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GLOBAL HEALTH LAW NOTES

THE PATHOGEN ACCESS AND BENEFIT SHARING SYSTEM: WHERE DO THE NEGOTIATIONS STAND?

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After two years of negotiations and five major revisions to what has become the revised draft of the negotiating text of the WHO Agreement on Pandemic Prevention, Preparedness and Response, the most recent version of the proposed agreement was released on 13 March 2024 in anticipation of the 9th Intergovernmental Negotiating Body (INB) Meeting (held from 18 to 28 March 2024). The original deadline for adoption of the proposed WHO Pandemic Agreement, decided in December 2021 at the offset of this ambitious initiative to strengthen global health security governance, is fast approaching. The 77th Meeting of the World Health Assembly, scheduled for 27 May 2024 marks the deadline for adoption of this proposed agreement.

1. Equity in Pandemic Prevention, Preparedness and Response

During the Covid-19 pandemic, high income countries had faster and priority access to vaccines, reflecting a major inequality between high income and low-income countries during a global emergency. Thus, a central aim of the pandemic agreement is to advance equity in pandemic prevention, preparedness and response. One of its guiding principles is "**equity as the goal and outcome** of pandemic **prevention, preparedness and response**, ensuring the absence of unfair, avoidable or remediable differences among groups of people" (Article 3.3).

To this end, Chapter II, entitled "The world together equitably: achieving equity in, for and through pandemic prevention, preparedness and response", includes 12 provisions aimed at improving equity: prevention and surveillance(Article 4); One Health (Article 5); health systems preparedness (Article 6), Health and care workforce (Article 7), preparedness monitoring (Article 8); Research and development (Article 9); sustainable and diversified production (Article 10), technology transfer and know how (Article 11), and pathogen access and benefit sharing (Article 12).

The purpose of this note is to focus on the Pathogen Access and Benefit Sharing (PABS) System in Article 12 and its role in advancing equity.

2. What is the PABS System?

The purpose of the PABS is to "ensure rapid, systematic and timely access" to pathogens with pandemic potential, to strengthen global surveillance and facilitate the development of health products, while enabling fair, equitable and rapid access to benefits, including medical countermeasures developed from the pathogens.

The PABS system is a multilateral mechanism where member states will share biological materials (clinical samples) of pathogens with pandemic potential and their associated genetic sequence data (GSD) with a WHO coordinated network of laboratories and with PABS sequence databases, respectively. Users of these biological materials and GSD (e.g. manufacturers and developers), are subject to benefit sharing provisions of the PABS system. Benefits listed include monetary or non-monetary contributions (e.g. capacity building, technology transfer), or real time contributions of the medical products developed (e.g. vaccines).

3. Why is the PABS System contentious?

High-income countries, the innovation pharmaceutical industry and developing countries have conflicting interests regarding pathogen sharing.

On the one hand, developing countries consider the PABS an **equitable** and "very important centerpiece" of the pandemic treaty. The reason is that the Global South has suffered from delayed access to vaccines and other health products during the Covid-19 pandemic as well as previous epidemics. Thus, they see the PABS system as key for enabling fair and equitable access to medical countermeasures or other benefits in a future pandemic. For example, Ethiopia and Egypt, representing 47 African states have stood their ground on desiring "concrete outcomes" on key priorities, including a PABS System with "binding terms and conditions for access and legal certainty for sharing monetary and non-monetary benefits."

On the other hand, the pharmaceutical industry has fiercely opposed an ABS system, as they consider that it undermines the rapid sharing of pathogens during an emergency situation. They base their claims on their experience with the Nagoya Protocol. Developed countries like the United States, United Kingdom, European Union, Canada, Switzerland and United Arab Emirates have conveyed their dissatisfaction with PABS, amongst claims of pharmaceutical industry's pressure on these high-income countries.

4. Discussions at INB 9 on PABS System

Debates regarding PABS have remained contentious in INB 9. The pharmaceutical industry seeks to advance an approach which decouples access and benefit sharing, whereas the Global South maintains that it is critical to maintain conditionality among access and benefit sharing.

