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The negotiations on the Pathogen Access and Benefit Sharing System under the WHO Pandemic Agreement: State of Play as of September 2025

### By Viviana Munoz Tellez, German Velasquez

The World Health Organization (WHO) Member States adopted a Pandemic Agreement in May 2025 but deferred negotiations on the critical Pathogen Access and Benefit Sharing System (PABS). Despite the tight timeline, the Intergovernmental Working Group (IGWG) has made minimal progress as of September 2025, with no draft text produced and formal negotiations yet to begin. The PABS system is essential for pandemic equity, balancing rapid pathogen sharing with equitable access to vaccines and treatments. But with the current approach to the IGWG process, without formal negotiations underway, Member States risk failing to finalize the PABS Annex by the March 2026 deadline.

Les États membres de l'Organisation mondiale de la santé (OMS) ont adopté un accord sur les pandémies en mai 2025, mais ont reporté les négociations sur le système crucial d'accès aux agents pathogènes et de partage des avantages (PABS). Malgré le calendrier serré, le groupe de travail intergouvernemental (IGWG) n'a réalisé que des progrès minimes en septembre 2025, aucun projet de texte n'ayant été produit et les négociations officielles n'ayant pas encore commencé. Le système PABS est essentiel pour garantir l'équité en matière de pandémie, en équilibrant le partage rapide des agents pathogènes et l'accès équitable aux vaccins et aux traitements. Mais avec l'approche actuelle du processus IGWG, sans négociations officielles en cours, les États membres risquent de ne pas parvenir à finaliser l'annexe PABS avant la date limite de mars 2026.

Los Estados miembros de la Organización Mundial de la Salud (OMS) adoptaron un Acuerdo sobre Pandemias en mayo de 2025, pero aplazaron las negociaciones sobre el crucial Sistema de Acceso a los Agentes Patógenos y Reparto de Beneficios (PABS). A pesar de la apretada agenda, el Grupo de Trabajo Intergubernamental (IGWG) ha logrado avances mínimos hasta septiembre de 2025, sin que se haya elaborado ningún borrador y sin que hayan comenzado aún las negociaciones formales. El sistema PABS es esencial para la equidad en materia de pandemias, ya que equilibra el intercambio rápido de patógenos con el acceso equitativo a las vacunas y los tratamientos. Sin embargo, con el enfoque actual del proceso del IGWG, sin negociaciones formales en curso, los Estados miembros corren el riesgo de no finalizar el anexo del PABS antes de la fecha límite de marzo de 2026.



#### **Background and Timeline**

The World Health Organization (WHO) Member States agreed in May 2025 to adopt a new Pandemic Agreement during the 78th World Health Assembly (WHA) that left unsettled one of the most important negotiation issues: the specifics for the Pathogen Access and Benefit Sharing System (PABS), as established in the Article 12 of the Pandemic Agreement. It was agreed that it would be negotiated separately and then become part of the Agreement as an Annex. Importantly, the entry into force of the Pandemic Agreement is subject to the adoption of the Annex by the WHA.

The Intergovernmental Working Group (IGWG) established by WHA Resolution A78/10 Add.1 must draft, negotiate, and finalize the Annex. The timeline is tight: adoption of the Annex is set for May 2026 at the 79<sup>th</sup> WHA. This means the negotiation should close in March 2026.

#### **PABS Is Key for Equity**

A multilateral PABS system is a <u>core component</u> of the Pandemic Agreement and central for it to deliver on equity. It provides the only concrete mechanism within the Agreement to ensure tangible access to vaccines, therapeutics, and diagnostics in a public health emergency of international concern, including a pandemic emergency, as agreed in Article 12.6 of the Pandemic Agreement. The PABS system must strike a balance between two commitments on equal footing: fair and equitable benefit-sharing from PABS Materials and Sequence Information, and rapid access to these materials. Developing countries prioritize the first, while developed countries the latter. But the implementation of this "tit for tat" agreement as a single system has its complexities.

The existing successful WHO Pandemic Influenza Preparedness (PIP) Framework could serve as a model for the PABS system to follow - it covers both the exchange of influenza viruses with human pandemic potential and facilitated access to vaccines during a pandemic as well as the sharing of other benefits. The transnational pharmaceutical industry opposes this approach, arguing that the PIP Framework should not be considered an access and benefit sharing (ABS) model for the PABS and lobbying their host Member States to adopt this position.

#### **IGWG Structure and Meetings**

The IGWG held its first meeting on 9–10 July 2025, focused on organizational matters, such as working methods and stakeholder participation. An informal briefing of the IGWG with participation of experts was held on 12 September. The second IGWG meeting (IGWG2) took place on 15–19 September 2025.

