GOVERNING PANDEMICS SNAPSHOT

A SERIES OF PERIODIC BRIEFINGS ON THE STATE OF GLOBAL REFORMS FOR PANDEMIC PREPAREDNESS AND RESPONSE (PPR) | JANUARY 2025

Welcome to the fifth issue of the Governing Pandemics Snapshot. This issue provides critical insight into the past six months of negotiations over a World Health Organization (WHO) Pandemic Agreement, examining whether a meaningful agreement can be achieved this year. It addresses remaining contentious issues such as Pathogen Access and Benefit Sharing (PABS) and One Health, whilst highlighting recent successes in Research and Development (R&D) and Sustainable Financing. The recent US withdrawal from the WHO, however, will add a significant layer of complexity to the negotiations, with potentially far-reaching implications for the future of the pandemic agreement and global health governance. The second piece explores the recent Convention on Biological Diversity (CBD) Decision on Digital Sequence Information (DSI) and its implications for the pandemic agreement negotiations, particularly for its PABS System. Finally, this edition analyzes the governance challenges that lie ahead in creating coordination and synergies between the newly amended International Health Regulations (IHR) and the pandemic agreement.

More frequent updates are available on our timeline at governingpandemics.org. Feedback is welcome at globalhealth@graduateinstitute.ch.

Authors: Daniela Morich, Ava Greenup, Suerie Moon, Gian Luca Burci, Adam Strobeyko
Editorial team: Elaine Fletcher, Ava Greenup, Bétina Zago, Ricardo Matute

WILL 2025 DELIVER A MEANINGFUL PANDEMIC AGREEMENT?

By Daniela Morich, Ava Greenup and Suerie Moon

Small steps in the right direction - but will the center hold?

Under the leadership of a reshuffled Bureau, the six-member body leading the negotiations, three additional rounds of negotiations of the International Negotiating Body (INB) took place in the last six months, and member states made some considerable progress.

At the most recent meetings, the INB agreed on essential provisions including Research and Development (Article 9), Sustainable and Diversified Local Production (Article 10), and Sustainable Financing (Article 20).

While this represents progress on some core provisions of the future pandemic agreement (PA), deep divides remain on issues such as establishing the novel Pathogens Access and Benefit-Sharing System (PABS), prevention and One Health, and more equitable access to pandemic health products.

Article 9: First internationally binding agreement on R&D?

If Article 9 is adopted as the text currently stands, the PA will be the first internationally binding agreement to mandate strengthening research and development (R&D) for health products and to reference the inclusion of conditions "*that promote timely and equitable access to [...] products*" in publicly funded R&D agreements.

This could set a global precedent by formalizing cooperation and promotion in the area of R&D, which has traditionally been guided by voluntary or non-binding agreements. Additionally, language incorporating equity into the publicly funded mechanisms for R&D, will have the power to potentially affect how pandemic-related products are developed and distributed, particularly benefiting developing countries.

Article 20 on sustainable funding requests member states to strengthen sustainable and predictable financing for the implementation of the Agreement "*to the extent feasible*". It also establishes a Coordinating Financial Mechanism

to promote the implementation of the Agreement but falls short of creating new funding sources devoted to the PA.

In a context of declining international assistance and widespread national fiscal constraints, this article is very much the product of its time. However, it strives to align with the newly adopted coordinating financial mechanism of the IHR, as further analyzed by Gian Luca Burci in the last section of this Snapshot.

On the procedural side, after continuous requests for greater access to the closed-door proceedings, the 11th meeting of the INB (9 - 20 September) saw the introduction of short, daily briefings open to relevant stakeholders duly accredited to the process. These sessions provided a glimpse into discussions from the previous day of negotiations and offered an opportunity to relevant stakeholders to make interventions and ask questions.

Since the resumed 12th meeting of the INB (2 - 6 December), these daily briefings are publicly webcast and onscreen negotiating text is shared with relevant stakeholders at the end of each day, enabling more informed interventions. This long-sought change in the working modalities increases transparency in the process. It is hoped that these practices will be maintained going forward.

