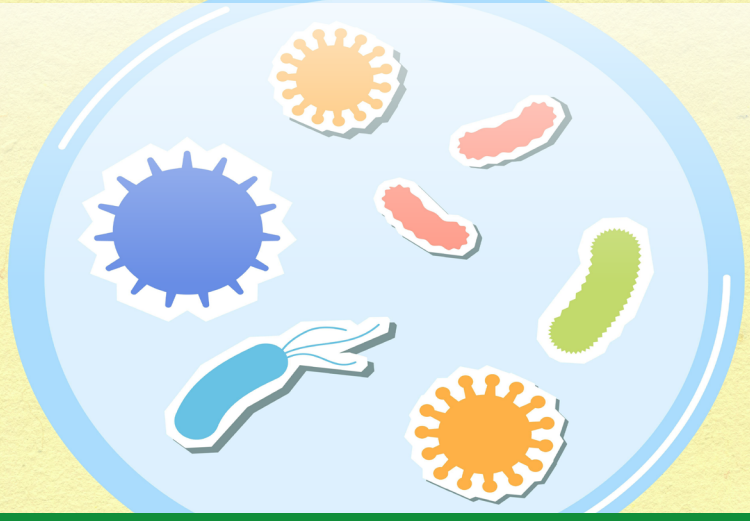

POLICY BRIEF

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Towards an Operative Pathogen ABS System: Implementing the Equal Footing Requirement of Article 12 of the WHO Pandemic Agreement

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ABSTRACT

Multilateral negotiations on the Pathogen Access and Benefit-Sharing (PABS) system remain deadlocked. As required by Article 12 of the World Health Organization (WHO) Pandemic Agreement, the annex operationalizing the PABS system must place on *equal footing* the rapid and timely sharing of PABS Materials and Sequence Information with the rapid, timely, fair and equitable sharing of benefits that arise from their sharing and utilization. The Annex cannot impose binding sharing obligations on State Parties while making it optional for users of PABS Materials to opt in to the PABS system voluntarily, without legally binding obligations on benefit sharing arising from the utilization of PABS Materials and Sequence Information. The Annex also cannot create a hybrid system providing alternative routes for access, either "open" or "restricted". This would be inconsistent with Article 12 of the Pandemic Agreement and with the obligations of parties under the Convention on Biological Diversity and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization. The Annex must include a standardized contractual framework binding all actors in the PABS chain, a minimum manufacturer participation threshold before country obligations become active, and ensure benefit-sharing is not confined to pandemic emergencies.

KEYWORDS: *Pathogen Access and Benefit-Sharing (PABS) System, World Health Organization (WHO), Pandemic Agreement, Intergovernmental Working Group on the WHO Pandemic Agreement (IGWG), Convention on Biological Diversity, Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, African Group, Group for Equity, Intellectual Property, Sovereign Rights*

Les négociations multilatérales sur le système d'accès aux agents pathogènes et de partage des avantages (PABS) restent dans l'impasse. Conformément à l'article 12 de l'Accord sur les pandémies de l'Organisation mondiale de la santé (OMS), l'annexe mettant en œuvre le système PABS doit placer sur un pied d'égalité *le partage rapide et en temps opportun des « matériaux PABS » et des « données de séquençage » avec le partage rapide, en temps opportun, juste et équitable des avantages découlant de leur partage et de leur utilisation. L'annexe ne peut imposer des obligations contraignantes en matière de partage aux États parties tout en laissant aux utilisateurs de matériel PABS la possibilité d'adhérer volontairement au système PABS, sans obligations juridiquement contraignantes concernant le partage des avantages découlant de l'utilisation du matériel PABS et des informations sur les séquences. L'annexe ne peut pas non plus créer un système hybride offrant des voies d'accès alternatives, qu'elles soient « ouvertes » ou « restreintes*

KEY MESSAGES

- "The Annex cannot impose binding sharing obligations on State Parties while making it optional for users of PABS Materials to opt in to the PABS system voluntarily, without legally binding obligations on benefit sharing arising from the utilization of PABS Materials and Sequence Information."
- "The central failure of the Bureau draft text of 9 March is its non-implementation of the equal footing requirement of Article 12.1. The access pillar imposes binding obligations on State Parties, while the benefit-sharing pillar includes no obligations on Parties at all."
- "Standardized contracts are essential for operationalizing access and benefit-sharing, ensuring states' sovereign rights are respected through mutually agreed terms governing access, use, benefit-sharing, and third-party transfers."
- "The 'Open Route' ... is not a modality for sharing with benefit-sharing protections — it is unconditional access without any enforceable benefit-sharing obligation. This directly contradicts the equal footing mandate of Article 12.1."
- "The absence of user registration means there is no mechanism to identify who accessed materials, or sequence information, for what purpose, or whether a benefit-sharing obligation has been triggered. ... There is no track-and-trace architecture: materials and data that enter the open route cannot be followed through successive research and commercial pipelines, making compliance monitoring impossible."

