GENEVA GRADUATE INSTITUTE | GLOBAL HEALTH CENTRE

# GOVERNING PANDEMICS SNAPSHOT

## A SERIES OF PERIODIC BRIEFINGS ON THE STATE OF GLOBAL REFORMS FOR PANDEMIC PREPAREDNESS AND RESPONSE (PPR) | JANUARY 2024

This issue of the Governing Pandemics Snapshot, the latest in the Geneva Graduate Institute series, recaps highlights of the past six months of negotiations over a new World Health Organisation (WHO) pandemic accord or agreement. Additionally, it takes a closer look at three strategic issues: the conundrum of parallel negotiations over a Pandemic Accord and revisions to the existing WHO International Health Regulations (IHR) governing health emergencies; proposals for turning the new Pandemic Accord into a WHO Pandemic "regulation" - sidestepping the thorny issue of country ratification; and finally the complex issues around the sharing of pathogen genetic sequence data (GSD), which is essential for the development of new medicines and vaccines - but also a resource that most developing countries assert needs recompense from the pharma industry.

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

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

## PANDEMIC ACCORD UPDATE: THE FINAL STRETCH BEGINS

*By Daniela Morich*

*As we approach the final months of member state negotiations over a World Health Organization (WHO) pandemic agreement, due to come before the World Health Assembly in May, the efforts to forge a consensus have witnessed modest progress. But the original divide between developed and developing countries on key issues such as finance, access and benefit sharing, transfer of health technologies, and One Health still cast a long shadow over the process. And some critics worry that an accord, if and when one is achieved by the May 2024 deadline, may be less meaningful in terms of substance and impact, because of the compromises required to reach agreement.*

### Key negotiation highlights: a recap of the past months

Following our last update in July 2023, several more sessions of the Intergovernmental Negotiating Body (INB), the WHO member state-led body negotiating the text, took place throughout 2023 and until the end of the year.

The sixth meeting of the WHO member state Intergovernmental Negotiating Body (INB), convened on July 17-21, 2023, had special significance as it centered around the draft compilation text of the proposed WHO Convention, Agreement or Other international Instrument (CA+). That draft, published in June, was developed by the six-member state body guiding negotiations, known as the "Bureau". The so-called "Bureau" text laid out multiple options for language on key, disputed issues related to issues such as access to medicines and vaccines, pathogen sharing, etc.

The July INB meeting was preceded by a series of intersessional informal meetings. These sessions, guided by volunteer co-facilitators, aimed to foster understanding and dialogue on key articles of the Bureau's text. The sessions focused on a specific set of topics including Research & Development (R&D), Access and Benefit-Sharing, and Global Supply Chain and Logistics.

The practice of supplementing the INB sessions with informal, intersessional meetings of the drafting group continued after INB 6, becoming a regular feature of the negotiation process. Following this approach, the INB Drafting Group convened again from September 4-6, engaging in discussions on the three aforementioned topics and additionally addressing articles related to "One Health" approaches to preventing pandemics (e.g. through better management of pandemic risks related to AMR, livestock, wild animal trade and deforestation), as well as the the co-development and transfer of technology and know-how.

Intersessional work persisted throughout September; this culminated in a one-day meeting of the INB Drafting Group on September 22. The group mandated the Bureau to prepare a new text of the pandemic accord in mid-October, intending to set the stage for the commencement of textual negotiations during INB 7 in early November and December 2023.

### UN adopts political declaration on pandemics

In late September 2023, the spotlight shifted from Geneva to New York City, where a High-Level Meeting on Pandemic Preparedness and Response unfolded on the sidelines of the 78th United Nations General Assembly. The purpose was to convene Heads of State to highlight the issue and secure commitments from UN Member States to strengthen pandemic prevention, preparedness and response (PPPR) at the global level. The result was a non-binding UNGA political declaration. Despite its symbolic political significance, the declaration was criticized for being rhetorical and lacking tangible commitments by member states to take concrete steps on policies and investments that could improve prevention, preparedness and response.

