Pandemic Agreement: A win for R&D!

The experience of inequitable access to COVID-19 vaccines and other related health products during the COVID-19 pandemic prompted many low- and middle-income countries (LMICs) and global health leaders to insist that we needed a new global framework for responding to pandemics that would strengthen global solidarity through more equitable collective action. In 2021, the World Health Assembly (WHA) established an intergovernmental negotiating body (INB) to negotiate a World Health Organization (WHO) “convention, agreement or other international instrument on pandemic prevention, preparedness and response" and submit the outcome for the assembly's consideration in May 2024. Nine negotiating rounds did not produce consensus by that deadline, and the INB’s mandate was extended for a year, with deliberations set to conclude by WHA later this year.

Now, after many difficult months, convergence has finally been achieved, and the latest draft includes obligations that span from research and development (R&D) to manufacturing, regulatory review, and stockpiling of products. Some provisions are more domestically focused, such as commitments to invest in R&D and strengthen regulatory capacities, while others underscore a more regional or global approach, like commitments for licensing of publicly owned technologies and requirements that prohibit certain levels of stockpiling of pandemic products. A connective thread throughout the text is transparency, including new country commitments for clear R&D priorities, clinical trial protocols, research results, licensing agreements, supply chains, and relevant terms of procurement contracts. R&D capacity-strengthening for the development of medical countermeasures is also a central element of the text. Lastly, given the inequitable response to the pandemic, it is encouraging to note that there is also a strong emphasis on access to health products in fragile or humanitarian settings and for underserved populations.

With the text now finalized and ready to be presented to member states, it is worth examining how the negotiations shook out and specifically zeroing in on the R&D articles of the Pandemic Agreement, many of which ended up being the most contentious topics during the negotiations.

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Article 4: Pandemic prevention and surveillance

Article 4 outlines the importance of detection and prevention as the front lines of defense against future pandemics, including integrating environmental risk factors and developing structures and commitments to enhance global surveillance capacity.

What's included in the text:

- **Provisions calling for countries to bolster coordinated multisectoral surveillance** to detect and conduct risk assessments of emerging or reemerging pathogens with pandemic potential, including those pathogens that may present significant risks of zoonotic spillover and those pathogens that are resistant to antimicrobial agents.
- **Text underscoring the need to strengthen effective routine immunization programs,** especially by increasing and/or maintaining high immunization coverage.
- Commitments to **enhance laboratory biological risk management**, including through biosafety and biosecurity training and practice.

Key takeaways:

Strengthening disease surveillance is foundational to early pandemic detection and control. INB negotiators stressed that surveillance systems must extend beyond health sectors, embracing a comprehensive One Health approach that links human, animal, and environmental health. The article mandates that parties "progressively strengthen pandemic prevention and coordinated multi-sectoral surveillance," including detection and risk assessment of pathogens with pandemic potential.

Parties are urged to strengthen mechanisms to report unusual public health events and reinforce routine immunization programs, hygiene infrastructure, and infection prevention and control measures in health care and other care settings.

The article also explicitly calls for "surveillance, risk assessments and prevention of vector-borne diseases" and "measures to address...pathogens that are resistant to antimicrobial agents," marking a significant expansion of what constitutes pandemic prevention.

Verdict:

While this article highlights the importance of building out surveillance capacity and the rules governing alert systems, many of the obligations outlined are subject to a government's available resources and domestic laws, as well as applicable international law. During negotiations, the United States and European Union (EU) sought ambitious surveillance obligations, while the Africa Group pushed back hard, highlighting concerns about affordability and fairness. Central to the deadlock was the balance between strengthening prevention systems and operationalizing a system for Pathogen Access and Benefit Sharing (PABS) in Article 12. LMICs also explicitly asked for resources to implement these new obligations, something that was never fully addressed in the current text.

On a more positive note, the inclusion of broader systemic drivers that increase pandemic risk—including environmental degradation, climate change, poverty, and antimicrobial resistance—can be seen as a win, especially as there was a specific battle over whether antimicrobial resistance should be part of the scope.

