GOVERNING PANDEMICS SNAPSHOT

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

The 78th World Health Assembly (WHA) adoption of the Pandemic Agreement sent a powerful message: multilateralism remains alive and countries can still pull together to find common understandings on collective problems.

But many steps on the Agreement still remain to be completed, and thus will not be open for signature for at least another year, as negotiations continue on contentious issues around an Annex on the Pathogen Access and Benefit-Sharing System (PABS). This sixth issue of the Governing Pandemics Snapshot explores the tradeoffs that were made in a final agreement and the steps remaining for it to be ready for parties' signature, setting off the countdown for it to enter into force. We also look at the implications of the final text on other critical issues, including: prevention measures and One Health, technology transfer, and governance issues under the Pandemic Agreement as well as the amended International Health Regulations.

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

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THE PANDEMIC AGREEMENT IS ADOPTED: ENTRY INTO FORCE AWAITS AN ANNEX

By Ava Greenup and Daniela Morich

The 78th World Health Assembly (WHA) adoption of the Pandemic Agreement (PA) on May 20, was the end of an arduous three-year negotiating process. But it also marked the beginning of another round of difficult negotiations on an annex for Pathogen Access and Benefit Sharing (PABS).

The Agreement will not be open for signature for at least another year, as negotiations continue on the PABS Annex. The Agreement must be signed by at least 60 countries for it to enter into force, a process that could take years.

This article reviews the tense 11th hour debates and tradeoffs that led to the final agreement, as well as the next steps to expect in the PABS negotiations.

February and April talks marked shift in tone and delivered a consensus text

In 2025, the International Negotiating Body (INB) met twice. The thirteenth meeting of the INB took place on 17 - 21 February, and worked on the basis of a new text proposed by the Bureau - a group of six country representatives leading the process.

The list of articles to resolve was long and included some of the most contentious issues that had seen little convergence over the previous years: prevention and One Health, technology transfer, PABS, supply chain and logistics, and governance elements in Chapter III. This was also the first session held without the participation of the United States, following the announced withdrawal from the WHO after the inauguration of the second Trump administration. Against this backdrop, progress was made - albeit slowly.

Some observers suggested that the absence of the U.S., combined with a heightened sense of urgency due to mounting pressures on the global health architecture and ongoing funding cuts, might have contributed to a more constructive attitude of delegation and a shift in tone.

The resumed session of INB13 – the final meeting on the INB calendar – took place on 7 - 11 April, with nightly sessions stretching into the early hours of the morning on each day of negotiations.

Progress was steady: negotiators gradually cleared all remaining articles, reaching consensus on the framework for the PABS System – including a fixed commitment for each participating manufacturer to share a percentage of real-time production during pandemics, one of the key requests of developing countries – followed by agreement on prevention and One Health (see Ricardo Matute piece on this Snapshot for an analysis of this topic). One by one, key issues began to fall into place during an extenuating week of negotiations.

On the final day, negotiators worked continuously for over 24 hours in an effort to achieve full consensus. However, one final point of contention remained: article 11 on technology transfer. Divisions persisted between countries favoring a strictly voluntary approach and those advocating for stronger obligations, including mechanisms to compel access to manufacturing know-how for pandemic-related health products during crises.

With consensus on the full text within reach, the meeting was suspended around 9am on Saturday 12th, after 24 hours of deliberation, and scheduled to resume on Tuesday 15th.

In the early hours of April 16th, the text was fully greened – culminating in an emotional and symbolically powerful moment.

The deadlock on technology transfer was resolved by inserting a footnote defining the expression 'as mutually agreed' after each reference in the text. A more detailed analysis of the outcome of this compromise is provided by Ellen 't Hoen in the fourth section of this Snapshot.

Adoption survives a surprise last-minute vote at the World Health Assembly

Following the green-lighting of the text in April, the INB transmitted the final draft of the Agreement as well as a draft resolution, that was agreed upon shortly after the finalization of the Agreement, to the 78th World Health Assembly (WHA) for formal adoption.

The PA was the first item for consideration in *Committee A*, one of the main committees of the WHA focusing on programmatic and technical issues, and with a consensus ready text, agreement should have been straightforward.

Yet, a last minute curveball came from Slovakia, which unexpectedly called for a vote. A statement released by the Slovak Prime Minister Robert Fico claimed that the Agreement "*violates the principle of the sovereignty of the member states and disproportionately interferes with the area of human rights*." Despite this challenge, Member States overwhelmingly showed support for this hard-won treaty: the final vote recorded 124 in favor, zero objections and 11 abstentions. A number of countries were absent from the meeting or had their right to vote suspended due to their arrears in assessed contributions.