### Pandemic Accord "negotiating text" and a fresh round of criticism

In October, the spotlight shifted back to Geneva where the Bureau unveiled the proposal for the Negotiating Text of the WHO Pandemic Agreement. Unlike the June version, this negotiating text selected just one option for language and approach to each of the contested articles, incorporating what the Bureau viewed as language with the greatest potential for agreement.

However, the text faced significant criticisms. To name a few, developing countries expressed concerns over the heavy burden imposed by proposed pandemic prevention and surveillance measures.

Those objections including even the very general reference in Paragraph 8 of the preamble to the support for "One Health" approaches to *"multisectoral collaboration at national, regional and international levels to: safeguard human health; detect and prevent health threats at the animal and human interface, zoonotic spill-over and mutations; and sustainably balance and optimize the health of people, animals and ecosystems [...]"*.

Developing countries also objected to what they regarded as relatively weak provisions on equitable access to medicines, vaccines and other countermeasures.

Conversely, several developed countries voiced firm opposition to a reference to countries to: *"commit to agree upon, within the framework of relevant institutions, time-bound waivers of intellectual property rights to accelerate or scale up the manufacturing of pandemic-related products to the extent necessary to increase the availability and adequacy of affordable pandemic-related products* [Article 11.3 (a)].

Civil society stakeholders have, meanwhile, lamented the perceived lack of ambition in provisions ensuring more equitable access to pandemic-related products, including the lack of reference to "access" provisions in relation to public R&D funding for medicines and vaccine development.

Others noted the absence of clear financing commitments for pandemic preparedness and response, and the intention to postpone many contentious issues post-adoption, risking a dilution of the accord's substance and impact.

The INB 7 unfolded over the period of November 6-10, resuming on December 4-6. This time, civil society stakeholders were invited to be physically present at the WHO premises, although not in the room where the proceedings were held.

This phase primarily involved an initial reading of the negotiating text, during which Member States suggested edits or deletions and thus contributed to yet another revision of the draft text.

So, rather than allowing for the beginning of formal negotiations, the INB 7 process resulted in a lengthy and intricate "rolling text," with each and every option incorporated once again - as had been the case in June. It appeared as if parties held firm in their stances, showing no inclination to yield ground on their original positions and increasing mistrust among negotiators.

This raises the question: are we moving backward instead of forging ahead?

### Tackling additional challenges as we near the finish line

With the May 2024 deadline looming forward, at least three additional challenges stand out.

Firstly, process. The current approach to negotiations is perceived as lacking effectiveness. The iterative textual method used so far involves the repeated issuance of new document versions by the Bureau, with member states subsequently incorporating edits without substantial engagement in real negotiations. The October text, which was originally 30 pages, had thus ballooned to around 100 pages by the end of the INB 7 sessions in December. This prompts legitimate questions about the ability of this process to bring parties closer to the finish line.

Secondly, time. The intricate and contentious nature of the issues at hand, combined with extensive small group work outside the official timetable, adds to the complexity. This year, there are only 19 official negotiation days scheduled for full INB group meetings on the calendar. So achieving any result poses a formidable challenge even to the most seasoned and well intentioned diplomats.

Thirdly, momentum. Amidst a myriad of pressing global issues competing for political attention, focus, and financial resources, and with leading actors like the United States worldwide gearing up for nationwide elections in 2024, there is a shadow of uncertainty around the commitment of member states to embrace new global health rules and to prioritize pandemic prevention. Obtaining such commitments will likely be even more difficult if the current May 2024 deadline for conclusion of negotiations and WHA review is pushed back - diminishing the sense of urgency and focus.

The next months will reveal if these challenges are surmountable.



## SHOULD TWO TRAINS BECOME ONE?: THE IHR VS PANDEMIC ACCORD CONUNDRUM

*By Suerie Moon*

May 2024 is when two trains are scheduled to arrive at the World Health Assembly station - the draft Pandemic Accord or Agreement and the revisions to the existing WHO International Health Regulations.