Article 9: Research and development (R&D)

Article 9 seeks to strengthen R&D for pandemic preparedness and response and to build, strengthen, and sustain geographically diverse capacities and institutions for R&D, particularly in LMICs.

What's included in the text:

- **Obligations aimed at promoting investment in the discovery and development of pandemic-related health products**, as well as fostering cooperation, collaboration, and information sharing.
- **A provision on post-clinical trial access to products**, advancing equity for trial populations and for populations at risk in their communities.
- **Commitments for transparency in clinical trial protocols and outcomes** to enable access to R&D information and help researchers learn from past and existing work to fuel their research.
- **A commitment to provide access to comparable products** for use in clinical trials.
- **Requirements to develop national policies that encourage the disclosure of equitable access provisions** to help hold entities that benefit from publicly funded R&D accountable for equitable access.

Key takeaways:

Much of the deliberations centered around enhancing transparency, setting access requirements for publicly funded R&D, and strengthening the broader R&D ecosystem.

Though some delegates (specifically the United States and the EU group) showed concern over the imposition of R&D transparency obligations and global access conditions for publicly funded R&D, negotiators reached consensus by March 2025 on most of Article 9.

The text calls for member states to protect sustained funding streams for research institutions, particularly those in LMICs, with the broader goal of building long-term, resilient research capacities globally. The agreement also highlights the importance of collaboration with scientists and institutions from LMICs to integrate these countries into global health R&D efforts, including technology cocreation and joint ventures.

For the first time, an international legally binding instrument includes a provision on post-clinical trial access to products, cementing a more equitable approach for the development of pandemic tools for trial populations and underserved communities. It would also be the first time that a legally binding instrument would commit countries to develop policies on attaching public interest conditions to R&D funding—an unprecedented move with the potential to transform how treatments, tests, and vaccines are developed and delivered during crises.

The text also outlines commitments to strengthening and sustaining geographically diverse R&D capacities in LMICs, focusing on collaboration and the rapid sharing of research findings, especially during an outbreak.

Lastly, the text acknowledges the importance of public-private partnerships to expedite the R&D pipeline during health emergencies, from manufacturing support to licensing deals and influencing affordable pricing policies.

Verdict:

This article represents a big win for the R&D community. If adopted in its current form, Article 9 would be the first internationally binding agreement to commit countries to strengthening R&D for health products and embedding equitable access conditions into publicly funded research. This could set a powerful global precedent, moving beyond voluntary frameworks to formalize cooperation, financing, and inclusion—especially for LMICs—in the development and distribution of pandemic-related tools. While some advocates had pushed negotiators to go even further on the obligations for publicly funded R&D, calling for those products to be global public goods, this article still marks a major positive shift toward global equity.

Article 10: Sustainable and geographically diversified local production

Article 10 emphasizes the need for local and regional production, including ensuring all member states have the resources to respond to health emergencies, as well as cross-sectoral partnerships for pandemic prevention, preparedness and response. Member states also established more concrete responsibilities for WHO in this section compared to other articles of the text.

What's included in the text:

- **Commitments from countries to diversify manufacturing geographically** and rapidly scale up production to improve access to pandemic-related health products.
- **Specific measures to be taken by countries to strengthen the manufacturing ecosystem**, which includes supporting new and existing production facilities, particularly in LMICs, through skill development and capacity-strengthening and facilitating their continuous and sustainable functioning through transparency of non-protected information across the value chain.
- Obligation of countries to **encourage** "**public and private sector investments**, purchasing arrangements, and partnerships, including public-private partnerships."
- **WHO is tasked, upon the request of the Conference of Parties (COP)** (a body to be set up to oversee implementation of the agreement), **with providing training, capacity-building, and production support** to achieve geographically diversified manufacturing.

Key takeaways:

Compared to more contentious sections of the pandemic agreement, Article 10 saw relatively strong alignment among member states, with most of the text reaching consensus during INB12 last November. Negotiators in both the Global South and Global North expressed support for the article, recognizing that strengthening local production and geographically diverse manufacturing is essential for reducing dependency, enhancing equity, and ensuring timely access during health emergencies.

