WHO PABS Annex Negotiations

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This is a note for negotiators at IGWG 8, beginning September 14, 2026.

Introduction

Negotiations over the Annex to Article 12 of the WHO Pandemic Agreement are stalled, with no obvious consensus emerging. A *quid pro quo*, linking access to the pathogen samples and digital sequences to equity provisions, has known flaws. A different approach should be taken, one that provides greater certainty and leverage for realizing the equity provisions, and also enables more liberal access to samples and digital sequences.

States should take responsibility for ensuring that manufacturers obtain contracts with the WHO, not as a condition of having access to PABS materials and digital sequences, but as a condition of registering and selling products, in an appropriate field of use -- as countermeasures for a pandemic emergency or a PHEIC, where the obligation does not extend to the registration or sale of products for other uses or indications of the same products.

Three reasons for favoring this approach.

1. There will be cases where researchers won't need PABS to get access to pathogens or their DSI, and in those predictable cases, companies will have little or no incentive to be legally bound to the concessionary sharing of production. This issue has been discussed extensively in the PABS negotiations. Not all pandemics or similar infectious disease outbreaks are similar. For COVID-19, the virus readily spread geographically, and obtaining samples was not difficult. Under PABS, the obligations to share with the WHO are not exclusive, and many countries have already signed agreements to share pathogens outside of PABS.

2. It is important that information about pathogens be shared widely and quickly, and for the information to be used with other data, in a broader eco-system of databases and research tools. This would include, for example. clinical, epidemiological and safety data,

animal model and *in vitro* data, protein structures, human genetic variation affecting susceptibility or immune response, host-pathogen interaction data such as receptor binding and cell entry mechanisms, environmental data on climate, vector distribution (for vector-borne diseases), and wastewater surveillance.

If access to pathogen information requires a negotiated agreement specifying permitted research purposes or uses, and traceability/tracking requirements that follows the data downstream, this can in practice create friction against pooling into open databases or federated research platforms. Maintaining chain-of-custody is hard to reconcile with rapid multi-source combinations. Requiring separate authorization for re-sharing or redistribution to third parties limits or blocks potentially useful collaborations.

The more complex the scientific challenges, the greater the value of openness, in terms of probability of finding solutions and the speed at which this occurs.

3. The role of AI in product R&D will continue to expand, which is a good thing when it comes to developing effective and rapid responses to health threats in an emergency setting. When AI models are trained and pathogen sequence information is combined with other data, it can be technically and legally challenging to assign provenance or impact. In machine learning models trained on viral or bacterial genomic sequences, digital sequence information (DSI) is projected into dense, high-dimensional latent spaces. Individual nucleotides, codons, and amino acid motifs are not preserved as isolated records; their mathematical representations overlap continuously across shared parameters. Proving that a specific, locally identified pathogen sequence contributed deterministically to an AI-generated candidate immunogen or small molecule remains technically intractable.

   An AI pipeline designing a broad-spectrum coronavirus or filovirus therapeutic synthesizes geometric constraints, evolutionary conservation patterns, and biochemical properties derived from millions of public viral sequences. Except in edge cases of literal sequence memorization (which AI drug developers actively train models to avoid), no single accession number can be mathematically isolated as the sole "cause" of a de novo candidate.

   Sequence models undergo repeated fine-tuning, active learning loops, and reinforcement learning against wet-lab binding assays. These optimization layers continually shift parameter spaces, severing any lingering direct chain of mathematical causation back to the pre-training ingestion of a specific PABS accession.

   This is a further reason that exclusive reliance on use-based tracking as the trigger mechanism may disappoint.

Summary

Point 1: Relying on a link between access to PABS materials and data does not create reliable leverage (due to non-exclusive sharing, alternate pathogen sources).

Point 2: Linking equity to access to information actively impedes scientific collaborative work important for rapid development of useful countermeasures.

Point 3: Use-based tracking may be technically impractical. Provenance is a substantially less reliable enforcement mechanism than market authorization and sale.

Point 4: A more direct approach is available, that provides more reliable leverage for access obligations and that does not create unwanted restrictions on scientific inquiry and collaborations. Benefit sharing can be enforced at the point where governments have reliable leverage over manufacturers, the authorization and sale of relevant pandemic products, rather than depend exclusively on proving that a manufacturer obtained or used a particular PABS material or sequence.

KEI Proposed Language for the Annex to implement Article 12, Paragraph 6

This proposed text would implement the equity provisions in paragraph 6 of Article 12 of the Pandemic Agreement, using the activation event of registering and selling products, enforced by treaty parties, and locking in the Article 12.6 allocations, for all manufacturers, not only the ones who sign PABS contracts as a *quid pro quo* to access PABS materials or data. The opposition has come from countries that (a) don't want to play a role in enforcing the paragraph 6 allocations, or (b) don't think other countries will do so.