We can think of amendments to the 2005 International Health Regulations (IHR) as a freight train and the negotiation of a Pandemic Accord (also known as the pandemic agreement ) as a passenger train. As we've mentioned before, the unusual spectacle of the same countries, often represented by the same diplomats, simultaneously negotiating two different sets of international rules to address the same problem could only be the product of political compromise.

With the deadline rapidly approaching, negotiators are focusing more intently on whether and how these two processes can produce a coherent, workable set of new international rules for pandemic preparedness and response, on the one hand, as well as more fit-for-purpose regulations on health emergencies more broadly, as per the 2005 IHR.

The stakes are high, as these rules will form the normative foundation for how countries and global actors address the threat of disease outbreaks for decades to come.

As my colleague Daniela Morich has written, countries remain far apart on a wide range of substantive issues that cut to the core of each instrument: surveillance, national health system readiness, vaccines and drugs, access to samples and data and related benefit sharing, intellectual property, technology transfer, One Health, and financing, to name just a few.

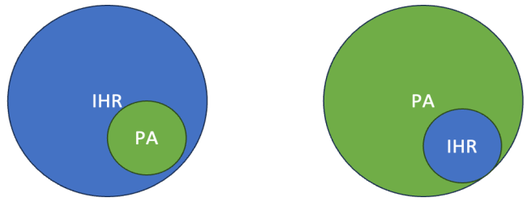
### Which issues belong in the IHR and which in the Pandemic Accord?

Nor is there agreement on which issue belongs in the IHR, and which in the Pandemic Accord. While it may seem rational to divide the issues between the two trains – freight here, people there – countries are unlikely to agree, as such decisions have far-reaching implications for which issues get priority.

With the IHR already binding on all 194 WHO Member States as well as two non-member observers (unless they opt out, which none have done), any obligations included in an amended IHR would enjoy the benefit of being universally legally-binding. On the other hand, a treaty is seen to have greater normative force and political weight in at least some countries, helping to mobilize the high-level political attention and financing that is required to actually implement legal obligations, but which usually wanes after every crisis.

Another approach is to ask whether one set of rules might be considered a sub-set of another. Should the IHR be nested within the Pandemic Accord, or vice versa? The answer seems to be: both. The IHR's scope of health emergencies (including not only infectious disease outbreaks, but also accidental or manmade disasters such as at nuclear reactors) covers a broader set of situations than pandemics (as depicted in Figure 1(a)). On the other hand, Covid-19 demonstrated that pandemics can become far more than health emergencies – they can be political, economic and security crises affecting all countries simultaneously, suggesting the scope of the Pandemic Accord should be considered far broader than the IHR (as depicted in Figure 1(b). In other words, one set of rules does not logically fit within the scope of the other. Rather, they are more like overlapping circles on a Venn diagram (as depicted in Figure 1(c)).

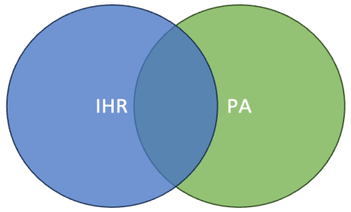
**Figure 1. Options for the relationship between the scope of the IHR and the Pandemic Accord**




a. Scope of hazards




b. Scope of potential impact




c. Scope of relevant sectors of society and government

Countries have a strong incentive to get their priority issues included in both instruments, or at least to get them into the instrument more likely to be adopted, implemented and respected. But which one would that be? One of the few principles everyone seems to agree on is that "nothing is agreed until everything is agreed." In other words, these two processes form a single political package deal. This means that if, for example, a country cares deeply about pandemic products, there's a strong incentive to push for favorable language in both instruments up until the last moment when it's clear where each train is headed. Then it jumps onto the train that looks more likely to arrive at the station.

### Finance - the challenge of consistent IHR and Pandemic accord provisions

It's a complex and often confusing set of issues. To clarify a bit, let's focus on just one – financing – to assess the implications of this two-track process. Agreement on how to mobilize and sustain adequate financing is critical for making a dent in pandemic preparedness. It is also potentially an important way to grease the wheels of compromise. But there is a risk of creating confusion and,arguably, unfairness if financing arrangements are inconsistent between the IHR and the Pandemic Accord.