The urgency of this objective was made stark during the COVID-19 pandemic, when vaccine production was highly concentrated among a few manufacturers in high-income countries (HICs). As a result, many LMICs received doses only after HICs had secured their own supply—often through restrictive export bans and national procurement strategies. In the wake of this inequity, WHO and partners launched initiatives such as the mRNA Technology Transfer Hub in South Africa and the Global Training Hub for Biomanufacturing in the Republic of Korea to expand access to technology and build a skilled workforce in LMICs. Regional efforts, such as the African Vaccine Manufacturing Accelerator, also emerged to address the need for more distributed production capacity. These efforts have been guided in part by WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, but they operate outside of any formal legal framework.

Article 10 represents an opportunity to codify and enhance these efforts under international law, with the COP potentially empowered to direct WHO to provide further support to geographically diverse manufacturing hubs.

Member states underscored the importance of achieving more equitable geographic distribution of pandemic-related health products throughout the proceedings, and, in this article, stressed the need to foster strategic and diverse partnerships and strengthen the role of the private sector. In the agreement, parties commit to implementing measures that reduce the global supply-demand gap, ensuring all regions can rapidly access and produce essential medical supplies during emergencies. This approach is also designed to prevent supply chain disruptions like those seen during the COVID-19 pandemic.

Article 10 further stresses that collaborative efforts with WHO will support the rapid scale-up of manufacturing capacity where it is needed most, prioritizing sustainable and timely access in underserved regions. Specifically, WHO is assigned a technical assistance role to offer “training, capacity-building, and timely support” for facilities, especially those in LMICs, with the aim to geographically diversify production.

Verdict:
While Article 10 uses relatively strong legal language—evident in its repeated use of “shall”—its implementation is still subject to national discretion. Phrases such as “as appropriate” and “subject to national and/or domestic law” provide flexibility that could dilute the strength of these commitments in practice in the agreement’s implementation. Still, the article sets an important foundation for future coordination and accountability.

Article 11: Transfer of technology and know-how for the production of pandemic-related health products

Article 11 addresses the transfer of technology and know-how during pandemics, including licensing, patent pooling, and the international mechanisms required to achieve these aims. However, unlike other sections, it has proven especially divisive, with member states split over whether these provisions should remain voluntary or include stronger obligations to ensure equitable access.

What's included in the text:

- Countries are encouraged to promote the **transfer of technology and know-how for pandemic-related health products** on *mutually agreed terms* and in line with national and international obligations.
- Governments should **facilitate voluntary sharing** of production-related information, including through licensing, patent pooling, and regulatory cooperation, particularly for government-funded or government-owned technologies. The provision also supports **capacity-building and regional manufacturing** for LMICs.
- Parties are called up to "encourage and incentivize" rights holders to engage in **non-exclusive licensing** and to consider public health needs in decisions related to **intellectual property during pandemics**.
- Member states **reaffirm the use of existing Trade-Related Aspects of Intellectual Property Rights, or TRIPS; flexibilities;** and other applicable international instruments but stop short of establishing new intellectual property measures or mandatory access mechanisms.
- **WHO is tasked with supporting countries**, upon request, in leveraging technology transfer hubs and promoting coordination for equitable access to pandemic-related health products.

Key takeaways:

Article 11 has proven one of the most contentious sections throughout the INB process. A core fault line in the negotiations has been the nature of technology transfer obligations all hinging on the word "voluntary."

However, in the last INB session, with pressure from country leaders and civil society mounting, member states compromised to finish the text. Brazil offered a compromise definition that reinforces the voluntary nature of such transfers—clarifying that "mutually agreed" implies a willing undertaking, without undermining existing rights and obligations under other international agreements.

Another sticky provision surrounds international mechanisms to facilitate technology and information sharing during health emergencies. While the article reaffirms member states' ability to tailor intellectual property protections to meet public health need through TRIPS flexibilities, it stops short of introducing new measures. This has sparked criticism from LMICs

and access advocates who argue that existing intellectual property frameworks are insufficient during public health emergencies, as evidenced by the slow voluntary sharing of COVID-19 vaccine patents.

The text also mentions potential nonexclusive licensing and patent pooling—particularly for government-owned technologies—but lacks enforcement mechanisms and encourages, rather than compels, participation by private holders.