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». Cela serait incompatible avec l'article 12 de l'Accord sur les pandémies et avec les obligations des parties au titre de la Convention sur la diversité biologique et de son Protocole de Nagoya sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation. L'annexe doit inclure un cadre contractuel normalisé liant tous les acteurs de la chaîne PABS, un seuil minimal de participation des fabricants avant que les obligations des pays deviennent effectives, et garantir que le partage des avantages ne se limite pas aux situations d'urgence pandémique.

MOTS-CLÉS: *Système d'accès aux agents pathogènes et de partage des avantages (PABS), Organisation mondiale de la santé (OMS), Accord sur les pandémies, Groupe de travail intergouvernemental sur l'Accord de l'OMS sur les pandémies (IGWG), Convention sur la diversité biologique, Protocole de Nagoya sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation, Groupe africain, Groupe pour l'équité, Propriété intellectuelle, Droits souverains*

Las negociaciones multilaterales sobre el sistema de acceso a los patógenos y participación en los beneficios (PABS) aún no han logrado un acuerdo. Tal y como exige el artículo 12 del Acuerdo sobre Pandemias de la Organización Mundial de la Salud (OMS), el anexo que regulará el funcionamiento del sistema PABS debe garantizar un tratamiento equitativo *al intercambio rápido y oportuno de materiales PABS e información sobre secuencias y a la distribución rápida, oportuna, justa y equitativa de los beneficios derivados de su intercambio y utilización. El anexo no puede imponer obligaciones vinculantes de distribución a los Estados Partes, al tiempo que deja a discreción de los usuarios de los materiales del PABS la posibilidad de adherirse voluntariamente al sistema PABS, sin obligaciones jurídicamente vinculantes en materia de distribución de beneficios derivados de la utilización de los materiales del PABS y la información sobre secuencias. El anexo tampoco puede crear un sistema híbrido que ofrezca vías alternativas de acceso «abierto» o «restringido». Esto sería incompatible con el artículo 12 del Acuerdo sobre Pandemias y con las obligaciones de las partes en virtud del Convenio sobre la Diversidad Biológica y su Protocolo de Nagoya sobre el acceso a los recursos genéticos y la participación justa y equitativa en los beneficios derivados de su utilización. El anexo debe incluir un marco contractual normalizado que vincule a todos los actores de la cadena del PABS, un umbral mínimo de participación de los fabricantes antes de que las obligaciones de los países entren en vigor, y garantizar que los beneficios no se limiten a las emergencias pandémicas.*

PALABRAS CLAVES: *Sistema de acceso a los patógenos y distribución de beneficios (PABS), Organización Mundial de la Salud (OMS), Acuerdo sobre Pandemias, Grupo de Trabajo Intergubernamental sobre el Acuerdo de la OMS sobre Pandemias (IGWG), Convenio sobre la Diversidad Biológica, Protocolo de Nagoya sobre el acceso a los recursos genéticos y la distribución justa y equitativa de los beneficios derivados de su utilización, Grupo Africano, Grupo para la Equidad, Propiedad intelectual, Derechos soberanos*

关于病原体获取与惠益分享 (PABS) 系统的多边谈判仍陷于僵局。根据世界卫生组织 (WHO)《大流行病协定》第12条的要求，落实PABS系统的附件必须将快速、及时分享PABS材料和序列信息，与快速、及时、公平和公正地分享因分享和利用这些材料及序列信息而产生的惠益，置于同等重要的地位。该附件不能一方面对缔约国施加具有约束力的惠益分享义务，另一方面却允许PABS材料的使用者仅以自愿方式加入PABS体系，且不对其利用PABS材料及序列信息所产生的惠益分享承担法律约束力。该附件亦不能建立一种混合体系，为获取提供"开放"或"限制"等替代途径。这将与《大流行病协定》第12条以及各缔约方根据《生物多样性公约》及其《关于获取遗传资源及其利用所产生惠益的公平和公正分享的名古屋议定书》所承担的义务相抵触。该附件必须包含一个约束PABS链中所有参与方的标准化合同框架，设定国家义务生效前的最低制造商参与门槛，并确保惠益分享不限于大流行病紧急情况。

关键词: 病原体获取与惠益分享 (PABS) 系统、世界卫生组织 (WHO) 、大流行病协定、《世卫组织大流行协定》政府间工作组 (IGWG) 、《生物多样性公约》、《关于获取遗传资源及其利用所产生惠益的公平和公正分享的名古屋议定书》、非洲集团、公平、知识产权与主权权利小组