The amended IHR could remain without clear financing commitments (the status quo), while the Pandemic Accord could have stronger ones. But the heavier obligations would only fall on countries that have signed onto the Accord, while also creating a disincentive to do so. Despite political rhetoric that addressing pandemics is a global public good to which all countries should contribute, different obligations in the IHR and PA could perpetuate uneven responsibility for that burden.

### Seeking Alternatives: What Are the Options?

At least three alternatives to the status quo could be pulled out of this spaghetti bowl. The first is to move all Pandemic Accord content into the IHR, significantly expanding the latter's scope. This would be akin to linking the trains together, so that all passengers and freight are on the same (now quite long) train, pulled by a single engine along a single track. This would offer the benefit of coherence, but might frustrate those who had hoped for an international treaty that would carry greater weight than a WHO regulation.

A second option is to put the same things on both trains. For example, negotiators could agree on common language on certain issues that may be applicable to both, such as ABS and financing – i.e. putting some boxes of tomatoes and people on each train.

A third option would be to adopt the Pandemic Accord as a "regulation" under Article 21 of the WHO Constitution rather than a treaty under Article 19, as Gian Luca Burci explores in more detail below. In other words, move people off the passenger train onto a new additional freight train – a different vehicle, with perhaps fewer bells and whistles, but the same substantive content. A key benefit would be universal legally-binding applicability of the rules without requiring Member States to ratify a new instrument; importantly, this would also open a politically feasible pathway for the US to join. But hopes would evaporate for a treaty that, at least in theory, would have carried greater political and legal weight.

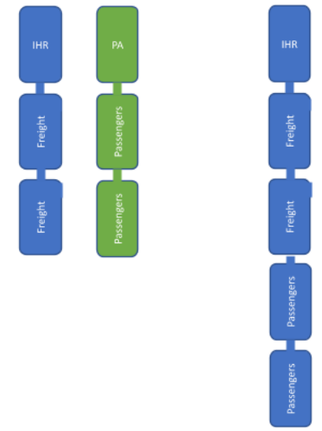
In theory. International law scholars have argued that a formal treaty agreed by states, but barely implemented, will be less effective than international rules that enjoy strong, widespread political support across society, even if such rules do not take the form of a treaty.[1]

One implication is that a regulation could, in principle, be implemented as effectively as a treaty. How? Governance arrangements matter. For example, a Pandemic "Regulation" with robust commitments for transparent monitoring, accountability, financing and regular meetings to build a community of practice could be more widely respected than the circa–2005 IHR were during the Covid-19 crisis, which came nearly two decades later. In other words, one could upgrade the freight train with more engine power and a nice paint job – it would still be a freight train (i.e. regulation) but stronger, more advanced and better-looking than others.

1 Joost Pauwelyn, Ramses A. Wessel, Jan Wouters, When Structures Become Shackles: Stagnation and Dynamics in International Lawmaking, European Journal of International Law, Volume 25, Issue 3, August 2014, Pages 733–763, https://doi.org/10.1093/ejil/chu051



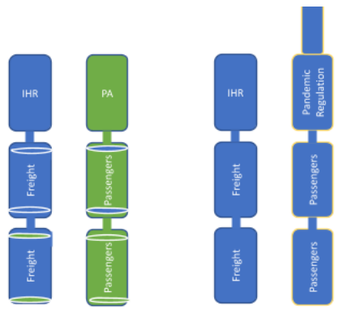
**Figure 2: Options for the Spaghetti Bowl**




Status quo: freight and passengers on parallel tracks




Alternative 1: Combine all freight and passengers (content) onto a single train (regulation)




Alternative 2: Common text (some freight, some passengers) across both trains




Alternative 3: Pandemic regulation with strong governance arrangements ("engine")

Whether countries decide to keep separate freight and passenger trains, a single combined train, or two freight trains, reaching agreement on form will take time – more time than may be available. With an eye to elections in the year ahead, some have suggested extending the talks for another few months, hoping to reach agreement before late 2024. Yet even that is no small feat. The next few months will be critical for finding common ground, not only on the substantive issues within each instrument (which passengers? what freight?), but also for agreeing on the vehicle(s) that can bring us safely into the station, more or less on time.

