LEGAL BRIEF
The Hybrid Model Is Incompatible with What Countries Agreed Under Article 12

The COVID-19 pandemic saw staggering inequity in access to vaccines, therapeutics, and diagnostics in the global south even as pathogen samples and genetic sequences were rapidly shared. The Annex to the Pandemic Agreement exists to correct this unconscionable failure, not to perpetuate an inequitable system.

Member States have already agreed on obligations under Article 12 of the Pandemic Agreement. Its terms are settled treaty text, adopted by consensus. The Annex under negotiation does not reopen that agreement; it operationalizes it. As such, this Annex should not introduce elements that are inconsistent with the Article it is meant to implement. As such, in our view, every proposal before the intergovernmental working group (IGWG) should be tested against the requirements of Article 12. On that test, the hybrid model is incompatible with the Article.

First, legal certainty. Article 12.5(b) requires modalities, terms and conditions on access and benefit sharing that provide "legal certainty." A provider-choice menu of green, orange, and red lights does not provide the legal certainty as to benefits that the system requires. The green light allows access while bypassing these central obligations altogether. The orange light fails because access is granted on nothing more than a commitment to sign a PABS contract later—at the moment access is granted that contract does not exist, and its benefit-sharing terms are unfixed. A commitment to conclude a future contract whose content remains undetermined is only an agreement to agree, and it establishes no legal certainty as to which benefits will be shared or on what terms. On either route, access is given before any enforceable benefit-sharing obligation is fixed, and neither route provides the legal certainty mandated under Article 12.

Second, equal footing. Article 12.1 establishes access and benefit sharing "on an equal footing," and Article 12.5(a) repeats that language. Access and benefit sharing are two components of one legal bargain. The hybrid model severs them. Proponents will point to the model's own framing that these obligations are legally binding "for all users" and apply "AT ALL TIME," and that the architecture is "ONE SYSTEM—NOT TWO." That framing does not survive the model's own access matrix: its "green light" provides access after a shipping agreement with "no benefit sharing conditions attached" (landing-zone deck, slide 4), not a lighter benefit-sharing obligation, but its absence, with only an incentive to sign a PABS contract at some later point. Access decoupled from benefit sharing is not access and benefit sharing on an equal footing, and a route built on that critical decoupling cannot be reconciled with Article 12, whatever is asserted elsewhere in the model's general design. The same applies to the orange route as a promise to contract is no contract at all.

Article 12.9 does not rescue the model. Proponents might invoke that provision's statement that the Article is "without prejudice to consideration of other elements for the effective operationalization of the PABS System" as license for a tiered-access design like the hybrid model's. But Article 12.9 permits additional elements that supplement operationalization of the mandatory obligations in Articles 12.1 through 12.8; it does not authorize elements that subtract from them. A design feature that lets a Party or a manufacturer circumvent the contractual benefit-sharing mechanism those Articles require is not an "other element for effective operationalization." It is a derogation from the operationalization Article 12 already mandates.

In Article 12.1, Parties have agreed to establish a multilateral system for "safe, transparent, and accountable access and benefit-sharing for PABS Materials and Sequence Information". The hybrid model back-tracks on this multilateral agreement, by offering routes of access that carries no enforceable benefit-sharing obligation and is neither accountable nor consistent with many aspects of Article 12. A pathway that severs access from the contractual

instrument through which those benefits are secured is incompatible with the Article as a whole.

A further, related concern arises on the sequence-information track. Article 12.3 does not mandate open access to data in the abstract: it requires that the PABS System "address traceability measures and open access to data" together. Databases that permit anonymous or unregistered access sever that pairing. They may satisfy the openness half of Article 12.3 while defeating the traceability half. This is not an argument against open access as such: international practice on open science, including UNESCO's 2021 Recommendation on Open Science, recognizes that conditions for benefit sharing and governance on the use of data including for vigilance on ecological and social consequences of the use are, not contrary to, open-data principles. The concern is more concrete: anonymous access forecloses the traceability Article 12.3 requires, and with it, the ability to operationalize and enforce benefit-sharing obligations attached to access to data.

It also raises the biosafety and biosecurity concerns that Article 12.5(e) requires the PABS System to address. Sequence information capable of synthetically producing highly pathogenic materials, under an anonymous-access model, not traceable to a known, accountable user creates significant biosafety and, biosecurity concerns. A PABS design that cannot identify who has accessed PABS Sequence Information, and under what conditions, cannot demonstrate compliance with Article 12.5(e).

Overall, the hybrid model is incompatible with consensus painstakingly reached on Article 12 of the Pandemic Agreement.

Looking ahead, we urge IGWG negotiators to take the green-and orange-lights modality off the table as incompatible with Article 12's binding requirements, and to concentrate the remaining negotiation on the design questions that can be reconciled with Article 12, including user registration, traceability and standard contracts that provide legal certainty on the terms of access including benefit sharing obligations, rather than on preserving a route that dispenses with benefit sharing altogether.

Respectfully submitted by undersigned attorneys, on behalf of the signatories below:

1. **Guilherme F. Faviero**, *Esq., MS, MPH, Relevant Stakeholder Representative for AHF Brazil and AHF Global Public Health Institute Director.*
2. **Kasish Aneja**, *BA, LLB, global health lawyer and policy adviser, Georgetown University*
3. **Sangeeta Shashikant**, *LLB, LLM, Coordinator of the Development and Intellectual Property Programme at Third World Network (TWN)*
4. **Nithin Ramakrishnan**, *LLM, Senior Researcher at Third World Network (TWN)*
5. **Oluwakemi Gbadamosi**, *Esq., MA (EGID), MA (Comms), Senior Director and Co-Lead, Global Advocacy & Policy, AIDS Healthcare Foundation (AHF)*
6. **Sharifah Sekalala**, *LLB, LLM, PhD, University of Warwick*
7. **Sreenath Namboodiri**, *LLM, International Law and Intellectual Property*
8. **Alexandra L Phelan**, *SJD, LLM, LLB/BiomedSc, Johns Hopkins Bloomberg School of Public Health*
9. **Lorena Di Giano**,*LLB, Access to Medicines and Intellectual Property, Executive Director of Fundación GEP (Argentina)*
10. **Judith Murungi**, *LLB, LLM*
11. **Allan Maleche**, *LLB, LLM, Executive Director of Kenya Legal & Ethical Issues Network on HIV and AIDS (KELIN)*