One Health: Divergence between higher- and lower-income countries

Some high-income countries, foremost among them the European Union, are pushing hard for detailed and operational commitments on prevention and the One Health approach. They see such obligations as the most important gain beyond the status quo that they would achieve through the PA.

In contrast, many low- and middle-income countries (LMICs) are concerned about the costs and potential trade disadvantages One Health commitments could entail, as they could require more extensive, and expensive, surveillance systems and have far-reaching implications for livestock rearing, wildlife and land use practices.

There is also continued debate over whether legally binding One Health rules should be under a WHO-managed treaty or involve all four international organizations (Food and Agriculture Organization, the United Nations Environment Programme, WHO, and the World Organisation for Animal Health) that now work together in a quadripartite collaboration and under whose competence the different components of the One Health approach fall.

Negotiation roadblock: The PABS system

Whether these and other open provisions can be finalized ultimately depends on resolving a complex and difficult issue, known as the PABS System.

In brief, tracking the spread and mutation of pathogens that could cause pandemics requires the global community of scientists to share pathogen samples and genetic sequence data rapidly and internationally, and scientists largely did so during the COVID-19 pandemic.

Such sharing is also the starting ingredient that allows researchers to develop diagnostic tests and vaccines rapidly when a new outbreak is detected. Currently, no international rule – including the recently amended IHR – requires governments to share pathogen samples and data internationally, and this gap in the legal architecture leaves every country at greater risk.

Yet many LMICs hesitate to accept such obligations without clear, binding guarantees of access to the benefits arising from the utilization of their samples and data, fearing they will be denied access to the products developed from what they share.

Complicating matters, the 1992 Convention on Biological Diversity (CBD) and its 2010 Nagoya Protocol govern benefit-sharing for access to genetic resources, including pathogen samples. However, these agreements typically involve lengthy bilateral negotiations, which are unsuitable for the urgency of a pandemic.

The rise of digital sequencing information (DSI), which can replace physical samples in developing new health products, falls in a legal grey zone and has further complicated agreeing on modalities to ensure fair and equitable benefit-sharing.

While CBD negotiations have tried to address the DSI issue, it remains a work in progress as analyzed by Adam Strobeyko in the next article of this edition of the Snapshot.

Also highly debated is the so-called ‘legal architecture’ of the treaty, including the level of detail that needs to be included in the text of the PA and how much can be deferred for further negotiation of one (or more) follow-on annex(s) to the treaty after the latter is adopted or after it enters into force. This issue is becoming increasingly significant in the PABS negotiations, as the complexity of the matter and the remaining two weeks of formal negotiations are unlikely to suffice in agreeing on detailed provisions.

US withdrawal from WHO

Adding another complicating factor into the mix is the US withdrawal from WHO, enacted by an executive order issued hours after Donald Trump was inaugurated as US President on Monday, 20 January.

The executive order specifically directs the US Secretary of State to cease negotiations on the PA and the amendments to the IHR and to take action to ensure the agreement and the amendments will have no binding force on the United States.

As the largest funder of the WHO, the withdrawal of the U.S. will greatly amplify the fiscal pressures on the remaining WHO member states and have immense consequences, not only for the treaty's future implementation, but for the stability and functionality of global health institutions and multilateral systems.

What remains to be seen is how WHO's other 193 member states will proceed within the INB. As the US ratification of a pandemic treaty has always been in serious doubt, they should remain focused and carry these negotiations to the finish line by May 2025.

WHAT DOES BIODIVERSITY HAVE TO DO WITH GLOBAL HEALTH? UN CONVENTION ON BIOLOGICAL DIVERSITY DECISION ON DIGITAL SEQUENCE INFORMATION AND THE PANDEMIC AGREEMENT

By Adam Strobeyko

Access to pathogen genetic sequences and the equitable sharing of related benefits have received significant attention in multiple international fora. At the 16th session of the Conference of the Parties of the Convention on Biological Diversity (CBD COP16), held in Cali, Colombia, from October 21 to November 1, 2024, States Parties adopted a decision establishing a multilateral mechanism for the sharing of benefits resulting from the use of Digital Sequence Information (DSI). DSI includes digitized information content of genetic resources crucial for genomic surveillance and the research and development (R&D) of health products.