## TURNING THE PANDEMIC ACCORD INTO A WHO REGULATION: CAN IT WORK?

*By Gian Luca Burci*

As my colleague Suerie Moon analyzes in more depth, the relations between the draft pandemic agreement (PA) and the many proposed amendments to the International Health Regulations (IHR), the placement of particular issues in either or both texts given the many overlaps, and how to avoid unnecessary fragmentation have been some of the most complex issues discussed since the launch of the two parallel negotiations in 2021-2022.

The Working Group on Amendments to the IHR (WGIHR) met on 7-8 December and appeared to make progress towards a consensus on the many amendments proposed for the IHR. The Bureau circulated its proposals on a considerable number of articles and annexes ahead of the meeting, while

leaving for discussion in the WGIHR some of the most controversial Articles such as 13A, 44 and 44A that deal respectively with equitable access to medical countermeasures, assistance and financing.

### Should the Pandemic Agreement become a WHO regulation?

Some delegations are very informally discussing the feasibility and implications of turning all or part of the current negotiating text into an Article 21 regulation. Regulations can be adopted by the Health Assembly on five specific issues including preventing the spread of diseases. They enter into force at the same time for all Member States that don't "opt out" by rejecting the regulations or filing reservations. There is no requirement of ratification as in the case of a treaty. In case of a partial "carve-out" from the Pandemic Agreement, surveillance, One Health and pathogen access and benefit sharing (PABS) are mentioned as plausible candidates. The rationale is reportedly to ensure universality and a level playing field for an instrument that is seen by many as expressing global public goods, embedding it within WHO's governance rather than establishing separate institutions, and simplifying financing arrangements.

The practical feasibility of such a far-reaching proposal four months away from the deadline of May 2024 can be questioned. However, it may be useful to highlight some possible implications and whether such "legal transformation" can meet the expectations of the delegations allegedly discussing it. I am going to raise four among many possible issues.

### Legal nature

First, what is the legal nature of a WHO regulation? Is it a treaty in a particular form or a different kind of instrument whose validity is based on WHO's Constitution, closer in nature, for example, to a Security Council resolution? The question could remain academic since all member states agree that regulations are legally binding for them, and we cannot give it justice in a short paper. However, legal advisers of foreign ministries (so far probably not focusing intently on the negotiations!) could raise the question because the law of treaties would not apply directly to a non-treaty, there would be questions about how to prepare internally for entry into force and implementation, and how to address interactions with a considerable number of treaties given the broad scope of the negotiating text.

### Constitutional considerations

Second, what are the constitutional implications of turning (in an adapted form if necessary) the entire substantive part of the negotiating text into a regulation given the emphasis on "procedures designed to prevent the international spread of disease" in Article 21 (a)? Can it all fit into the concept of "prevention"? An argument has been made in favor of consistency with the WHO Constitution for the following reasons: "prevention" does not mean in 2024 what it may have meant in 1946 and has to be interpreted in a holistic manner, and one could argue that global and equitable access to medical countermeasures can prevent or reduce the risk of the international spread of diseases. Moreover, the 2005 IHR has already moved beyond prevention and included response to the international spread of disease without any challenge to their compatibility with Article 21(a).

### Universality and level playing field?

Third, universality and level playing field through entry into force at the same time for all member states that do not reject a regulation (Article 22 Constitution) are advantages when compared to an international agreement that will initially only enter into force for a limited number of parties. As Suerie Moon notes, no member states have remained out of the 2005 IHR that are also open to non-member states. While the appeal of universality is understandable, its feasibility would depend on a solid political commitment by all member states that will have to navigate the text through their internal procedures – including possibly unpredictable parliamentary approvals – to avoid "opting out" from the agreed text or submitting extensive reservations. Even though it is not yet posted on WHO's website, it has been informally reported that four states have notified rejection of the "technical amendments" adopted by the WHA in 2022. Rejection is therefore not a theoretical possibility especially if the final text is ambitious and broad. Reservations in the previous and current IHR fall under a more complex legal regime that cannot be summarized here, but they also are a concrete possibility; India and the USA, for example, have entered reservations to the 2005 IHR. If the risk of rejections and reservations to a hypothetical new regulation materializes, it may end up looking like a treaty with parties subject at least in part to different obligations.