The IGWG is composed of WHO Member States who have elected a Bureau to assist the process, with Co-Chairs Ambassador Tovar da Silva Nunes of Brazil and Mr. Matthew Harpur of the United Kingdom of Great Britain and Northern Ireland, and Vice-Chairs Ambassador Vuyile Dlamini of the Kingdom of Eswatini, Dr. Hanan Mohamed Al Kuwari of the State of Qatar, Dr. Viroj Tangcharoensathien of the Kingdom of Thailand and Ms. Madeleine Heyward of Australia. The meetings are being held in hybrid format, in the WHO headquarters in Geneva and online. Relevant stakeholders that are accepted as observers can participate in open segments of the meetings, at the opening of every day and closing session, though the Member States' negotiations are closed.

### **Member State Proposals and Stress-Test Exercise**

To date there are <u>17 proposals</u> that have been submitted by Member States, either individually or as groups, to the IGWG. The most substantial proposals are from developing countries. The South Centre made a <u>preliminary analysis</u> of these.

The IGWG has not agreed yet to begin negotiations based on text proposals, rather conducting a "stresstest" exercise on issues. The Bureau has no mandate to date to suggest any text. The IGWG agreed for the Bureau to develop an outline of elements to be addressed in the PABS system based on Article 12. The draft elements document was a basis for discussions in the IGWG2. It was reported that the IGWG2 discussed and provided comments on the draft outline of elements to be addressed by the PABS System, including on operation, access, benefit-sharing and governance and, in addition, there was discussion on scope and use of terms. The meeting overall made little progress, though it served to mark issues on which Member States converge or diverge.

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Relevant stakeholders expressed frustration throughout the week over the lack of transparency—substantive discussions were closed to Member States only, keeping them out of public view. While stakeholders were invited to speak in brief daily open sessions, they could not contribute meaningfully without knowing what Member States were discussing behind closed doors. The South Centre statement to the IGWG2 echoed this sentiment.

At the closing of IGWG2, the Group of Equity, composed of 36 developing countries, delivered a statement that called on the Bureau to prepare a draft text of the Annex, based on Member States' submissions, to begin text-based negotiations in November. The group also proposed enhancing the participation of relevant stakeholders in the IGWG.

The South Centre called on the IGWG to accelerate the PABS system negotiation, and offered the following recommendations: 1. Negotiate simultaneously all components of the system to ensure coherence; 2. Align to the international health regulations (IHR) the trigger for the obligation of Parties to share PABS materials and sequence information for purposes of the PABS system, while these may voluntarily decide to further facilitate access; 3. Reach early agreement in the negotiations on operationalizing the benefit sharing during a public health emergency of international concern (PHEIC) including a pandemic emergency; 4. Involve all kinds of users of PABS materials in sharing benefits from research and development, appropriate to their roles; 5. Other key negotiation priorities should be sustained financing for the PABS system and clear WHO management structures.

# Importantly, the upcoming Bureau draft text for the IGWG3 must establish safeguards and guardrails for what has already been agreed under Article 12.

The IGWG2 agreed to allow relevant stakeholders to observe the discussions of the IGWG3 in their entirety – a win for transparency. The IGWG2 also agreed that informal meetings with inputs from selected experts will be held from 6-10 October 2025. Following these meeting, the IGWG Bureau, with support from the WHO Secretariat, will prepare a draft PABS Annex text for the IGWG at its third meeting in November 2025.

It is uncertain, however, whether Member States will reach agreement at the November IGWG3 session to begin text-based negotiations.

## State of Play of the PABS: No Negotiations and a Ticking Clock

The IGWG2 resolved an important issue on inclusivity and transparency in the process, by allowing more meaningful participation of relevant stakeholders in the IGWG3. However, it has made little progress on shaping the PABS system with the elements of Article 12 of the Pandemic Agreement.

As of September 2025, no draft text has emerged from the IGWG on the PABS system, and formal negotiations have not started. With only six months until the scheduled conclusion date, accelerating progress is critical.

Member States, as noted, have submitted proposals showing different implementation options for key issues including definitions, the scope of covered PABS materials, benefit-sharing mechanisms, legally binding contractual obligations, accountability and oversight structures, financing, and the relationship with existing international legal frameworks. Discussions should focus on the practicability of these options and their alignment with Article 12, which already provides a significant framework for shaping the PABS system. The provisions in Article 12 are not open for re-negotiation.

The WHO Secretariat has suggested guiding questions for the informal meetings of 6-10 October that are overly broad and miss the opportunity to test the concrete implementation options already presented for operationalizing the Article 12 framework. As a result, the current approach lacks sufficient focus to advance the IGWG mandate in the short time available to conclude the negotiations.

Authors: Viviana Munoz Tellez is the Coordinator of the Health, Intellectual Property and Biodiversity Programme (HIPB) at the South Centre. German Velasquez is the Special Adviser on Health and Policy of the South Centre.

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For more information, please contact Anna Bernardo of the South Centre: Email <u>abernardo@southcentre.int</u>, or telephone +41 22 791 8050.