The following day, the text moved to the Plenary session, where it was adopted by consensus, surrounded by cheers and a surge of emotion in the room.

Several crucial steps ahead before entry into force

Negotiators deliberately designed the PA's architecture to accommodate further negotiations, particularly those required to operationalize the PABS System.

Although the PA includes a dedicated article on PABS, it merely establishes the system's foundational principles. The specifics — such as how benefits will be shared and what obligations apply to countries and companies — remain to be determined. To this end, the WHA mandated the creation of an Intergovernmental Working Group (IGWG), open to all WHO Member States, to negotiate the elements necessary to operationalize the PABS System in the form of an Annex to the Agreement that will have to be adopted separately by the WHA.

A consequential addition was made to Article 33 on Signature: the PA will only be open for signature once the PABS Annex has been adopted by the WHA.

The IGWG is scheduled to hold its first organizational meeting no later than 15 July 2025, during which it will presumably determine the composition of the Bureau that will lead the next phase of negotiations, and its program of work. It is unclear whether former INB Bureau members will be reappointed or if new leadership will step in.

The IGWG must present the outcome of its work – whatever this may be – to the 79th WHA in May 2026. This leaves less than a year to resolve one of the Agreement's most complex and contentious components. A detailed analysis of what to expect from these negotiations is addressed by Adam Strobeyko in another piece of this Snapshot. Should consensus prove elusive, it will fall to the WHA to decide how to proceed.

Importantly, the IGWG's mandate extends beyond finalizing the Annex. It is also tasked with laying the groundwork for the Agreement's implementation and eventual entry into force.

These tasks include drafting the rules of procedure for the Conference of the Parties, establishing financial rules and a draft budget; defining the structure and functions of the Global Supply Chain and Logistics Network; suggesting reporting obligations; and proposing details on the functioning of the implementation mechanism for the PA. These institutional and procedural issues are explored further by Gian Luca Burci in the next section of this Snapshot.

Once the Annex is adopted, the PA will be open for signature and ratification. It will require ratification by at least 60 countries to enter into force — a process that could take years.

As many analysts have indicated, the adoption of this historic Agreement marks not an endpoint but rather a beginning. As negotiations continue on the PABS Annex and the operational structures needed to implement the Agreement, the focus must now shift to ensuring that these ambitious commitments are translated into real-world impact, strengthening global preparedness and response to future pandemics.

SHAPING THE GOVERNANCE OF THE PANDEMIC AGREEMENT AND THE IHR - CHALLENGES AHEAD?

By Gian Luca Burci

A number of governance issues will have to be addressed in the next months and probably years both under the Pandemic Agreement (PA) as well as the amended International Health Regulations (IHR), also with a view to framing the relationship between the two instruments.

Most of the preparatory work will have to be undertaken by the World Health Organization (WHO) secretariat, usually in consultation with Member States, for subsequent approval or endorsement by the relevant governing body: the Conference of the Parties (COP) of the PA once it enters into force, and either the World Health Assembly (WHA) or the newly established States Parties Committee in the case of the IHR. At a time when the WHO's budget has been substantially reduced from initial expectations, and in view of the foreseeable reduction in the workforce during the next few months, dealing timely and effectively with these preparatory tasks will be challenging.

Governance of the Pandemic Agreement

Under the PA, as noted by Ava Greenup and Daniela Morich in the previous section, the WHA has just established an Intergovernmental Working Group (IGWG) to perform an ambitious number of tasks:

1) Negotiate the Annex to operationalize Pathogen Access and Benefit Sharing (PABS) under Article 12 as a priority;

2) Following completion of that negotiation, prepare the beginning of the work of the COP including notably with regard to two institutional mechanisms - the Global Supply Chain and Logistics Network established by Article 13 of the Agreement, and the implementation mechanism foreseen in Article 19;

3) Develop proposals for the terms of reference and the operationalization of the Coordinating Financial Mechanism established by Article 18, in coordination with the corresponding mechanism established by the amendments to the IHR.

All these processes display a mix of technical, legal and political complexities that will require leadership, commitment and realism in order to reach a solid consensus and establish the bases for the operationalization of the Agreement. As noted in the previous section, the adoption of the PABS Annex is essential to "unlock" the PA and open it to signature and ratification. This unusual construct begs the question of what happens if Member States are unable to reach consensus in a reasonable time, since the PA should not be "held hostage" indefinitely by the PABS negotiations. Even though this crucial issue is not dealt with in the resolution, the WHA may have to consider an alternative way forward if negotiations are unsuccessful.

