Commentary

Pathogen Access and Benefit-Sharing: Can the WHO Pandemic Agreement Bridge the Equity Divide?

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ABSTRACT

The adoption of the WHO Pandemic Agreement in May 2025 marks a pivotal shift toward institutionalizing global pandemic governance. Anchored in principles of equity, solidarity, and human rights, the agreement establishes a Pathogen Access and Benefit-Sharing (PABS) System, which aims to ensure equitable access to pandemic-related health products (PRHPs). However, operational ambiguities — particularly in defining pathogen scope, integrating traditional knowledge, enforcing manufacturer obligations, and coordinating with multilateral frameworks like the Convention on Biological Diversity and the Nagoya Protocol — pose significant implementation risks. Crucially, the agreement's effectiveness is intertwined with broader health system resilience. However, specific provisions for PABS integration within a strengthened health system architecture remain underdeveloped. Moreover, critical gaps persist regarding financing, compliance, One Health integration, digital governance, community engagement, and alignment with broader health systems. The success of the agreement hinges on resolving these gaps through subsequent protocols and sustained political commitment.

The coronavirus disease 2019 (COVID-19) pandemic has exposed some critical flaws in global health security, such as fragmented supply chains, vaccine nationalism, and systemic inequities in accessing diagnostics, therapeutics, and vaccines (*1*). Consequently, World Health Organization (WHO) member states initiated negotiations for a legally binding Pandemic Agreement in December 2021. After extensive deliberations, the agreement was adopted at the 78th World Health Assembly on May 20, 2025 (*2*). Its mandate is clear: transform ad hoc crisis responses into a cohesive, equity-driven framework for pandemic prevention, preparedness, and response. However, the success of this framework is intrinsically linked to underlying health system capacities and a broader preparedness ecosystem.

This commentary examines critical ambiguities within the Pathogen Access and Benefit-Sharing (PABS) mechanism established by the Pandemic Agreement. Key unresolved issues include defining pathogen scope (particularly those with zoonotic sources), enforcing manufacturer obligations for equitable product allocation, establishing transparent benefit-distribution criteria, and harmonizing the system with multilateral regimes such as the Convention on Biological Diversity (CBD) and the Nagoya Protocol. Furthermore, it explores foundational yet unaddressed issues, including specific compliance and financing models, the operationalization of One Health and digital equity principles, community-centric engagement frameworks, and mechanisms for resolving legal and ethical dilemmas arising from implementation. Future negotiations on the PABS operational protocol must urgently address these gaps to strengthen the mechanism and ensure effective implementation of the agreement.

Pathogen Access and Benefit-Sharing (PABS) System under the Pandemic Agreement

The Pandemic Agreement established the PABS system to advance global solidarity and address health equity challenges. Article 12 of the agreement mandates that parties rapidly share "materials and sequence information of pandemic-potential pathogens" and equitably distribute associated benefits based on the principles of justice and fairness. To operationalize this, the agreement implements a mechanism for allocating pandemic-related health products (PRHPs), contingent on a pandemic emergency declaration, as outlined by the following guidelines: 1) participating manufacturers must prioritize supplying 20% of the real-time production of

vaccines, therapeutics, and diagnostics targeting pandemic pathogens to the WHO under legally binding contracts; 2) this provision further specifies that no less than 10% of this allocation shall be donated, with the remainder provided at affordable prices commensurate with manufacturers' capacities. Critically, distribution must prioritize countries based on public health risk assessments, with explicit consideration for developing nations' needs.

However, the agreement establishes these obligations without specifying the requisite funding mechanisms to support LMIC implementation, nor does it define clear enforcement or incentive structures for manufacturer compliance, raising significant questions regarding its feasibility.

Core Implementation Challenges and Key Ambiguities in the Pathogen Access and Benefit-Sharing (PABS) Mechanism

Ambiguity in pathogen scope and the need for one health integration: Despite setting minimum standards for the PABS framework, Article 12 of the Pandemic Agreement fails to clearly define the scope of "materials and sequence information." Current negotiations have predominantly focused on human-derived pathogens and their genetic sequences. However, approximately 75% of emerging infectious diseases are zoonotic [e.g., severe acute respiratory syndrome (SARS) (*3*), Influenza A(H1N1) (*4*), Middle East respiratory syndrome (MERS) (*5*), Ebola virus disease (*6*), mpox (*7*), anthrax (*8*), and brucellosis (*9*)]. Consequently, it remains unclear whether the PABS system encompasses animal-sourced pathogens (e.g., wildlife and livestock) and broader microbiological agents (viruses, bacteria, fungi, and parasites). This narrow-scope risk undermines the agreement's preventive potential. Embedding an explicit One Health framework, mandating cross-sectoral data sharing, and joint risk assessment between the human, animal, and environmental health sectors is imperative to strengthen spillover prevention and comprehensive surveillance, which must explicitly delineate the covered pathogen types to ensure comprehensive surveillance.