The CBD COP decision requires companies above a certain threshold[1] which benefit "directly or indirectly" from DSI to contribute either 1% of their profits or 0.1% of their revenue to the "Cali Fund" established for that purpose. The funding raised in this way will be distributed directly to countries, with at least 50% allocated to the "self-identified needs of indigenous peoples and local communities," for the conservation and sustainable use of biodiversity.

The establishment of the multilateral mechanism and its fund marks a significant development in the long-standing discussions on regulating DSI and the benefits derived from its use. It creates a unique (though not legally binding) international framework for the issue. However, the implementation of the CBD COP decision, its connection to ongoing Pandemic Agreement's (PA) Pathogens Access and Benefit-sharing System (PABS) discussions and to specific needs of the health sector, raise a host of legal issues.

Unresolved legal challenges surrounding DSI

Firstly, concerning the scope of the decision: there exists no agreed formal definition of DSI. With the precise meaning of DSI subject to ongoing discussions, the term is broadly understood to also cover "sequence information" discussed in the context of the PA and potentially falling under PABS, if and when it is established. Notably, the CBD COP decision does not exclude pathogen data from its scope and identifies the pharmaceutical and biotechnological industries among the sectors benefiting from DSI and, thus, subject to benefit-sharing.

Secondly, concerning the means of calculating percentages for benefit sharing: it remains unclear whether the criterion applies to company's overall corporate revenues and profits or to specific activities benefitting from DSI. Sequence data is foundational in scientific R&D, especially in the context of mRNA technologies and advancements in synthetic biology. Given the sheer scale at which DSI is used - with commercial R&D often involving searches of millions of sequences potentially falling under various jurisdictions and international instruments - it may prove impossible to separate business activities for the purpose of DSI benefit sharing. On the other hand, demanding companies to contribute 1% of their global profits or 0.1% of revenue in the form of an international levy, is likely to be perceived as a burden on high-risk pharmaceutical R&D. Therefore, it remains crucial for PABS to establish benefit-sharing mechanisms tailored to the specificities of global health, addressing its inequities and the need for genomic surveillance and rapid pandemic response.

Thirdly, concerning the implementation of the decision for DSI-hosting databases, it is worth noting that the decision indicates that "*public databases, academic, and public research*

1 'entities which on their balance sheet dates exceed at least two out of three of these thresholds (total assets: USD 20 million Sales; USD 50 million; Profit: USD 5 million)' - https://www.cbd.int/doc/c/bd4f/2861/9dce4f46d43a637231a442e0/cop-16-l-32-rev1-en.pdf

institutions are not expected to make monetary contributions to the global fund." However, it also requires entities operating databases to inform users about ABS commitments, ensure submission of information on the DSI's country of origin, associated metadata, and traditional knowledge, align with open science principles, and verify that the submitted DSI is free from restrictions that prohibit sharing.

Legal nature of the decision

The situation is complicated by the fact that the CBD COP decision is not binding under international law and lacks enforcement mechanisms to ensure compliance and payments. Enforcement relies on national-level measures to implement its principles and incorporate them into domestic law if individual Parties to the CBD so decide. The Annex of the CBD COP decision, which addresses the operationalization of the multilateral benefit-sharing mechanism, specifies that it applies to DSI that is "*made publicly available, in compliance with national legislation*" and that is not subject to mutually agreed terms that would preclude its free availability. This effectively leaves States Parties the freedom to regulate access to DSI at the national level.

However, the focus on national-level implementation undermines a key advantage of international decisions: the ability to establish a single, unified set of rules that enhance legal certainty and clarity for multinational businesses. Consequently, it remains unclear, for instance, how double payments under different regimes can be effectively avoided, as well as what incentive exists for industry to contribute. The sheer complexity of domestic legislation on the topic - described as 'at least 100 distinct ABS laws around the world' - has already created challenges for companies and is likely to impose higher transaction costs on businesses unless it is harmonized internationally. With rapid access to data and health products being crucial for effective public health responses, PA negotiators should leverage the experience from these negotiations and prioritize international legal clarity when establishing the PABS for pandemic-potential pathogens.