High income countries and the pharmaceutical industry

At the start of INB 9, developed countries' response to the revised text of Article 12 was unaccepting. Switzerland (which houses many pharmaceutical companies) said "it does not accept the text in its current state". The United States, United Kingdom and the president of the International Federation of Pharmaceutical Manufactures and Associations (IFPMA), the main international trade association representing the interests of the pharmaceutical industry, called the text "a step backwards". IFPMA criticized the PABS System for being stringent and conditional, arguing that demanding a fee for using the PABS System will prove to be a disincentive for pharmaceutical companies to join it. According to them, "coercion will not work".

Decoupling access and benefit-sharing

After a four-day stall in progress of negotiations, IFPMA proposed an alternative to the current PABS System's conditions of use. While stating that the IFPMA supports the adoption of a pandemic agreement, it presented a unified stance of manufactures in the global north and south. The IFPMA is willing to work with elements of the European Union's proposal on PABS System and demands unconditional and "free access" to pathogens and their GSD, which decouples access and benefit-sharing. In return, "companies are willing to accept mandatory commitments to delivering equitable access to essential medical countermeasures." These commitments propose pre-pandemic and during-pandemic obligations, including a real-time percentage donations of vaccines and therapeutics to low income countries and a percentage of equity-based tiered pricing "based on medical need", which may also arise in high income countries.

A key issue that arises with a PABS system is that the genetic sequence data used to develop vaccines cannot always be traced back to an identifiable country of origin. Thus, the PABS system alone can't solve the problem of equitable access by awarding benefits to an identifiable country that shared data used in developing the vaccines.

For example, in the case of Moderna's mRNA vaccines for Covid-19, no SARS-CoV-2 sequences were used. The mRNA vaccine drew from 176 genetic sequences derived from other respiratory viruses and obtained from a large range of countries, including the USA, UK, China and Thailand.

Further, 96 new sequences were revealed in the Moderna mRNA patent with many sequences being artificially engineered which do not have country origins.

These new vaccine technologies render an ABS system which relies on tracking and tracing the original provider of a pathogen/genetic sequence negligible in improving equitable access. Hence, there is some support for decoupling access to data and benefits. Open-data propoents and the pharmaceutical industry have been calling for a system whereby there is, on the one hand, open-access to GSD, and, on the other hand, monetary benefits which are determined at the aggregate (irrespective of GSD contribution by country receiving the benefits), such as through defined sectoral commitments, levies, and percentage of the revenue from retail sales.

Developing countries

WHO South East Asia represented by India, and the Equity Group represented by Bangladesh, have maintained that to operationalize equity, clearly-defined legal obligations with responsibilities vis a vis developing and developed countries (currently missing from the text) need to be made. The Global South sees this as an opportunity to create legally-binding commitments for manufacturers and high-income countries, ensuring access to life-saving medical interventions at affordable prices.

The IFPMA's ask for "free" access to pathogens, based on the EU proposal for PABS has been argued to perpetuate more inequity in access to vaccines and may result in erosion of trust in the PABS system. Additionally, by refusing monetary contributions, the IFPMA's proposal risks exacerbating inequitable access to benefits for low and middle income countries as the operationalization costs of a PABS system are high and cannot be maintained without a sustainable financing mechanism to ensure its upkeep. These costs include transportation/shipping costs for pathogen samples, costs of maintaining a GSD database, costs of deployment of pandemic response products including vaccines in low and middle income countries and the cost of running a WHO-coordinated laboratories network. A self-financing mechanism is integral to the optimum functioning of PABS System.

5. PABS System's interaction with the Nagoya Protocol

Article 12 recognizes the PABS System as a specialized international instrument governing ABS of "biological materials" and "GSD for pathogens with pandemic potential" within the meaning of Article 4 of Nagoya Protocol. This would render the Nagoya Protocol inapplicable to pathogen GSD sharing (Article 12.12). The implication of this provision may be viewed as a relief to the pharmaceutical industry's concern of delays in rapid sharing of pathogen samples arising out of

their experiences with working within national regimes causing delays, previously cited as a reason to oppose PABS.

However, a significant number of countries (137) have ratified the Nagoya Protocol and have enacted compliant national legislations on ABS which they have applied to pathogen sharing. Of these, 77 restrict access to physical pathogen samples and 39 restrict access to GSD. If the PABS is adopted, these countries would need to amend their national statutes and clarify that they exclude pathogen GSD and clinical samples.