Article 11 of the agreement reinforces the importance of capacity-building and regional manufacturing, with the text outlining provisions for support to LMIC manufacturers and WHO-led technology transfer hubs. It is important to note that implementation remains dependent on available resources, national discretion, and voluntary cooperation—again falling short of what many LMICs consider necessary for equitable access.

Verdict:

While the text touches on major aspects of technology transfer and intellectual property, the outcome includes few binding commitments, relying instead on discretionary language that leaves obligations open to interpretation. However, despite falling short of earlier ambitions, the agreement still represents a significant achievement—laying the foundation for stronger cooperation on equitable access to pandemic-related health products within a remarkably short negotiation period.

Article 12: Pathogen Access and Benefit-Sharing (PABS) System

This article outlines the PABS system, a new structure that seeks to ensure that countries that provide genetic materials and data to enable research eventually benefit from the tools that they contributed to. The article outlines key principles for benefit sharing provisions but does not cement details around the operations, instead establishing modalities for future negotiations to build this new structure.

What's included in the text:

- A **new mechanism (yet to be negotiated) that provides WHO with 20 percent of the real-time production of medical countermeasures** (with 10 percent as a donation) for equitable distribution.
- Additional **benefit-sharing provisions, including royalty-free licenses and technology transfer** to LMIC manufacturers during emergencies.

Key takeaways:

Article 12 has emerged as one of the most politically fraught parts of the pandemic agreement. The core of the provision establishes the PABS system—a new platform meant to ensure that biological samples and genetic sequence data from pathogens with pandemic potential are rapidly shared and that the benefits arising from their use are fairly distributed. The path to agreement has proved bumpy: hard lines have formed between LMICs and HICs, with negotiations stalling over what, when, and how much should be shared.

The PABS system is intended to facilitate the safe, transparent, and accountable sharing of "PABS Materials and Sequence Information"—a term that encompasses both physical pathogen samples and digital sequence data. The system is to be developed via a legally binding annex, the "PABS Instrument," which will define operational details and legal obligations.

The current draft stresses open access and traceability of pathogen materials while maintaining consistency with the Nagoya Protocol—a touchpoint for LMICs that asserts their sovereign rights over biological resources. However, the implementation details remain vague, and what qualifies as "pandemic potential" and how to avoid duplicating existing access and benefit sharing systems (like the Pandemic Influenza Preparedness Framework) are still under negotiation. The current draft also outlines allocation targets, with the goal of 20 percent of pandemic product production being allocated to WHO—10 percent being donated to WHO by manufacturers and the rest at affordable or reserved pricing.

Verdict:

Member states could not come to a final agreement on PABS, and the details of this system will be added later to the agreement as an annex. This decision, which breaks the pandemic agreement into two parts—an agreement at WHA and the PABS instrument to be finalized

through the COP at a later date—could be a hard line for many LMICs who are adamant that PABS is essential to ensuring equity. This item could prove to be a sticking point for some countries.

In addition, based on the draft text, the instrument would only be binding for those parties to the pandemic agreement that specifically accept it. This approach could mean fewer WHO member states accept the PABS Instrument than join the pandemic agreement—an outcome seen elsewhere, including with the WHO Framework Convention on Tobacco Control (183 parties) and its protocol on illicit tobacco trade (69 parties).

Article 13: Supply chains and logistics

Article 13 on supply chains and logistics emphasizes the need for coordinated supply chains that promote equitable allocation of and access to health technologies, including the materials necessary to produce new tools—such as glass, plastics, metals, biomaterials, and polymers.

What's included in the text:

- **Establishes a Global Supply Chain and Logistics (GSCL) Network tasked with rationalizing and stabilizing the international supply chains of pandemic-related health products** to promote "equitable, timely, and affordable access" to such products. The responsibility for developing, coordinating, and convening the GSCL Network falls on WHO under the authority of the COP, but the functions of the GSCL Network will be discharged by the organizations best placed to perform them.
- **Requires parties to ensure transparency in their purchase agreements with manufacturers of pandemic-related health products** (paragraph 1), commit to promoting equitable access and to sharing health products with countries in need (paragraphs 2 and 3), and avoid market disruptions through excessive stockpiling (paragraph 6).