Potential linkages with other international instruments

This brings us to another issue, which concerns institutional linkages between CBD COP Decisions with other regimes and instruments. The Annex excludes from its scope DSI for which fair and equitable sharing of benefits is provided by another international instrument, "*except if those instruments choose the [CBD] multilateral mechanism for that purpose*." This implies that, if the sharing of benefits under PABS is deemed fair and equitable by an internationally agreed procedure, the sequence data covered by PABS would fall outside the scope of the CBD COP decision unless PABS explicitly opts to provide benefits through the Cali Fund. This could be achieved by linking the requirement to provide "*annual monetary contributions*," as envisioned under PABS, with the Cali Fund. Such a decision could arguably be made by the COP of the PA after the latter enters into force.

However, the meaning of what constitutes "fair and equitable" sharing of benefits, as well as the question of who decides whether it has been achieved, has been the subject of extensive analysis and debate, without a clear conclusion. The designation of a specialized international access and benefit-sharing instrument for this purpose is established under Article 4.4 of the Nagoya Protocol, not under the CBD, raising doubts about how conflicts between different regimes can be resolved without clear legal rules to that end.

Managed by the Multi-Partner Trust Fund Office of the United Nations Development Programme, the Cali Fund is expected to take several years to fully materialize. While the primary focus of allocations will likely be on biodiversity conservation and sustainable use, the decision includes the possibility of supporting other objectives, should other fora choose it as their benefit-sharing mechanism.

Conclusion: a new beginning for DSI regulation

The CBD COP decision creates an ambitious framework for sharing DSI-related benefits. The decision represents a significant stepping stone in the regulation of DSI and should be viewed in the context of the longstanding discussions on the topic. However, it is not the final word on DSI regulation but part of an ongoing process. A useful parallel is the "soft law" Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits (2002), which eventually led to the legally binding Nagoya Protocol. With the CBD COP decision's call to continue exploring benefit-sharing modalities, this should be seen as a new beginning rather than a last word on the topic.

The decision's success will depend on political support, especially from megadiverse and industry-hosting countries. However, if the Cali Fund fails, the status quo of largely unregulated ABS may continue, with some states potentially resorting to restricting access to sequence data at the national level, potentially disrupting scientific R&D. If PABS fails to materialize, the publicly available pathogen DSI is likely to fall under the

scope of the CBD benefit sharing mechanism. In the future, States Parties to the CBD may also push for an internationally binding instrument on DSI benefit sharing negotiated under the auspices of the CBD.

This underscores the importance of establishing a functional PABS that addresses public health objectives and provides equity and legal certainty by being recognized as a specialized international instrument for the sharing of pathogen sequence data and related benefits. These developments highlight the urgent need for greater collaboration and coordination among international fora to harmonize emerging rules. Without such efforts, we risk ending up with sets of fragmented rules that may prove impossible to navigate for access and benefit-sharing purposes. Following the adoption of the CBD COP decision, the ball is now in WHO's court to make that happen.

THE PANDEMIC AGREEMENT AND THE AMENDED INTERNATIONAL HEALTH REGULATIONS (2005): COMPLEMENTARITY, SYNERGIES, DIFFERENCES

By Gian Luca Burci

The draft Pandemic Agreement (draft PA)[2] and the International Health Regulations (2005) as amended by the 77th World Health Assembly (WHA) in May 2024 (hereafter IHR) address similar and complementary aspects of global health security.

One of the challenges for their future implementation will be ensuring complementarity and synergy, while avoiding unnecessary fragmentation and duplication in their governance. At the same time, the two instruments are different in nature and will have an asymmetric participation for an indefinite period since the IHR has 196 parties while the PA will have 60 parties when it enters into force.

These considerations raise a number of challenges that have been discussed by the INB. What follows is a short overview of some of the issues in question, which aims at promoting discussion rather than necessarily proposing solutions.

Definitions

Various provisions in Articles 9 to 13 of the draft PA raise obligations or require additional consideration by Parties in case the WHO Director-General determines a public health emergency of international concern (PHEIC) including a pandemic emergency under the IHR. In other words, the alert mechanism in Article 12 of the IHR triggers a number of legal consequences under the PA.

