GSD, and equitable access to the health technologies that result is one of the most contentious issues in pandemic treaty and IHR amendment negotiations.

Strengthening the governance of pathogen sample- and benefit-sharing (PBS) is necessary to achieve both greater equity in access to pandemic technologies and a more effective, reliable system for PPR. In 2022 it became one of the most technically, legally and politically challenging issues in the ongoing negotiations towards a pandemic treaty and to amend the IHR. The current momentum offers a historic opportunity for the establishment of a comprehensive PBS system, but tough political negotiations lie ahead.

The Conceptual Zero Draft of the pandemic treaty flags the importance of "fair, equitable and timely access and benefit-sharing" in its draft Article 9. The draft text refers to the development of a rapid, transparent and comprehensive system for governing PBS. However, a key question subject to negotiation is whether states would commit to take such measures or whether this would largely be voluntary and discretionary. The issue is also relevant in the context of the IHR amendment process, with multiple states having proposed to include GSD sharing as part of reporting obligations, while the African Group in particular has clearly stated that such data-sharing obligations are unacceptable in the absence of a credible benefit-sharing system.

The rapid, yet inequitable response to Covid-19 was the latest chapter in a long-standing controversy: since the mid-2000s, cross-border outbreaks of infectious diseases have been accompanied by debates about the equitable sharing of pathogen samples and benefits. As the pharmaceutical industry can use the pathogen samples and GSD provided by countries to develop and commercialize new products, many countries (particularly developing countries) have demanded access to the resulting benefits.

Years of negotiations on these issues gave rise to a complex patchwork of arrangements that currently governs PBS. Adopted in 2011, the Pandemic Influenza Preparedness Framework (PIP Framework) established a system that places fair and equitable benefit sharing on equal footing with rapid and timely access to influenza viruses of pandemic potential. The PIP Framework is based on reciprocity: countries share influenza viruses with the WHO laboratory network (Global Influenza Surveillance and Response System – GISRS). In exchange, companies that obtain samples from GISRS commit to provide the WHO with benefits related to their use, for example, the commitment to provide 10% of real time pandemic influenza vaccine production. Meanwhile, the Nagoya Protocol to the Convention on Biological Diversity (CBD), adopted in 2010, requires sharing of biological resources such as pathogen samples to be based on Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) and reinforces the principle of national sovereignty over such resources.

Existing legal arrangements for PBS are insufficient: the PIP Framework only applies to the sharing of pandemic influenza viruses, and the bilateral system

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under the CBD's Nagoya Protocol may be too slow for disease outbreaks. The scope of these two instruments has also been outpaced by technological change: they lack specific provisions to govern GSD which has resulted in a lack of legal certainty and a regulatory blind spot that has yet to be addressed.

Some important steps forward were made in December 2022, when the Conference of the Parties to the CBD reached a decision (CBD/COP/15/L.30) to establish a multilateral mechanism for benefit-sharing from the use of digital sequence information (DSI), a term which also includes GSD. Notwithstanding the pressure from pharmaceutical lobbying groups, the CBD agreement chose not to exclude pathogens and their GSD from its scope and called for the latter to be shared on public platforms. The specific benefit sharing and financing arrangements are to be finalized at the next UN Biodiversity Conference in 2024. The agreement also makes reference to other DSI governance processes and calls for solutions across different fora to be mutually supportive. As diplomats in Geneva deliberate upon a new pandemic treaty and amendment of the IHR, these decisions make clear that they must find solutions to sharing of GSD, and PBS more broadly.

The CBD decision has also shown that there is broad political will to support multilateral PBS mechanisms, and that these can be consistent with the open science objectives of rapid, widespread data sharing. The ball is now in the court of the global health community. If countries want to reach agreement on any new international pandemic rules, PBS will constitute an important part of the equation. The industrialized countries need access to pathogen samples and GSD. Meanwhile, when asked to provide samples and data, many developing countries are unlikely to compromise on their demands concerning access to technology. The current reform process therefore offers a historic opportunity to establish a comprehensive PBS mechanism, which would provide for expeditious sharing of pathogen samples and GSD and the sharing of benefits on an equal footing for all types of pathogens with pandemic potential. The outcome of this process will determine how well we are equipped to deal with future pandemics.