Weak oversight and enforcement of manufacturer obligations: Under the obligations framework, Article 12 imposes two core requirements on manufacturers when a pandemic emergency is declared: donating 10% of their PRHP production to the WHO, and supplying an additional 10% at affordable prices. Notwithstanding these legally binding contractual commitments, one critical limitation is the agreement's lack of mechanisms to monitor compliance and define enforcement protocols. To ensure accountability, the operational protocol must establish an independent, multidisciplinary monitoring body with the authority to audit manufacturers' contributions and supply chains. This could be complemented by a tiered system of consequences for non-compliance, ranging from public reporting and financial penalties to exclusion from future publicly funded research and development partnerships, along with positive incentives such as preferential access to pathogen data or technology transfer pools for high-performing entities. Consequently, the current ambiguity risks inconsistent implementation, while simultaneously undermining accountability for equitable PRHP allocation.

Deficiencies in benefit-allocation equity and sustainable financing: Regarding benefit-distribution mechanisms, the PABS system exhibits critical flaws despite mandating manufacturers' contributions. Fundamentally, the "public health risk and need" principle lacks quantified parameters such as transmission coefficients and healthcare capacity, thereby enabling subjective interpretations. Furthermore, resource allocation faces ethical tensions between prioritizing high-transmission urban zones to curb the spread and vulnerable regions to prevent system collapse — a dilemma compounded by the absence of triage guidelines. Most critically, political capture risks emerge as high-income countries may leverage their bargaining power to divert resources. A fundamentally unresolved question is how to secure sustainable financing. The operational protocol should mandate the establishment of a dedicated, multi-source PABS implementation fund, potentially financed through assessed contributions from states; levies on manufacturers benefiting from PABS-shared materials; and multilateral donor funds, specifically earmarked to build regulatory, surveillance, and health system capacities in LMICs. The agreement also lacks sustainable financing mechanisms to support LMICs in implementing PABS obligations.

Challenges in multilateral framework complementarity and dispute resolution: Concerning institutional coherence, achieving complementarity between the PABS system and existing regimes presents several challenges. The primary focus of the negotiations has been the relationship with the CBD and the Nagoya Protocol, given the latter's requirements for prior informed consent and benefit-sharing of genetic resources. Defining the complementarity between these

systems is crucial to avoid legal uncertainties, particularly regarding pathogen sovereignty and access. Subsequently, jurisdictional overlap occurs in DSI governance; both the CBD's multilateral mechanism (Decision 16/2) and PABS claim authority over pathogen digital sequence information, potentially fragmenting the data infrastructure. Additionally, the agreement does not specify how equitable digital infrastructure and governance will be ensured, nor does it include clear dispute resolution mechanisms for conflicts between legal frameworks. Critically, the agreement lacks a dedicated mechanism for resolving conflicts that will inevitably arise between its provisions, the Nagoya Protocol, and the International Health Regulations. The establishment of an impartial technical arbitration panel or the referral of intractable legal disputes to an agreed-upon international judicial body should be considered to provide legal certainty and prevent diplomatic gridlock. Furthermore, the protocol should institutionalize a standing ethics advisory group to guide allocation decisions and resolve the ethical dilemmas inherent in prioritizing scarce resources.

The Path Forward: Addressing Critical Gaps Through Subsequent Negotiations

The Pandemic Agreement undoubtedly represents a pivotal moment for global health governance (*10*); nevertheless, its transformative promise remains contingent upon imperative actions that extend beyond its current text. First, finalizing the PABS operational annexes must specifically define the pathogen scope within an explicit One Health framework. Second, establishing robust and transparent monitoring and enforcement mechanisms for manufacturer obligations is non-negotiable. Third, creating a clear framework for complementarity with the Nagoya Protocol, coupled with a formal dispute-resolution mechanism, is essential. Moreover, the operational protocol must be considerably more ambitious, incorporating 1) legally binding and innovative sustainable financing mechanisms for LMICs; 2) mandates for equitable digital infrastructure and data governance; 3) operational frameworks for community engagement, trust building, and dynamic risk communication to counter misinformation and hesitancy; and 4) concrete obligations for upstream capacity building, including mandatory intellectual property sharing through multilateral pools and technology transfer initiatives to empower LMICs' production of PRHPs, thereby addressing inequities at their source. Critically, without these foundational and interconnected steps, the agreement risks perpetuating the health inequities that it seeks to resolve, thereby undermining its core mandate.

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