I. Introduction

Article 12 of the WHO Pandemic Agreement[1] establishes the Pathogen Access and Benefit-Sharing (PABS) system as a multilateral framework to promote the rapid and timely sharing of pathogens with pandemic potential and their genetic sequence information, while ensuring the equitable and fair distribution of benefits arising from their use, including from the production of vaccines, therapeutics, and diagnostics (VTDs). Adopted at the 78th World Health Assembly on 20 May 2025, the Pandemic Agreement mandates that the PABS system be operationalized through a dedicated Annex. The multilateral PABS system must be grounded in States' sovereign rights over biological resources and must respond directly to the profound inequities exposed during the COVID-19 pandemic. While building on the WHO Pandemic Influenza Preparedness (PIP) Framework,[2] it must significantly expand in scope to cover a broader range of pandemic threats.

The Open-Ended Intergovernmental Working Group (IGWG), composed of WHO Member States, has been negotiating the PABS Annex since mid-2025. The sixth session of the IGWG (IGWG6) was held from 23 to 28 March 2026. Negotiations at IGWG6 were based on the IGWG5 on-screen text as of the last day of IGWG5, while the Bureau text of 9 March 2026 served as additional input rather than the basis for further negotiation. This was agreed at the request of many delegations that considered the IGWG5 text to better reflect the proposals that delegations have made to date. Negotiations continued in closed session with limited participation

1 World Health Organization (WHO), WHO Pandemic Agreement, document WHA78.1. Available from https://apps.who.int/gb/ebwha/pdf_files/WHA78/A78_R1-en.pdf.
2 World Health Organization, Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits, 2nd edition (2021). Available from https://www.who.int/initiatives/pandemic-influenza-preparedness-framework.

of relevant stakeholders.

IGWG6 concluded with agreement to hold a resumed session from 27 April to 1 May 2026, with informal negotiations from 21 to 23 April. Negotiations in the resumed IGWG6 will continue based on the IGWG6 on-screen text as of 25 March 2026. The analysis in this Brief remains relevant to that text, as there have been no significant advances in reaching agreement on provisions for the PABS Annex beyond restating elements in Article 12 of the Pandemic Agreement. Many developing countries continue to express concern that the current draft text largely omits or dilutes their core proposals. These countries, led by the African Group and the Group for Equity, represent over 80 countries and approximately 75% of the global population. The current draft text does not meet the standard set by the WHO Pandemic Influenza Preparedness (PIP) Framework, which established binding Standard Material Transfer Agreements for participating manufacturers and laboratories. Rather than building on and strengthening the PIP Framework model, the current text retreats from it by avoiding mandatory contractual arrangements and leaving benefit-sharing largely voluntary.[3] This Brief examines the joint proposals of the African Group and the Group for Equity (Section II), analyses the key shortcomings of the IGWG Bureau's draft Annex against Article 12 requirements (Section III), critically examines the informal hybrid model proposal (Section IV), sets out the minimum elements the Annex must include (Section V), and advances recommendations (Section VI).

II. Joint Proposals by the African Group and the Group for Equity

In December 2025, the African Group and the Group for Equity submitted three joint proposals for the PABS Annex[4] (hereinafter 'the joint proposals'). Their defining feature is the operationalization of the PABS system through legally binding standardized contracts, rather than voluntary guidelines or political commitments. Under these proposals, access to pathogen materials and sequence information is conditional on the prior acceptance of enforceable obligations, structured through three interlinked instruments: Standard Material Transfer Agreement (SMTA) 1, governing transfers within the WHO Coordinated Laboratory Network (WCLN); SMTA 2, governing transfers from WCLN laboratories to entities outside the WCLN, particularly commercial actors; and a Data Access Agreement regulating access to and use of PABS sequence information through WHO-managed or WHO-recognized databases.

The proposed contracts draw on precedents from the PIP Framework and extend the standardized agreement model to pathogen sequence information — a critical gap not addressed by the PIP Framework. Standardized contracts are essential for operationalizing access and benefit-sharing, ensuring states' sovereign rights are respected through mutually agreed terms governing access, use, benefit-sharing, and third-party transfers. They provide the legal certainty and enforceability mandated by Article 12. Pathogen sequence information is already commonly governed by contractually enforceable access agreements that condition access on legally binding terms governing permitted use, benefit-sharing obligations, and traceability requirements, such as the GISAID Database Access Agreement,[5] agreements used by the Global Biodiversity Information Facility,[6] and the European Genome-phenome Archive,[7] demonstrating that standardized contractual controls over sequence data are both feasible and well established. In this context, "contractually enforceable" means that access is conditioned on users accepting legally binding terms governing permitted use, benefit-sharing obligations, and traceability requirements — including the retention of unique persistent identifiers throughout downstream research and commercial pipelines — rather than merely notifying users of conditions after the fact.