Governance of the amended IHR

Although most of the attention is now focused on the PA and the work still left to do before its entry into force, it shouldn't be forgotten that the 2024 amendments to the IHR will enter into force on 19 September 2025 (in September 2026 for the four countries that rejected the 2022 amendments). Additionally, the IHR amendments establish a number of governance bodies and processes that require preparation by the Secretariat and consultations with States Parties before their final approval and operationalization.

The main issues are, firstly, the terms of reference and procedural rules for the States Parties Committee for the Implementation of the IHR (Implementation Committee) and its expert subcommittee established by Article 54 bis; and secondly, terms of reference and modalities for the operationalization and governance of the Coordinating Financial Mechanism established by Article 44 bis. These are the two institutional innovations introduced by the 2024 amendments. The Implementation Committee is composed of all Parties to the IHR and aims at promoting the effective implementation of the Regulations; the Coordinating Financial Mechanism is not a funding arrangement but rather a mechanism to promote resource mobilization for the implementation of the IHR.

Article 54 bis states that it will be the Implementation Committee that will adopt by consensus not only its own terms of reference and its working arrangements, but also the corresponding terms of reference and governance modalities for the Coordinating Financial Mechanism. This arrangement is unusual because both new bodies have been established by the WHA and should therefore be accountable to it (a point which is explicitly addressed in Article 44 bis paragraph 3 with regard to the Coordinating Financial Mechanism), and the latter would have normally kept for itself the authority of operationalizing them by adopting their terms of reference and working modalities. The apparently self-contained nature of the Implementation Committee, which will adopt its own governance arrangements as well as those of the Coordinating Financial Mechanism and is not explicitly placed under the authority of the WHA, seems to elevate it above the rank of the customary subsidiary bodies of the WHA or the Executive Board (EB) as the equivalent of a COP for the IHR.

In this connection, it is indicative that under paragraph 2 of Article 54 bis the Implementation Committee "*will be comprised of all States Parties*" to the IHR. The Regulations count among their parties two states that are not members of WHO - i.e. the Holy See and Liechtenstein - and may soon count one more in view of the invitation that the Director-General will extend to Palestine to become a party as just decided by the WHA. It may be that the difference in membership between the IHR and WHO was at the basis of the unusual construct adopted by the WHA, in order to enable non-Members to participate in the governance of the IHR through the Implementation Committee since as non-Members they cannot enjoy the same rights in the WHA.

Governance linkages between the PA and the IHR

Finally, both the PA and the resolution adopting the IHR amendments foresee governance links between the two instruments. In particular, article 18 of the PA has already decided that the IHR Coordinating Financial Mechanism will serve the same function for the PA, a decision supported by paragraph 2 (3) of resolution WHA77.17 pursuant to which "*future instruments on public health emergencies or pandemic prevention, preparedness and response, adopted pursuant to the Constitution of the World Health Organization, may utilize the Coordinating Financial Mechanism contained in Article 44 bis of the amended International Health Regulations (2005) to serve the implementation of such instruments*." Moreover, in setting up the implementation mechanism under Article 18 of the PA, the COP may take into account the corresponding mechanism under Article 54 bis of the IHR. These and other linkages between the two instruments are explained in more detail in our previous snapshot.

For the moment the Secretariat has not disclosed any preparatory activity for the implementation of the amendments to the IHR, and it is to be expected that it will report to the 79th WHA on its progress. Paragraph 3 (6) of resolution WHA77.17 requests the Director-General to convene the Implementation Committee within one year from the entry into force of the amendments, i.e. by September 2026, and the Coordinating Financial Mechanism will become operational once its terms of reference and working modalities are adopted by the Implementation Committee.

THE DEVIL IS IN THE ANNEX: PATHOGEN ACCESS AND BENEFIT SHARING

By Adam Strobeyko

The adoption of the Pandemic Agreement (PA) after three years of negotiations was met with applause and relief. Yet, the most technically difficult and politically sensitive part of the Agreement—the rules governing the Pathogen Access and Benefit Sharing (PABS) System—remain unresolved.

The newly adopted treaty includes only a skeletal outline of the future PABS System. Over the next year, and likely longer, governments will negotiate a detailed Annex to the Agreement that will determine how countries share virus samples and genetic sequence data (GSD), alongside

the associated benefits—including vaccines, diagnostics, therapeutics, and financial resources. As described in the first piece of this Snapshot by Ava Greenup and Daniela Morich, the PA will only be opened for signature once the PABS Annex is adopted.

The question now is whether countries can bridge deep divides over sovereignty, scientific progress, and equitable access to health products, with important consequences for pharmaceutical research and development (R&D).