Key takeaways:

This article primarily focuses on reducing the risk of restrictions and disruptions to international trade during a pandemic through a broadly agreed upon market stabilization mechanism. Specific references to the General Agreement on Tariffs and Trade show that World Trade Organization members still enjoy broad discretion in restricting international trade at times of need or crisis in ways that may be particularly disruptive during a pandemic. While the World Trade Organization has a dispute settlement system to enforce limits on export restriction, it functions too slowly to be useful during acute health emergencies. The new provisions included in this section task WHO with facilitating equitable access to health products, including through assessing the need for and availability, accessibility, and affordability of such products and through the use of WHO-coordinated mechanisms.

Specifically, this article would establish the GSCL Network—a new coordinated supply chain system to be developed by WHO and member states to improve equitable, timely, and affordable access to pandemic-related health products, including in humanitarian settings. Additionally, member states focused on strengthening transparency around the allocation of health products. For developers and manufacturers, predictable and transparent supply chains reduce uncertainties and encourage further investment in innovations that address the needs of underserved populations.

Verdict:

It was great to see equity considerations play such a strong role in the deliberations, with the agreement's GSCL Network prioritizing the equitable distribution of pandemic-related health products based on public health risk and need.

While this article wasn't one of the more contentious ones, ten countries did push for and eventually fail to get the terms "unimpeded access" included in Article 13 to ensure that pandemic products are also available in conflict settings. These countries have unilateral sanctions they want lifted during pandemics. This topic is likely to be raised again during WHA.

Article 13bis: Procurement and distribution

Article 13bis zeroes in on the often-overlooked last mile: procurement, distribution, and delivery of health technologies. Drawing directly from the lessons of COVID-19, this section aims to embed transparency, equity, and efficiency into how countries purchase and share pandemic-related health products, reflecting on the balancing act between national interests and global solidarity through procurement transparency and equitable allocation.

What's in the text:

- Call for parties to **publish the relevant terms of their purchase agreements with manufacturers** for pandemic-related health products at the earliest reasonable opportunity.
- Encouragement for parties to **consider including provisions in their publicly funded purchase agreements for pandemic-related health products that promote timely and equitable access,** especially for LMICs.
- **Provision stating that each party should avoid maintaining excessive national stockpiles of critical supplies at the detriment of other countries during active public health emergencies**
- Measures that ensure **shared products meet minimum standards—such as adequate shelf life, appropriate packaging, and compatibility with recipient** country capacities.

Key takeaways:

This amended portion of Article 13 was added to the agreement early last year after member states pushed for greater transparency in how countries negotiate and disclose procurement deals for pandemic-related health products. Under Article 13bis, countries are asked to publish the terms of their purchase contracts "at the earliest reasonable opportunity" and are discouraged from using confidentiality clauses that prevent disclosure. Further, countries are urged to include public interest safeguards—especially in publicly funded purchase agreements—such as donation clauses, delivery flexibility, and global access plans to ensure that public funding translates into broader, more equitable benefits during health crises.

Article 13bis also calls on member states to proactively reserve portions of their pandemic product procurement, including for diagnostics, therapeutics, and vaccines, for use in other countries struggling to meet public health needs. Negotiators also delineated expectations for member states to avoid excessive national stockpiling and to ensure shared products meet minimum standards—such as adequate shelf life, appropriate packaging, and compatibility with recipient country capacities. The provision includes INB bureau-provided language that emphasizes coordinated distribution through WHO's GSCL Network—such as facilitating timely product delivery—and calls on WHO to help countries manage the legal risk around novel vaccines, especially in humanitarian settings. Like Article 10, Article 13bis further incorporates WHO in a technical support role compared to other R&D-adjacent articles.

Verdict:

While this article could have created stronger obligations, particularly to avoid excessive national stockpiling, it does offer some robust language and provisions on transparency around purchase agreements, embedding those principles into procurement frameworks in a more explicit way, which represents a solid step forward.