II.1 Legally Binding Rules on Access

The joint proposals tightly regulate access through use restrictions, traceability requirements, and consent conditions. PABS materials and sequence information may be used only for pandemic prevention, preparedness, and response; any use outside this scope requires prior informed consent from the originating country or laboratory. Unique persistent identifiers must be attached to all materials and retained throughout downstream research, regulatory submissions, and product development. Materials and data may be transferred only to entities that have concluded the relevant PABS agreement (a "no contract, no transfer" rule). The Data Access Agreement further requires that sequence information be shared only with users registered with a WHO PABS sequence database who have accepted its terms.

3 See South Centre, Analysis of the European Union Proposal on the Pandemic Agreement Annex dated 17 October 2025. Available from https://www.southcentre.int/wp-content/uploads/2025/11/SC-comments-on-EU-Proposal-on-PABS-of-17-October-2025.pdf.
4 The Group for Equity and the African Group made three joint proposals: proposal on Data Access Agreement (2 December 2025); proposal on PABS material and sequence information agreement 1; and proposal on PABS material and sequence information agreement 2. Available from https://apps.who.int/gb/igwg/e/e_igwg2-initial-text-proposals.html.
5 GISAID, GISAID EpiFlu™ Database Access Agreement. Available from https://gisaid.org/terms-of-use/.
6 GBIF, Data User Agreement. Available from https://www.gbif.org/terms/data-user.
7 European Genome-Phenome Archive. Available from https://ega-archive.org/access/data-access-committee/policy-documentation/.

II.2 Prohibition of Intellectual Property Claims

Across all the three proposals, there is a blanket prohibition on intellectual property claims over PABS materials, sequence information, and any derivatives or innovations developed from them. This provision aims to prevent the legal monopolies and downstream access barriers that contributed to vaccine inequity during COVID-19. An intermediate position consistent with Article 12 is to require the grant of non-exclusive, royalty-free, worldwide sublicensable licenses to WHO for onward sublicensing to manufacturers in developing countries.[8] This remains a contested element in the negotiations.

II.3 Binding Benefit-Sharing Obligations

The joint proposals treat benefit-sharing as a contractual obligation triggered by use, not a general aspiration. Commercial users generating revenue from PABS materials or sequence information are required to make annual monetary contributions of up to 1.5% of gross revenue per product or service, flowing into a dedicated PABS fund. Participating manufacturers must enter legally binding contracts with WHO guaranteeing reservation of at least 20% of real-time production during a pandemic, with a minimum of 10% as donations and the remainder at affordable prices. Separate obligations apply during a Public Health Emergency of International Concern (PHEIC), with a 20% production reservation and supply at not-for-profit prices.[9] Manufacturers must also grant WHO non-exclusive, royalty-free licenses with sublicensing rights for developing country manufacturers, covering patents, regulatory dossiers, know-how, cell lines, assays, and enabling technologies. Explicit enforcement mechanisms include suspension or revocation of access, loss of WHO designation, and dispute resolution and arbitration.

III. The Failed Bureau Draft Text Proposal

The Bureau draft text of 9 March 2026 revealed significant structural and legal gaps. The text removed most square brackets from the February IGWG5 on-screen text giving the appearance of convergence. However, this bracket reduction reflects a consolidation of the text rather than substantive agreement. The most contested provisions, i.e. monetary contribution rates, PHEIC obligations, and the scope of benefit-sharing options, were replaced with formulations of general character. During IGWG-5, several developing countries had raised concerns that the Bureau-led drafting methodology reduces transparency and narrows the negotiating space, as key elements of their proposals are no longer visible in the text.[10] During IGWG6, this concern was reiterated, and a formal motion was made by developing countries to list in the adoption of the IGWG6 agenda the IGWG5 last on-screen text as a basis for the negotiation, with the Bureau text as an input.

The central failure of the Bureau draft text of 9 March is its non-implementation of the *equal footing* requirement of Article 12.1. The access pillar imposes binding obligations on State Parties, while the benefit-sharing pillar includes no obligations on Parties at all. Parties bear no obligation to require commercial users within their jurisdictions to enter WHO PABS contracts, or to enforce such contracts once signed.[11] State Parties face unqualified pathogen sharing obligations regardless of their technical capacities or infrastructure — yet Article 12.6 explicitly provides that benefit-sharing obligations for manufacturers are differentiated by their nature and capacity. No equivalent qualification applies to States. Without Party-level obligations on benefit-sharing, the equal footing mandate of Article 12.1 cannot be implemented.