Walking the PABS tightrope: What's agreed so far

The PABS System has been one of the most contentious issues in the PA negotiations. At the heart of the debate lie diverging political and economic interests.

High-income countries with advanced R&D capabilities generally prioritize rapid, unrestricted access to pathogen samples and data. They emphasize the importance of non-monetary forms of benefit-sharing, such as open access to data, collaborative research, and scientific acknowledgments.

In contrast, many low- and middle-income countries see PABS as a mechanism to redress global inequities—made evident during the COVID-19 pandemic—by mandating comprehensive, enforceable benefit-sharing provisions, including monetary or in-kind contributions, such as access to vaccines.

The PA attempts to bridge this divide. Article 12 affirms that countries have sovereign rights over their biological resources, echoing the principle expressed in 1992 in the UN Convention on Biological Diversity, and recognizes that sharing of pathogens and associated GSD must be linked to benefit-sharing. It promises a new multilateral system but delegates the technical details to the Annex on the "PABS instrument."

One of the few concrete provisions is a requirement for manufacturers participating in the system to reserve 20% of their pandemic-related production for World Health Organization (WHO) allocation during pandemic emergencies: half as donations and the other half at affordable prices that will need to be negotiated and are not guaranteed.

Distribution will prioritize public health risks and needs, especially in developing countries. This measure is politically significant but operationally complex, as it depends on enforceable contracts to be concluded between manufacturers and WHO, and active participation from industry. The drafting of model contracts could be a part of the Intergovernmental Working Group's (IGWG) work given the importance of globally agreed conditions.

Additional benefit-sharing provisions to be included in the PABS Annex may encompass further access to health products during public health emergencies of international concern. Other potential benefits could include capacity-building and technical assistance, R&D cooperation, the granting of non-exclusive licenses, and other forms of mutually agreed technology transfer.

High hopes meet hard limits: Unresolved technical issues

The technical details, including definitions, legal arrangements, modalities, and benefit-sharing terms will be the focus of a new IGWG, which the WHA has tasked with developing the PABS Annex. The IGWG is due to hold a first organizational meeting by 15 July 2025 and must submit the outcome of its work to the 79th WHA in May 2026, an ambitious timeline to reach agreement on a highly technical and at the same time political issue.

Moreover, WHA Resolution WHA78.1 that adopted the WHO PA envisages only a limited role of experts who may be only "*requested by the IGWG to provide technical advice and inputs, as and when necessary*," raising concerns that political disagreements may prevent access to necessary technical expertise.

Below, I address some legal and technical questions that remain unresolved and need to be addressed.

I. Scope and relationship with other instruments

Negotiators will have to define what constitutes "*pathogens with pandemic potential*." One proposed approach is to align the definition with the WHO R&D Blueprint's priority pathogen list. However, additional clarity is required—especially for zoonotic pathogens which constitute the majority of emerging diseases—to determine the point at which the PABS system applies.

This is because, when PABS is agreed, it will not be the only access and benefit sharing mechanism in place. The Pandemic Influenza Preparedness (PIP) Framework applies to pandemic influenza samples, while the Convention on Biological Diversity (CBD) covers "genetic resources" and now also "digital sequence information" (DSI), understood to also cover GSD, under its multilateral benefit sharing mechanism. Moreover, national biodiversity laws increasingly address genetic resources.

A clearly defined pathogen carveout would help define the scope of application of the PABS System and its recognition as a specialized international instrument that takes precedence over other international legal frameworks, notably within the meaning of Art. 4 of the Nagoya Protocol to the CBD which envisages the creation of specialized international ABS instruments.

An important issue concerning temporal scope arises from the fact that the PABS system is intended to apply only to new pathogen samples (and their associated data) shared after the entry into force of the PA including the Annex. However, precise rules for retroactivity and legacy data will have to be defined, particularly for databases that already contain GSD uploaded without benefit-sharing conditions. A practical solution could involve non-retroactive application paired with voluntary benefit-sharing mechanisms discussed in subsection IV.

II. Establishment of a science-policy interface

Given the uncertainty surrounding the next pandemic, the WHO R&D Blueprint explicitly includes a placeholder for a so-called "Disease X"—a recognition that the next international epidemic could be caused by a pathogen not currently known to cause human disease. To ensure responsiveness to emerging scientific knowledge and technological developments, the PABS System should be linked to a dedicated expert body that translates science into actionable policy.

Attempts to establish such a body in the main text of the PA have so far proven elusive. However, the Conference of the Parties (COP), acting under Article 19.4 of the Agreement, could establish a science–policy interface as a subsidiary body. This body should include scientists, database and biobank managers, and innovators, providing a mechanism to keep the PABS System up to date with the latest research and technological capabilities and to provide needed scientific evidence and analysis on emerging pathogens.