This mechanism in turn requires that PHEICs and pandemic emergencies are defined consistently in the two instruments. There are two ways to achieve this in the PA: either including self-standing definitions identical to those in the current text of the IHR; or to simply state that the definitions in Article 1 of the IHR at any given time apply to the PA. The problem with the former solution is that the WHA may amend the IHR definitions in the future, thus creating inconsistencies or requiring an amendment of the PA. The draft PA reproduces the IHR definitions with a footnote reading "pursuant to the amended IHR (2005)," thus apparently choosing the first approach.

Governance

Article 21 of the draft PA establishes a conference of the parties (COP) tasked with taking stock of the implementation of the agreement and reviewing its functioning. Similar functions with regard to the IHR are exercised by the WHA, which has just established as part of the May 2024 amendments a dedicated "States Parties Committee for the Implementation" of the IHR by inserting a new Article 54 bis.

The Implementation Committee is composed of all States Parties and shall facilitate the effective implementation of the IHR in a non-adversarial, non-punitive, assistive and transparent manner. The Committee shall benefit from the advice of an expert Subcommittee. Given the significant overlap of functions and the concern to avoid unnecessary duplications and ensure coherence between the two instruments, Article 21 of the draft PA foresees (in two variants not yet agreed) the creation of a mechanism, by the COP, to strengthen implementation of the PA that should engage with/take into account existing mechanisms, including the IHR Committee or Subcommittee.

The generality of the language leaves the door open to many possible solutions that could promote coherence while reflecting the differences between the two instruments. It is hard to imagine that the IHR mechanism may just serve as its equivalent for the PA because that would imply that non-Parties to the PA (but Parties to the IHR) would review implementation by Parties, which seems legally and politically questionable. However, it could be envisaged for example that the IHR and the PA mechanisms exchange reports of their

2 For draft PA we refer to the text circulated on 6 December 2024 at the end of INB 12.

sessions, that the two may hold joint sessions to consider overlapping or closely connected issues (e.g. equitable allocation of health products) or that the chairs/bureaus of the two mechanisms meet regularly to discuss overlapping issues.

Financing

Both the draft PA (Article 20, entirely green) and the amended IHR (Article 44bis) establish coordinating financial mechanisms with very similar functions and methodologies.

The PA mechanism shall function under the authority of the COP, while the IHR mechanism shall do so under the authority and guidance of the WHA. Whether to maintain two separate mechanisms or to try to merge their activities has been the subject of difficult discussions within the INB, but the outcome seems to point towards some form of unification. Article 20 paragraph 3 of the draft PA provides that the IHR mechanism "*shall be utilized as the Mechanism to serve the implementation of this Agreement, in a manner determined by the COP*." The WHA, in the resolution that adopted the 2024 IHR amendments (WHA77.17), decided that "*future instruments on public health emergencies or [PPPR], adopted pursuant to the Constitution of the World Health Organization, may utilize*" the IHR mechanism.

The momentum towards some kind of unification is therefore evident, but how to go about it?

The PA cannot prescribe what the IHR should do, and it is difficult to envisage that the same mechanism may be subject to the authority of two different bodies, one of which (the PA COP) will not even be part of WHO's governance. At the same time, neither instrument contains prescriptive provisions on the governance of their respective mechanisms, thus leaving some room for creative solutions. For example, the COP and WHA could adopt parallel decisions – or conclude an agreement – with terms of reference, modalities and differentiated criteria, accountability and reporting lines for the use of the mechanism under either instrument. The open-ended tone of resolution WHA77.17 leaves the possibility open that the IHR mechanism, under the ultimate authority of the WHA, may become the financial coordinator for further future PPPR instruments, similar to the role played by the Global Environment Facility with regard to multiple environmental conventions.

Conclusions

Besides agreeing on the remaining substantive issues as well as on the modalities to develop annexes or similar further instruments, INB negotiators will also have to grapple with these complex governance challenges as part of a final package. There is scope for creative and straightforward solutions to ensure regular coordination, communication, and constructive engagement between the PA and the IHR and it is important that these be agreed and tested during "peacetime" rather than waiting for the next crisis.