Article 12.2 requires all elements of the PABS System to come into operation simultaneously. The Bureau draft text is silent on this, having deleted the bracketed minimum manufacturer participation threshold that appeared in the IGWG4 text. Without such a threshold, State sharing obligations activate upon Annex entry into force regardless of whether any manufacturer has joined, effectively reversing the logic that simultaneity was designed to guarantee. The Bureau text also provides no standardized contractual instruments governing onward transfers and use: pathogen materials and sequence information could move through successive research and commercial pipelines without enforceable benefit-sharing obligations or effective traceability. Relying on existing sequence databases as "WHO-recognized databases" without prior verification of their governance frameworks may allow users to access sequence information without accepting benefit-sharing obligations.

On traceability, the Bureau text tracks material provenance from source to WCLN to database but does not provide for user traceability. There is no mechanism to identify who accessed PABS sequence information, for what purpose, or whether that use triggered a benefit-sharing obligation — a direct failure to implement Article 12.3 for the benefit-sharing pillar. No user registration is required, making the change-of-intent mechanism self-reporting and unenforceable, and the access-denial sanction structurally

8 WHO Pandemic Agreement, Article 12.8(d) and (e).
9 See Nirmalya Syam and Viviana Munoz Tellez, "The US Bilateral Specimen Sharing Agreement in the Proposed PEPFAR MOUs Would Leave African Countries More Vulnerable in the Next Pandemic", Policy Brief, No. 150 (Geneva, South Centre, 2025). Available from https://www.southcentre.int/wp-content/uploads/2025/12/PB150_The-US-Bilateral-Specimen-Sharing-Agreement-in-the-Proposed-PEPFAR-MOUs-Would-Leave-African-Countries-More-Vulnerable-in-the-Next-Pandemic_EN.pdf.
10 See South Centre and Group for Equity Statements to IGWG5, *South News* 551, 9 February 2026. Available from https://us5.campaign-archive.com/?u=fa9cf-38799136b5660f367ba6&id=233b81d27a.
11 The proposed SMTA 1 by the African Group and the Group for Equity governs the rights and obligations of provider and recipient laboratories sharing PABS material and sequence information as part of a WHO Coordinated Laboratory Network (WCLN). The draft SMTA 2 lays down the terms of access and benefit-sharing for recipients that are participating manufacturers including developers that receive PABS material and sequence information from a WCLN laboratory.

impossible for anonymous users. Cybersecurity and biosecurity risks compound this gap.[12] Concerning benefit-sharing during PHEICs, the current draft contains no PHEIC-specific obligation, no standard for affordable pricing, and no WHO-request mechanism to activate PABS benefit-sharing during early containment — the period when equitable access to countermeasures matters most. Non-exclusive licensing and technology transfer appear only as selectable options that a participating manufacturer need not choose, falling far short of the mandatory obligations proposed by the African Group and the Group for Equity.[13]

IV. The Proposed Hybrid PABS Model: An Informal Proposal That Should Not Be Incorporated

In the margins of IGWG6, a so-called hybrid PABS model has been aired informally as a potential compromise approach to the access architecture. It has not been formally tabled or reflected in the negotiating text. This section examines its structure and explains why it is inconsistent with Article 12 of the Pandemic Agreement, the Nagoya Protocol and the proposals advanced by developing countries.

IV.1 Structure of the Hybrid Model

The hybrid model would divide the PABS system into two parallel access tracks. Under the "open" route, laboratories — designated as Provider A — could share PABS materials and sequence information through open-access databases with no requirement to sign any PABS contract or accept any terms and conditions prior to access. Databases operating under this route would require no user registration, and access would be available without institutional identification. Under the "restricted" route, laboratories — designated as Provider B — would share only with users who have signed contracts or agreed to terms and conditions, with databases requiring registration and Data Access Agreements (DAAs) as preconditions of access.

The model is presented as a pragmatic accommodation of providers with different preferences — preserving the option of open sharing for those who choose it while maintaining a rights-based track for those who insist on contractual protections. Its political logic is to attract buy-in from countries and institutions that resist mandatory contractual requirements. However, as explained below, this apparent flexibility masks structural deficiencies that are fatal to the equal footing requirement of Article 12.1.

IV.2 Why the Open Route Fails the Equal Footing Requirement

The "open" route contains three structural shortcomings that make it incompatible with Article 12.1. First, it requires no contract or terms and conditions governing access and benefit-sharing. A commercial actor that accesses pathogen sequence data through the Open Route would face no enforceable benefit-sharing obligation under the PABS system, regardless of the commercial value generated from that access. Second, the absence of user registration means there is no mechanism to identify who accessed materials, or sequence information, for what purpose, or whether a benefit-sharing obligation has been triggered. The change-of-intent mechanism — designed to capture users who transition from non-commercial to commercial activity — is structurally inoperable without user identity. Third, there is no track-and-trace architecture: materials and data that enter the open route cannot be followed through successive research and commercial pipelines, making compliance monitoring impossible.