III. Open vs closed regulatory system design for databases

Some countries support an open-access model where data is freely available and benefits are voluntary. Others want a more controlled system, where access is limited to those who commit to binding benefit-sharing, e.g. by registering in the system and agreeing to its access terms (as is the case in GISAID). However, any new benefit-sharing obligations must be carefully designed to avoid increasing transaction costs for database managers, scientists, and companies, and to ensure technical feasibility. The new system should not undermine existing open scientific infrastructures, such as the International Nucleotide Sequence Database Collaboration (INSDC), which are central to global surveillance and research.

Trying to impose new obligations on databases located in countries that may not be parties to the PA risks low compliance and the creation of data silos—threatening the global capacity to conduct R&D for pandemic preparedness and response.

IV. GSD traceability and benefit sharing

GSD is vital for outbreak detection and the development of countermeasures, yet it is difficult to trace and regulate due to its digital and replicable nature. It appears technically infeasible to regulate billions of sequences, hosted on thousands of databases, with millions of users worldwide, without disrupting the underlying scientific infrastructure. This challenge is acknowledged in CBD Decision 16/2 which established a multilateral mechanism for equitable sharing of benefits from the use of DSI on genetic resources.

The CBD Decision 16/2 appropriately avoids interfering in database governance or imposing monetary obligations. It expects database operators to inform users about relevant ABS commitments and to promote transparency by including DSI's country of origin information and relevant metadata in line with open science principles, and ensuring that submissions are free from legal restrictions that would impede sharing.

Such additional information is valuable for increasing transparency and recognizing data inequalities. However, PABS negotiators should also bear in mind that it is unlikely to ensure full traceability of GSD from the country of origin to the final product. This is due to fundamental constraints, including the high similarity between sequences across different organisms, the way modern research integrates vast and diverse datasets, and the frequent absence or inconsistency of relevant metadata.

Moreover, the term "*benefits arising from the sharing and/or utilization*" in the PA text requires clarification, particularly regarding the point at which benefit-sharing obligations are triggered. Drawing on CBD experience, benefit-sharing for GSD is most effective when focused on downstream stages, with access decoupled from benefit-sharing.

Given the complexity of regulating GSD, the PABS System should build on the experience of the CBD Decision 16/2, while reinforcing it with stronger monitoring and enforcement mechanisms. A feasible approach in this context could consist of implementing downstream monitoring at key R&D milestones: such as scientific publications, patent applications, clinical trial documentation, and regulatory approvals.

Similar to academic publications, the GSD used in R&D or patents could be accompanied with searchable tags and digital object identifiers (DOIs). However, such practices are not yet widely implemented or standardized. Employing them would first and foremost require building capacities and norms among scientists on whose contributions the exchange of GSD depends.

A national or international register could then collect relevant metadata, including country of origin, and serve as a mechanism to trigger benefit-sharing at the point of commercialization. The benefits could be distributed through a multilateral fund, or linked to the Cali Fund established under the CBD.

A system akin to scholarly and patent search engines could help monitor the use of GSD and ensure compliance. This model offers a practical, cost-effective, and politically viable alternative to traditional access-based benefit-sharing.

A narrow window of opportunity

PABS exemplifies how a system originally intended to address technical challenges can become entangled in broader debates over sovereignty, equity, the governance of scientific infrastructures, and trust in multilateralism. While addressing global health inequities, it is thus important not to place too far-reaching expectations on a system that must first and foremost function technically.

In this context, aligning the PABS System with other existing and emerging benefit sharing norms can strengthen legal coherence and reduce the risk of fragmentation. A fragmented or delayed outcome would risk regulatory confusion, reduced data sharing, and the withholding of critical pathogen information—outcomes the world simply cannot afford when faced with health emergencies.

Without a workable Annex, the pandemic treaty remains stalled. Yet precisely because of the tensions described above, getting the PABS System right is more urgent than ever. As the world continues to face pandemic risks, the ongoing negotiations present a historic opportunity to establish an internationally agreed framework that brings legal clarity to key design elements. The months ahead will be decisive.

PREVENTING THE NEXT PANDEMIC: A CLOSER LOOK AT PREVENTION AND ONE HEALTH IN THE WHO PANDEMIC AGREEMENT

By Ricardo Matute

Recognizing that most infectious diseases originate from human-animal interactions, Member States included prevention, as well as an article stressing the importance of the One Health approach for Pandemic Prevention, Preparedness and Response (PPPR), early in the Pandemic Agreement (PA) negotiations. This component of the PA focuses on root causes rather than just response and symptom control. Typically, One Health is understood to include measures related to the management of wildlife, ecosystems, and livestock that can help prevent the emergence and spread of drug resistant pathogens, and new zoonotic infections diseases in human communities.