### Governance and financing

Fourth and final point is governance and financing. The 2005 IHR are "embedded" into WHO's governance and structure, and that model can offer a blueprint for a new regulation. As noted above, the existence and validity of a regulation rests on WHO's Constitution more directly than an Article 19 agreement. Article 19 enables the WHA to adopt international agreements on any matter within WHO's competence, that have to be signed and ratified by each state that wishes to participate. The WHA is the supervisory and governance body of the IHR; most of the secretariat functions are performed by WHO's health emergencies programme (WHE) and other parts of the secretariat actively contribute to the IHR's implementation. As a matter of fact, some of the proposed amendments foresee a compliance review role for the WHA or an open-ended body established by it. This approach could facilitate coherence with the IHR, alignment with WHO's strategic directions as well as reliance on the whole machinery of WHO, and would reduce the risk of fragmentation and inconsistencies. At the same time, there could be equally legitimate political reasons for aiming at a more independent governance that would militate in favor of an Article 19 agreement. Financing is obviously a most delicate issue as pointed out by Suerie Moon; the interests and priorities between Global North and South appear divergent and the proposals in the two processes are controversial. Turning the negotiating text into a regulation would require consistency with WHO's financial regulations and rules as well as its budgetary structure, whether the financing of the regulation should be based on assessed contributions or a different formula relying more on voluntary contributions. Whether such consistency could constrain political compromise and financial effectiveness would depend on the finer details of the negotiations.

## GENETIC DATA TIGHTROPE: NAVIGATING THE EMERGING RULES FOR GSD/DSI

*By Adam Strobeyko*

*The sharing of pathogen genetic sequence data (GSD), also known as digital sequence information (DSI) in environmental law, is crucial to the global genomic surveillance and the research and development (R&D) of pandemic-related products. Such sharing takes place through digital platforms, subject to their various policies. However, the rules governing GSD/DSI sharing are soon likely to change, as the topic features in multiple ongoing international negotiations. We examine recent discussions in the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources (WGDSI) under the UN Convention on Biological Diversity (CBD) and their implications for the pandemic agreement.*

In day-to-day practice, scientists, laboratories, governments and industry regularly share and access pathogen GSD for purposes of research, development and production of medical countermeasures. Balancing access to GSD and the sharing of benefits resulting from its use is crucial for effective PPPR and more equitable access to the fruits of science; how to achieve it has been one of contentious issues in the pandemic agreement negotiations. As diplomats in Geneva deliberate upon a new pandemic agreement, they will have to be conscious of the discussions happening in parallel under the CBD.

### Negotiations at the CBD

In its Decision 15/9, the CBD Conference of the Parties (COP 15) decided to establish a multilateral mechanism for benefit-sharing from the use of digital sequence information (DSI), a term which also encompasses GSD. 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 for DSI are to be finalized at the next UN Biodiversity Conference in 2024.

To lay the groundwork for the future mechanism, the WGDSI was established and met for the first time in November 2023 in Geneva. WGDSI-1 aimed to develop a list of possible elements of the future multilateral mechanism. WGDSI-1 reflected the tensions between countries regarding the preferred Access and Benefit Sharing (ABS) arrangements: multiple developing countries saw the Nagoya Protocol, which requires bilateral negotiations of fair and equitable benefit-sharing related to access to genetic resources, as relevant also in the context of DSI.[2] However, references to the Nagoya Protocol were opposed by a group consisting mostly of developed countries and were not included in the list of agreed elements of the new mechanism. Instead, questions about potential conflicts between a new mechanism for DSI and the Nagoya Protocol, and the coexistence of multilateral and bilateral ABS arrangements, will require further discussions. So will the question of whether countries that require, through their national legislation, benefit sharing from the use of DSI in international public databases, should also receive benefits from the new multilateral mechanism.