Taken together, the "open" route is not a modality for sharing with benefit-sharing protections — it is unconditional access without any enforceable benefit-sharing obligation. This directly contradicts the equal footing mandate of Article 12.1, which requires access obligations and benefit-sharing obligations to rest on the same legal footing. An Annex that encodes both a binding-contract track and an obligation-free track does not implement Article 12.1: it creates a two-speed system in which the obligation-free track determines the practical norm.

IV.3 The Internal Fragmentation Problem

The two-track architecture would create a predictable internal dynamic that will undermine the "restricted" route in practice. Where a novel pathogen with pandemic potential emerges and multiple variants are isolated by laboratories in different provider countries, some providers may allow their variants to be uploaded to open-route databases while others may insist on the "restricted" route. The result would be a fragmented genomic landscape in which some variants are accessible without obligation, others only under contractual terms. Research institutions and commercial manufacturers face an immediate incentive to preferentially use open-route variants, avoiding the contractual obligations that a restricted-route access entails. Over time, provider countries that insist on contracts will find their materials underused and their benefit entitlements unenforceable, while the scientific and commercial community works from a dataset that systematically underrepresents restricted-route samples. The hybrid model thus would lead to the practical dominance of the obligation-free route.

12 Boris A. Vinatzer, *et al.*, "Cyberbiosecurity Challenges of Pathogen Genome Databases", *Frontiers in Bioengineering and Biotechnology*, vol. 7 (2019). Available from https://doi.org/10.3389/fbioe.2019.00106.

13 The Bureau text does not propose any obligations on promoting access to or transfer of technology by researchers, academia or other users of PABS material not falling within the "Participating Manufacturing" definition.

IV.4 Inconsistency with the CBD, the Nagoya Protocol, and Sovereign Rights

It is important to distinguish between the hybrid model's "open" route and the legitimate exercise by States of their sovereign rights to choose to share biological resources openly on a bilateral basis. The Convention on Biological Diversity (CBD) recognizes in Article 3 the sovereign rights of States over their natural resources. Article 15.1 confirms that the authority to determine access rests with national governments. Article 15.2 provides that each Party shall endeavour to facilitate access to genetic resources for environmentally sound uses, subject to the sovereign discretion of the provider State. Article 19.1 and 19.2 further require Parties to take measures to ensure the effective participation of countries providing genetic resources in biotechnological research, and the fair and equitable sharing of the results and benefits arising therefrom. Parties may thus choose, pursuant to their sovereign rights and in conformity with their national access and benefit-sharing (ABS) legislation, to share materials openly or through bilateral arrangements, without such decisions being dictated by the PABS system itself.

The "open" route in the hybrid model is a fundamentally different matter. It would structure the PABS system itself — a multilateral framework — to encode an obligation-free access channel, effectively stripping provider countries of the protections that their national ABS frameworks and the Nagoya Protocol afford them, without their individual consent and without corresponding benefit--sharing. This is inconsistent with the CBD and Nagoya Protocol's requirements for mutually agreed terms (MAT) and prior informed consent (PIC) as preconditions of access to genetic resources. While the application of MAT and PIC to digital sequence information remains under discussion under the CBD and Nagoya Protocol, the PABS system should at minimum not structurally facilitate the circumvention of these requirements for the underlying physical materials and the sequence information generated from them. A PABS system that institutionalizes the circumvention of MAT and PIC for any category of users does not complement the CBD/Nagoya framework, it undermines it.

IV.5 The Hybrid Model Does Not Resolve Non-Party Access

A hybrid model would not resolve the problem of regulating access by entities from countries that would choose not to become Parties to the Pandemic Agreement.

Bilateral Memoranda of Understanding (MOUs), such as those proposed in the context of US-linked specimen sharing agreements, [14] can provide an avenue for non-parties to the Pandemic Agreement like the US access to pathogen materials outside the PABS framework entirely, creating parallel access channels untethered from the benefit-sharing architecture. Under the Open Route of the hybrid model, this problem becomes compounded. If sequence information is accessible through open-access databases with no registration requirement and no terms and conditions, then institutions and manufacturers from non-party countries can access it freely, develop commercial products from it, and face no consequences under the PABS system. The Restricted Route, by contrast, offers at least a partial remedy: entities from non-party countries seeking access to restricted-route databases would need to register, accept terms and conditions, and thereby bind themselves contractually to benefit-sharing obligations — even if their home State has not ratified the CBD/Nagoya Protocol or the Pandemic Agreement. By preserving the Open Route alongside the Restricted Route, the hybrid model ensures that non-party commercial actors are not required to use the restricted route and face no obligation to do so. Only a universal, single-track contractual architecture can address the non-party access problem effectively.