The negotiations on prevention and One Health were contentious and politically charged throughout. From the outset, developed countries supported strong and clear prevention obligations, including a separate One Health article, while many developing countries emphasized the financial and operational challenges such obligations posed and the need for adequate support.

The prevention and One Health provisions (Articles 4 and 5 of the PA) began with strong ambition in early drafts (INB2–INB4), calling for stringent multisectoral plans and international cooperation. One Health was framed as central, with specific obligations and references to cross-sectoral risks like zoonotic spillovers and antimicrobial resistance (AMR).

By mid-2023, political tensions began to surface, and flexibility clauses and softer language were introduced. Later drafts further diluted commitments, emphasizing national discretion and framing implementation as subject to resources and legal contexts. In the adopted text these provisions remain, but with reduced binding force, and their success will depend largely on national action and political commitment, as well as financial and technical support for developing countries.

In addition, Article 4, which covers the overall obligations of countries to prevent pandemics, took on certain One Health concepts, over the course of the negotiations.

What's in Articles 4 and 5?

Article 5 - One Health approach for Pandemic Prevention, Preparedness and Response

The PA is the first international legally binding instrument to incorporate a "One Health approach", expanding the scope of the international legal architecture by addressing the sources of outbreaks and moving away from a purely anthropocentric approach to also consider the environmental and animal health factors that contribute to the emergence and spread of infectious diseases.

Member States did not retain the "One Health" definition developed by the One Health High Level Expert Panel (OHHLEP) and supported by the "quadripartite."[1] Instead, they agreed in Article 1 - *Use of terms*, on a narrower version that, however, reads more as a statement of principle than a classical definition in treaty terms:

"One Health approach" for pandemic prevention, preparedness and response recognizes that the health of humans is closely linked and interdependent with the health of domestic and wild animals, as well as plants and the wider environment (including ecosystems), aiming for a sustainable balance, and uses an integrated multisectoral and transdisciplinary approach to pandemic prevention preparedness and response, which contributes to sustainable development in an equitable manner."

Article 5 establishes obligations to take measures "*aimed at identifying and addressing the drivers of pandemics*" and "*promoting human, animal, and environmental health*." According to the provision, these measures should include "*developing, implementing, and reviewing relevant national policies and strategies that reflect a One health approach*", as well as "*promoting or establishing joint training and continuing education programs for the workforce*."

While Articles 4 and 5 focus predominantly on national implementation, they provide limited guidance on cross-border coordination or data sharing. This is notable given the transboundary nature of pandemics and the inherently interconnected scope of the One Health approach.

In contrast to Article 5, **Article 4**, sets out the overarching obligations **for pandemic prevention and surveillance.**

Article 4 paragraph 2 contains a broad range of requirements for Parties to progressively strengthen relevant measures through the development and implementation of comprehensive, multisectoral national plans and programs. These plans must align with the International Health Regulations (2005), reflect national public health priorities, and promote collaboration across sectors to address the drivers of infectious disease emergence.

The article also emphasizes in paragraph 1 the importance of strengthening pandemic prevention and surveillance capacities through international collaboration, in recognition that bilateral, regional and multilateral collaboration is essential to early detection and response.

Article 4 also includes a commitment to support multisectoral surveillance systems capable of detecting emerging threats and conducting risk assessments. These efforts aim to improve early warning capabilities and inform targeted prevention strategies. Additionally, paragraph 2 (d) recognizes the role of community engagement in designing and implementing local strategies to detect and reduce the risk of disease emergence, acknowledging that effective prevention requires action at all levels.

Significantly, Article 4 does not just prescribe measures to be adopted in response to an outbreak but includes "deep prevention" measures to be mainstreamed throughout the health systems of Parties. Examples include an emphasis on access to safe water, sanitation and hygiene, strengthening routine immunization and infection prevention and control measures.

Over the course of the negotiations, Article 4 also "absorbed" some of the elements previously included in the article on One Health, employing a broad and holistic approach that reflects the complexity of addressing the interactions among humans, animals and ecosystems.

Specific attention is given to reducing the risk of zoonotic spillovers by identifying and managing risks associated with human-animal interactions, alongside addressing broader environmental and socioeconomic drivers such as hunger and poverty.