Another relevant issue concerned principles governing the storage of DSI. Suggestions included storing DSI in 'public databases,' with questions raised about compatibility with open access and with already existing databases. The potential implications of database fragmentation and the idea of creating a family of linked databases emerged for further discussions. Other issues requiring further discussion include the DSI's role in generating funding and its potential use as a trigger for non-monetary benefit sharing, the structure and governance of the new multilateral mechanism, and its relation to other fora and systems.

### Relevance for the Pandemic Agreement

The developments at WGDSI are relevant in the context of the pandemic agreement negotiations, where multiple delegations have advocated for including pathogen GSD in the WHO Pathogen Access and Benefit-Sharing System (WHO PABS System), seeing it as a way to ensure rapid and systematic access to data and to achieve more equitable and timely access to pandemic-related products and other benefits.

However, the developments at the WGDSI and CBD show that the pandemic agreement negotiations of the provisions dealing with the sharing of GSD and related benefits will not happen in a legal vacuum. The negotiators of the pandemic agreement will have to consider the real possibility of GSD soon falling under the scope of the benefit sharing mechanism envisaged by the CBD Decision 15/9. While very much a work in progress, the latter mechanism would likely focus on biodiversity protection and may not be adequately designed to facilitate risk assessment, immediate access to data and rapid development of pandemic-related products.

To remedy this situation, the scenario currently envisaged in the pandemic agreement would see the WHO PABS System recognized as a specialized international ABS instrument within the meaning of Art 4.4 of the Nagoya Protocol, exempting sequences falling into its scope from additional access and benefit sharing requirements. Such a solution would be desirable from the public health perspective, obviating the need for bilateral case-by-case negotiations for access to pathogen GSD or samples, thereby saving precious time in the context of an emergency.

### Recommendations for the future instrument(s)

The negotiators will therefore have to strike a careful balance when walking the GSD/DSI regulation tightrope. Leaving the questions of implementation aside for a moment, the first policy recommendation from the perspective of global PPPR is perhaps as simple as: do not fail at the balancing act and establish a functioning WHO PABS System. A multilateral, specialized system

2 IISD, "Summary report, 12–18 November 2023. 12th Meeting of the Ad Hoc Open-ended Intersessional Working Group on Article 8(j) and Related Provisions and 1st Meeting of the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources," https://enb.iisd.org/article8j-oewg-12-digital-sequence-information-genetic-resources-dsi-cbd-summary

for the sharing of GSD and related benefits is likely to be better designed for public health needs and goals than a benefit sharing mechanism established under the CBD.

The second consideration concerns the need for legal clarity and simplicity. Once established, the WHO PABS System will need to be recognized as a specialized international ABS instrument to avoid the possibility of conflicting, non-hierarchical norms governing the sharing of GSD/DSI at the international level. One of the ways of ensuring that is to identify and delineate specific instances where the WHO PABS System would apply, e.g. by identifying the pathogens with pandemic potential whose samples and GSD would fall under its scope and by clarifying the rights and obligations related to their use. Sequences falling outside the scope of WHO PABS System would be governed by the CBD benefit sharing mechanism. Achieving clarity with regard to WHO PABS System's scope and obligations would likely help with its implementation by and within countries, which is necessary for its proper functioning.

Finally, to be effective in the long term, the WHO PABS System will need to be forward-looking and able to adapt in light of scientific knowledge and technological change. Procedures should be set in place that would allow WHO and/or the Conference of the Parties of the pandemic agreement to adapt the list of pathogens and to address technical challenges (including integration of databases and the impact of AI on product development), to ensure consultation of relevant stakeholders, and provide a venue for learning and adapting the system to the changing needs of its participants. Only this way can we ensure that the regulatory tightrope does not end mid-way to the intended objectives of the new rules.