V. Minimum Elements in the Annex

The PABS Annex must implement in full the binding requirements of Article 12 of the WHO Pandemic Agreement. As required by Article 12.1, the Annex must place on equal footing the rapid and timely sharing of PABS Materials and Sequence Information with the rapid, timely, fair and equitable sharing of benefits arising from their use. This means that access and benefit-sharing must be governed by the same legal framework: a standardized contractual architecture binding on all actors in the PABS chain, including Parties, laboratories, databases, and all categories of users and third parties that receive the materials or information. An Annex that imposes binding sharing obligations on States while leaving benefit-sharing by commercial users entirely voluntary does not satisfy this requirement and would be inconsistent with Article 12 and with the obligations of parties under the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization.

The Annex must include a minimum manufacturer participation threshold before State sharing obligations become active, giving operational meaning to the simultaneity requirement of Article 12.2. It must provide for user traceability, including user registration, to underpin compliance with benefit-sharing obligations. It must contain operative provisions on benefit-sharing during PHEICs, with mandatory non-exclusive licensing and technology transfer obligations for participating manufacturers. And it must qualify State Party access obligations by capacity, with a corresponding obligation on WHO to provide technical and financial assistance

14 See Nirmalya Syam and Viviana Munoz Tellez, "The US Bilateral Specimen Sharing Agreement in the Proposed PEPFAR MOUs Would Leave African Countries More Vulnerable in the Next Pandemic", Policy Brief, No. 150 (Geneva, South Centre, 2025). Available from https://www.southcentre.int/wp-content/uploads/2025/12/PB150_The-US-Bilateral-Specimen-Sharing-Agreement-in-the-Proposed-PEPFAR-MOUs-Would-Leave-African-Countries-More-Vulnerable-in-the-Next-Pandemic_EN.pdf.

upon request. These elements must be resolved in the text of the Annex itself; they cannot be deferred to later implementation by WHO or COP decisions after adoption.

VI. Recommendations

The resumed IGWG6 session from 27 April to 1 May 2026, working on the basis of the IGWG6 onscreen text, represents a critical opportunity for all Parties to engage seriously with all the proposals before them and deliver an Annex that is treaty-compliant, equitable, and fit for purpose.

Article 12 of the WHO Pandemic Agreement establishes the obligations that the PABS Annex must implement in full. The following ten elements should be included in the Annex to satisfy that mandate and to ensure a system that is equitable, enforceable, and treaty-compliant.

1. Standardized terms and conditions accepted by all actors in the PABS chain as a condition of access. The Annex must establish standardized terms and conditions binding on Parties, WCLN laboratories, WHO-recognized databases, and all categories of users, commercial and non-commercia, as a condition of access to PABS materials and sequence information. A standard contractual architecture has been proposed by the African Group and the Group for Equity through SMTA 1, SMTA 2, and the Data Access Agreement. Without such standardization, and a system to monitor compliance, pathogen materials and sequence information will continue to move through research and commercial pipelines without enforceable benefit-sharing obligations.

2. State Party obligation to ensure and enforce user compliance. Parties must be required to ensure that commercial users within their jurisdictions either accept applicable terms and conditions or enter into WHO PABS Contracts, and to enforce such obligations once accepted. This is consistent with Article 12.5(d)(ii), which requires Parties to ensure ABS alignment. The current draft imposes no such obligation: a State whose commercial manufacturers choose not to join the PABS system would not be in breach of the Annex. Absent this provision, the equal footing mandate of Article 12.1 cannot be implemented through an international agreement that can only bind State Parties.

3. Click-wrap acceptance as a precondition of database access. WHO-recognized databases must be required to obtain active user acceptance of terms and conditions through click-wrap agreements prior to providing access to PABS sequence information, rather than mere notification after the fact. A notification that a user has been told of a consequence does not constitute acceptance of an obligation. Databases must also be required to actively enforce compliance, including by suspending or reporting non-compliant users. Without mandatory acceptance, the entire benefit-sharing architecture for sequence information users is rendered inoperable.