1 The Food and Agriculture Organization of the United Nations (FAO), the World Organisation for Animal Health (OIE), the United Nations Environment Programme (UNEP), and the World Health Organization (WHO)

Tactical dynamics: The interplay between Prevention, One Health, and PABS in the negotiations

Progress on prevention and One Health provisions, on the one hand; and on the equally contentious provisions in Article 12 for Pathogen Access and Benefit Sharing (PABS) on the other hand, also became closely linked in the INB process. There was a strong impression that the two issues were often treated by the negotiating parties as bargaining chips to force compromises - a dynamic that continued to shape the negotiations until their conclusion.

Compromise and flexibility in the final stages of negotiations

At the final INB meeting, most of Article 4 remained unresolved, while Article 5, on One Health, was entirely open. In the final stages of the meeting, one Member State proposed removing Article 5, arguing its content was already addressed in Article 4, and opposed the previously agreed "use of terms" for the "One Health approach".

In the final hours of negotiations, Ms. Fleur Davies of Australia, Vice-Chair of the INB and facilitator of the discussions on prevention and One Health, presented a compromise package. The proposal included revisions to the "use of terms" for the One Health approach in Article 1, and addressed concerns regarding specific provisions both in Article 4(2) and Article 5(3). Developing countries accepted the package, signaling a willingness to compromise, which led to the adoption of Articles 4 and 5 in a single motion and created momentum toward agreement on the full text.

As with the rest of the text, Articles 4 and 5 attempt to strike a balance between flexibility in implementing obligations and the strength of the commitments adopted by including various caveats, such as "*taking into account national capacities and national and regional circumstances*" and "*in accordance with its national and/or domestic laws and applicable international law, and subject to the availability of resources*."

Next steps and implementation

Paragraph 3 of Article 4 mandates the Conference of the Parties (COP) to develop and adopt guidelines, recommendations, and other non-binding measures to promote the effective implementation of the obligations set out in paragraphs 1 and 2 of the same article. It implicitly recognizes that prevention is not a static target but requires flexible adaptation to scientific developments as well as normative developments in other international legal regimes.

Paragraph 5 of Article 4 acknowledges the need to provide Parties with the resources they need to prevent pandemics at the earliest possible stage and to implement the provisions of the article, including a mandate for the COP to address implementation through technical assistance, capacity building, research collaboration, facilitating equitable access to relevant products and tools, technology transfer as mutually agreed and financing. Also Article 5 paragraph 3 recognizes the need for support from WHO and other relevant intergovernmental organizations in developing and implementing national policies and strategies that reflect a One Health approach.

Together, these provisions aim to transform PPPR policy by addressing the root causes of outbreaks. Their success will depend on their effective implementation, which will vary from country to country, as well as on the mechanisms created to support and ensure such implementation.

GUEST CONTRIBUTOR

TRANSFER OF TECHNOLOGY AND KNOW-HOW FOR THE PRODUCTION OF PANDEMIC-RELATED HEALTH PRODUCTS: THE PROVERBIAL HALF GLASS

By Ellen 't Hoen

During the COVID-19 pandemic, the delayed access to vaccines in low- and middle-income countries revealed the lack of effective global measures for the equitable distribution of pandemic health products and for scaling up manufacturing of such products. In May 2020, before COVID-19 vaccines were developed, the World Health Organization (WHO) established the COVID-19 Technology Access Pool (CTAP). However, as soon as the vaccines were developed, manufacturers turned their backs on CTAP. High-income nations became the first to procure the products, sometimes in quantities far exceeding their populations' needs. Multinational pharmaceutical companies mainly denied requests to share intellectual property and manufacturing know-how, frustrating efforts toward a more diverse and expanded vaccine production. In a letter to the G20 in 2021, WHO Director-General Dr Tedros and other leaders pointed out that, for every 100 people in high-income countries, 133 COVID-19 vaccine doses had been administered, while in low-income countries, only four doses per 100 people had been

administered.

In October 2020, nine months into the pandemic, India and South Africa proposed, at the World Trade Organization (WTO) Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS), a temporary waiver of certain provisions of the TRIPS Agreement for the duration of the pandemic. On 17 June 2022, after nearly two years of discussions, WTO Members adopted the Decision on the TRIPS Agreement, valid for five years, which primarily reiterated existing WTO Members' rights to use compulsory licensing to enhance vaccine access. The Decision excluded COVID-19 therapeutics, for which the use of compulsory licensing would have been much better adapted. The Decision did not address the critical issue of access to know-how and technology transfer, which, is essential for vaccine production. The decision to extend it to therapeutics, foreseen within 6 months of the adoption of the Decision, was never taken.