Article 14: Regulatory system strengthening

A robust regulatory system capable of responding to evolving health crises is integral for pandemic response, as demonstrated by regulators' rapid implementation of emergency procedures to greenlight COVID-19 medical countermeasures. For instance, in 2020, the US Food and Drug Administration approved the first COVID-19 vaccine under emergency authorization just nine months after the pandemic was declared, and WHO listed the vaccine for emergency use less than three weeks later. Article 14 reflects the need for elastic regulatory policies and focuses on improving regulatory resilience, facilitating emergency authorization procedures, and enhancing regulatory transparency and cooperation among member states.

What's included in the text:

- Calls for parties to collaborate, as appropriate, toward **improving the WHO processes for Emergency Use Listing and prequalification, as well as any other relevant WHO processes** for recommending the use of pandemic-related health products.
- Commitment by countries to **strengthen their national and, where appropriate, regional regulatory authority responsible for the authorization and approval of pandemic-related health products**, including through technical assistance from and cooperation with WHO and other international organizations.
- Provisions emphasizing the need to **support expedited regulatory review and/or emergency regulatory authorization**.
- Obligation of countries to **strengthen rapid alert systems and take regulatory measures to respond to substandard and falsified pandemic-related health products**.

Key takeaways:

In the text, negotiators have underscored the need for countries to strengthen their national and regional regulatory authorities to ensure the quality, safety, and efficacy of pandemic-related health products. The text references that through technical assistance, capacity-building, and financial support, member states can better develop resilient regulatory ecosystems capable of responding rapidly during emergencies.

Article 14 also outlines WHO's role in offering technical assistance and cooperation to ensure "the quality, safety and efficacy of such products." To accelerate access to critical health products, the text encourages the establishment of streamlined regulatory pathways, including expedited reviews, emergency use authorizations, and reliance mechanisms, including through WHO's prequalification process and emergency use listing procedure. For global health R&D, this means faster market entry for innovations, ensuring that lifesaving technologies are deployed quickly where they are needed most.

The text also urges member states to publish information on product authorizations, approvals, and safety data, fostering international coordination and confidence in health innovations. Philippines and fellow 'Equity Group' INB members supported the addition of this provision last fall, though member states have mostly agreed on Article 14's contents since 2023.

Verdict:

Overall, negotiators have largely seen eye to eye on the importance of regulatory strengthening, with Article 14 remaining steady through the past year of talks. This consensus reflects growing recognition that strong, agile, and transparent regulatory systems are not just technical necessities—they're essential foundations for equitable, effective global health R&D and pandemic response.

What happens next:

Though the agreement marks a major milestone, the instrument is not yet entered into force. After three years of intense negotiations and significant progress made toward aligning key provisions, critical procedural steps remain before the agreement can be formally adopted and implemented.

So, what comes next to translate this agreement into action?

- May 2025: Consideration and ratification at WHA
    - The next step will be formal consideration and adoption at WHA, either via consensus or a two-thirds majority vote. However, even if this occurs, the text remains incomplete without the PABS annex—a central component of the agreement that will determine how pathogens are shared and how resulting benefits, such as vaccines and diagnostics, are equitably distributed.
- May 2025- May 2026: Drafting the PABS annex
    - The current proposal envisions establishing an Intergovernmental Working Group (IGWG) to finalize negotiations on the PABS annex and to prepare for the first meeting of the COP. According to the agreement, the IGWG will remain in negotiation mode until the PABS annex is completed and submitted for consideration at the 2026 WHA. Until then, other preparatory work—such as developing implementation or monitoring mechanisms—will remain on hold.
    - Importantly, the agreement will not enter into force until the PABS annex is adopted. This means that while countries may be able to sign or even begin domestic ratification processes after WHA 2025, many are likely to wait until the full package is finalized.
- May 2026: Adopting the PABS annex at WHA79?
    - Ideally, the PABS annex will be finalized and put up for ratification at WHA next year.
- After May 2026:
    - More countries start signing and ratifying the *complete* agreement. Once adopted, the agreement will enter into force after 60 countries ratify it. Under the current timeline, this could realistically occur sometime after WHA 2026.
    - IGWG prepares for the first meeting of the COP, which will be held one year after the full text enters into force.