4. Institutional user registration as a precondition of database access. User registration at institutional level must be a precondition of access to PABS sequence information through WHO-recognized databases. No anonymous access should be permitted. A WHO-maintained registry of institutional users should record identity, institutional affiliation, intended use, and acceptance of benefit-sharing obligations, serving as the foundation for compliance monitoring. The compliance obligation — including the notification of any change of intent from non-commercial to commercial activity — should rest with the institution rather than individual researchers, consistent with the model used in the PIP Framework. UNESCO's 2021 Recommendation on Open Science confirms that open access frameworks do not require anonymous access and calls on governments to prevent harmful applications of scientific research.[15]

5. Minimum manufacturer participation threshold before State sharing obligations activate. A defined minimum number or category of manufacturers must have entered into WHO PABS Contracts before the sharing obligations on State Parties become active. This gives operational meaning to the simultaneity requirement of Article 12.2, which is the treaty's principal protection for provider States against a situation where they share without receiving benefits. The deletion of the bracketed participation threshold in the current draft means that State sharing obligations now activate immediately upon Annex entry into force, with no assurance that any manufacturer has committed to the benefit-sharing side. This asymmetry is structurally incompatible with the equal footing mandate of Article 12.1 and must be corrected.

6. Enforceable change-of-intent mechanism. The Annex must include a mechanism to capture and trigger benefit-sharing obligations when users transition from non-commercial to commercial activity. The current draft's change-of-intent provision is self-reporting and unenforceable without user registration: if a user cannot be identified, neither a notification requirement nor a benefit-sharing trigger can operate. An enforceable change-of-intent mechanism requires institutional registration as its foundation and must specify the legal consequences of a failure to notify, including suspension of access, referral to the compliance mechanism, and financial liability for benefits accrued during the period of non-disclosure.

15 UNESCO Recommendation on Open Science, 2021. Available from https://unesdoc.unesco.org/ark:/48223/pf0000379949.

7. Operationalization of benefit-sharing during PHEICs. The Annex must contain specific, operative provisions on benefit-sharing during a Public Health Emergency of International Concern (PHEIC), distinct from a declared pandemic emergency. The current draft contains no PHEIC-specific obligation, no standard for affordable pricing during a PHEIC, and no WHO-request mechanism that would allow PABS benefit-sharing to activate during the early containment phase. This is a critical gap: the most important window for equitable access to vaccines, therapeutics, and diagnostics (VTDs) is often the PHEIC stage, before advance purchase agreements have concentrated supply. Applying benefit-sharing obligations at the PHEIC stage, with a 20% production reservation and supply at not-for-profit prices as proposed by the African Group and the Group for Equity, would help prevent the hoarding and supply concentration widely observed during COVID-19.

8. Mandatory non-exclusive licensing and technology transfer during pandemics and PHEICs. Participating manufacturers of VTDs must be required to grant WHO non-exclusive, royalty-free, worldwide sublicensable licenses — covering intellectual property, regulatory dossiers, know-how, cell lines, assays, and reference standards — as a mandatory obligation during pandemics and PHEICs, not as a selectable option that can be avoided by choosing other benefit-sharing modalities. Under the current draft, a manufacturer could satisfy its entire non-monetary obligation through capacity-building and R&D cooperation without granting any licenses. This is inconsistent with Article 12.6(a), which already requires legally binding contracts for the 20%/10% production allocation. Licensing and technology transfer are not supplementary measures; they are the mechanism through which the concentration of manufacturing capacity exposed during COVID-19 can be systematically addressed.

9. Qualification of State Party access obligations by capacity. State Party access obligations must be qualified by capacity, with a binding obligation on WHO to provide technical and financial assistance to Parties that request it. The current draft imposes unqualified access obligations on all Parties regardless of their laboratory infrastructure, sequencing capabilities, or data management systems. This is inconsistent with the differentiated treatment explicitly provided for participating manufacturers under Article 12.6 of the Pandemic Agreement, and with the spirit of the International Health Regulations, which couple State obligations with a corresponding WHO duty to provide assistance. Without this qualification, the access pillar disproportionately burdens developing countries that lack the necessary infrastructure while providing them no support to build it.

10. Obligations on Parties and/or WHO to facilitate access to enabling technologies. The Annex must establish obligations on Parties and/or WHO to facilitate developing country access to the full range of technologies needed to implement their sharing obligations and to benefit from the PABS system. This includes sequencing platforms, genomic analysis tools, bioinformatics software, diagnostic technologies, and laboratory and research infrastructure. Drawing from the experience of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, the PABS system could include provisions requiring Parties to facilitate access to relevant technologies on fair and most favourable terms for developing countries. Complementary capacity-building measures should further support the development of sustainable regional production and research capacity. Without these provisions, the access obligations in the Annex will remain aspirational for the majority of provider States.

Without these elements, the PABS system will entrench existing inequities and undermine the global health cooperation that the Pandemic Agreement aims to achieve. A system that allows unconditional access without corresponding and enforceable benefit-sharing obligations risks perpetuating the very inequities that the Pandemic Agreement seeks to remedy.

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