It was therefore no surprise that technology transfer took centre stage at the WHO Pandemic Agreement negotiations. The issue of technology transfer quickly became contentious, with fault lines appearing between parties that insisted technology transfer should only take place on a voluntary basis and those that were seeking firmer commitments that manufacturing know-how would be made available to enable production of pandemic health products, including the ability to compel access to such know-how in the absence of voluntary arrangements.

In the final hours of the negotiations in April 2025, the talks came close to collapsing when the European Union, spurred on by Germany, sought to define technology transfer as "voluntary and on mutually agreed terms", leaving the decision of whether to share essential manufacturing information in the hands of the rights holders. This was unacceptable to developing countries, who were seeking stronger assurances to access technology, and because such framing would have curtailed existing flexibilities. For example, WTO law recognises members' rights to take non-voluntary measures to gain access to technology, IP, and know-how, especially for public health. While a WHO agreement cannot alter WTO law, defining technology transfer as only achievable on a voluntary basis would have had political, legal and practical consequences. In the end, a compromise was found, to delete the term "voluntary" and only refer to "as mutually agreed", which was formulated in footnote 8: "*For the purposes of this agreement, "as mutually agreed" means willingly undertaken and on mutually agreed terms, without prejudice to the rights and obligations of the Parties under other international agreements*." Footnote 8 was subsequently inserted in the text where transfer of technology was mentioned.

This compromise leaves existing rights under international law, to compel access to IP and know-how, untouched. Voluntary sharing of technology can be very effective in expanding production capacity. But if rights holders refuse to make voluntary arrangements, governments need to be able to regulate access to pandemic technologies.

Article 11 of the Pandemic Agreement contains the main provisions on technology transfer. Article 9, which covers research and development (R&D), also contains a provision to facilitate the sharing of technology. Article 9.5, for example, commits parties to develop policies with regard to publicly financed innovations to ensure access to such innovations, which may include licensing and access to technologies for R&D and local production. Because the term "access" to technologies is used here and not "transfer", Article 9.5 remained free of the footnote. The Pathogen Access and Benefit Sharing (PABS) system, still to be finalized and annexed to the Agreement, will likely include technology transfer provisions.

Article 11.1 commits parties to promote the transfer of technology "as mutually agreed" and sharing of information needed for the production of pandemic-related health products. It encourages measures to make licences available for innovations in which governments own rights and measures to encourage private rights-holders to do the same. It further encourages such voluntary licensing at no or reasonable royalties and with a broad geographic scope, increasing transparency of the terms of license agreements, and transferring technology to regional or global technology transfer hubs or other mechanisms.

Efforts to include a provision for compelling cross-border access to trade secrets when necessary for manufacturing failed. This was particularly important for countries without a technological base and who are dependent on know-how developed elsewhere. Instead, Article 11.1 (f) solely encourages private rights-holders to share information related to production.

Article 11.3 is a barely recognisable reference to IP-waivers, which could for example be agreed upon at the WTO: committing parties to collaborate, where appropriate, "*with regard to time-bound measures to which they have agreed within the framework of relevant international and regional organizations to which they are a party, to accelerate or scale up the manufacturing of pandemic-related health products [...]*."

Article 11.4 further reaffirms parties' rights to use the full flexibilities contained in the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health. This refers, of course, primarily to the use of non-voluntary measures, such as compulsory licensing. In an acknowledgment that parties often experience political difficulties when exercising such rights, Article 11.4 includes the provision "*The Parties shall respect the use of these flexibilities that is consistent with the TRIPS Agreement*." This became known as the 'peace clause'.

Article 11.5 contains measures for strengthening and/or developing licensing mechanisms (presumably this refers to multilateral initiatives such as the Health Technology Access Pool, the successor to CTAP, and the Medicines Patent Pool (MPP), but these entities are not explicitly mentioned in the Agreement).

The last provision, Article 11.6, again in veiled terms, refers to existing flexibilities under WTO law and requires parties to "*consider amending, as appropriate, its national and/or domestic legislation with a view to ensuring that it is able to implement this Article in a timely and effective manner.*" This article finds its origin in the difficulty at the country level to make effective use of TRIPS flexibilities when easy-to-use domestic rules are lacking.

Article 11 touches upon crucial issues in relation to technology transfer, but provisions remain vague and fall short in creating new binding obligations for parties that will change the status quo. Further, many of the provisions containing actions are couched in caveats such as "*as appropriate*", "*in accordance with applicable law and policies*" or "*subject to available resources*". These words offer an escape to parties that are reluctant to take action and may hamper holding parties accountable.

But perhaps the most important achievement is the establishment of a multilateral mechanism and process that will allow for regular interaction, collaboration and review of the actions needed in responding to pandemics.