It has been widely assumed that recognizing a PABS System as a specialized international instrument (SII) for the purposes of Nagoya Protocol is a decision that the negotiating parties at WHO are competent to make. However, what instrument may be categorized as a SII is currently being discussed by the Convention on Biological Diversity's (CBD) Conference of Parties. To be mutually supportive of objectives of the CBD and Nagoya Protocol, the ability to deliver "fairness and equity in the sharing of benefits" [Annex 4(b)] is a formal criterion. It is not enough to internationally agree that the WHO Pandemic Agreement is a SII without also ensuring that it is consistent with and mutually supportive of the CBD's objectives. Whether or not the PABS system will be fair and equitable in sharing of benefits, to satisfy the condition of CBD COP, arguably needs to be seen through its operationalization and not merely based on the claim that it is so.

Further, academics have been discussing the implications of PABS interacting with a CBD proposed multilateral system to govern access and benefit sharing of digital sequence information (DSI), a placeholder term for GSD. The CBD DSI mechanism does not yet exclude pathogens from its scope and there is high likelihood that if PABS only applies to GSD, other data including proteomics and metabolomics data would fall under the CBD. Since the CBD DSI mechanism is more focused on biodiversity conservation and not health, it's likely not the best model to facilitate rapid and timely sharing of pathogens with pandemic potential. The CBD DSI mechanism could become operational as early as this year. If the PABS System is not adopted under the WHO Pandemic Agreement, the CBD DSI mechanism is the default alternative for bilateral agreements, with the potential of higher transaction costs, legal uncertainty concerning implementation of benefit sharing and consequently, delayed sharing of pathogen data in emergencies. It is also possible then that third parties (vaccine developers, manufacturers) may choose to opt out of multilateral mechanisms like the CBD DSI mechanism and continue to operate bilaterally, dissolving the hope of equitable pandemic related products' ABS for all countries.

Conclusion

The pandemic treaty's aim is to advance equity in pandemic prevention, preparedness and response. The PABS System is considered by many as a central mechanism towards advancing such equity. In practice, however, conflicting interests between the pharmaceutical industry and high-income countries and the global south make this a very contentious provision. Some Civil society organizations fear that "with five minutes to midnight, developing countries will be forced to accept whatever consensus the EU and the US can live with." INB 9 culminated with an agreement to meet again from 29 April to 10 May 2024, and a revised consensus text to be circulated on 18 April 2024.[1] With a few weeks to go before the World Health Assembly Meeting starting 27 May 2024, it will be interesting to follow and to see what compromise has been achieved, if any.

ANNEX

Table of main amendments

Article 12 has undergone some overhaul in revisions from the last proposed draft to the latest negotiating text of the agreement. PABS System in the Revised draft of the negotiating text of the WHO Pandemic Agreement[2] (13 March 2024) and Proposal for the negotiating text of the WHO Pandemic Agreement[3] (30 October 2023) are being briefly compared in the table below.

Issue	**Proposal (30 October 2023)**	**Revised draft (13 March 2024)**
Terminology	PABS materials Standard Material Transfer Agreements (terminology borrowed from the PIP Framework)	PABS biological materials and PABS GSD Standard PABS contracts
Benefit-sharing commitments by manufacturer of relevant	10% donation and 10% at affordable prices	10% free of charge and 10% at not-for-profit prices

[1] https://healthpolicy-watch.news/pandemic-dis-agreement-talks-limp-into-extra-time/

[2] A/INB/9/3
[3] A/INB/7/3

therapeutics, diagnostics and vaccines to WHO		
Benefit-sharing by users of materials for purposes **except** therapeutics, diagnostics and vaccines	**Encouraged** manufacturers from HICs to collaborate with developing countries' manufactures; create tiered-pricing; actively seek participation of scientists from developing countries in research related on PABS	For **commercial use:** Support PABS through **voluntary contributions** including monetary, capacity-building, non-exclusive licensing agreements, tech transfer, scientific collaboration For **non-commercial use:** Acknowledge providers of data in relevant presentations/publications, public dissemination of research results, and basis capacity- scientific and training collaborations, training and capacity-building
Deadline for operationalization	31 May 2025	No concrete deadline proposed.
Review period	5 years	No defined time period, but obligation to "regularly review the operation, monitor adherence and effectiveness" of PABS System.
Monetary contributions by recipients of PABS	Annual, based on their "nature and capacity", to the sustainable funding mechanism established under Article 20.	Annual, to support the PABS System and "relevant capacities in countries"