Implementation of Market Access and Product Allocation

Paragraph 1: Scope and Market Access Requirement

Each Party shall take all necessary legal, administrative, or regulatory measures to ensure that any manufacturer seeking to register or sell pandemic-related products within its jurisdiction provides verifiable evidence of a legally binding agreement with the World Health Organization (WHO) that addresses access to such products, consistent with Article 12, Paragraph 6, of the Pandemic Agreement.

Paragraph 2: Specific Pathogen and Field of Use Alignment

The obligations outlined in this Annex shall apply exclusively to products used within the specific field of use and indication required to address the specific pathogen being shared under the Pathogen Access and Benefit-Sharing (PABS) System. This obligation shall not extend to other uses or indications of the same products. It remains strictly binding on the manufacturer regardless of whether that individual manufacturer utilized materials or digital sequence information (DSI) from the PABS System for its development or production.

Paragraph 7 of Article 12

Paragraph 7 of Article 12, states:

> The PABS Instrument shall also include benefit sharing provisions, in the event of a public health emergency of international concern as determined in accordance with Article 12 of the International Health Regulations (2005), including options regarding access to safe, quality and effective vaccines, therapeutics, and diagnostics for the pathogen causing the public health emergency of international concern, pursuant to legally binding contracts signed by participating manufacturers with the World Health Organization.

Prior to the 2024 amendments, the International Health Regulations (2005) were almost entirely silent on equity. The original IHR focused primarily on technical surveillance, reporting obligations, and preventing the international spread of disease without unnecessary interference with international trade and traffic. Following the COVID-19 pandemic, the World Health Assembly adopted a targeted package of amendments to embed equity into the IHR, particularly regarding the response to a PHEIC and its newly introduced higher-tier category, a "pandemic emergency".

For the IHR, the core of the equity reforms during a PHEIC are in Article 13, which in 2024 was retitled to include “equitable access to relevant health products.” The IHR mandates the WHO treat equitable countermeasures as an integral part of PHEIC response, leaving the direct contractual benefit-sharing tools to instruments like Article 12 of the Pandemic Agreement.

Unlike Article 12.6, the requirement in 12.7 is to provide options, without specific set-asides mentioned. Like paragraph 12.6, there is a reference to legally binding contracts signed by participating manufacturers with the WHO. This text would greatly enhance the leverage of the WHO to obtain such contracts, because it would require manufacturers seeking to register or sell vaccines, therapeutics or diagnostics relevant to the public health emergency within its jurisdiction to provide evidence of a legally binding agreement with the WHO.

KEI Proposed Language for the Annex Relating to Paragraph 7 of Article 12

Annex text for Article 12, Paragraph 7 **Public health emergency of international concern**

In the event of a public health emergency of international concern (PHEIC) determined in accordance with Article 12 of the International Health Regulations (2005), each Party shall take legal, administrative or regulatory measures to ensure that manufacturers seeking to register or sell vaccines, therapeutics or diagnostics relevant to the public health emergency within its jurisdiction provide evidence of a legally binding agreement with the World Health Organization addressing the need for timely and equitable access to such products.

Such agreements shall provide WHO with options to obtain supplies of relevant products, including at affordable prices or as donations, in quantities and on terms appropriate to the public health risks and needs identified by WHO. The agreements may also provide for measures to expand supply, including non-exclusive licensing, technology transfer, access to manufacturing know-how and regulatory information, and other measures appropriate to facilitate timely and equitable access.

The obligations in this paragraph shall apply regardless of whether the manufacturer utilized PABS Materials or PABS Sequence Information in the research, development or production of the relevant product.

Nothing in this paragraph shall limit the obligations applicable in the event of a pandemic emergency pursuant to Article 12.6 of the WHO Pandemic Agreement.

The paragraph 6 Annex text has a more specific obligation for the narrowly defined event (a declared pandemic emergency, and a matching pathogen), while the paragraph 7 Annex text has a more flexible obligation ("options" not set-asides)., for the more broadly defined event ("relevant to the public health emergency, PHEIC tier.

FAQs

Q1. Does this limit what the WHO can include in an SMTA?

No. It sets a floor for the obligations contained in Article 12.6, which would no longer depend on evidence that products were developed using PABS Materials or PABS Sequence Information. The negotiations over contracts for Article 12.7 cases would provide WHO with greater leverage, while retaining flexibility regarding the terms of the binding contracts negotiated, which is appropriate given the diverse contexts involved. The proposal does not eliminate transactional agreements governing access to PABS Materials or PABS Sequence Information. It means that WHO does not depend exclusively on such agreements to achieve the equity objectives of Article 12.

Q2. Can manufacturers or countries ignore the obligations?

In theory, yes, and as COVID-19 has illustrated, in some cases, governments involve national security like prerogatives. This will be true for any PABS system. What the provisions will provide is considerably more leverage to obtain and enforce obligations when a sufficient number of countries implement the obligations, and where relevant, donor institutions also condition procurement to compliance with the obligations.

Unlike a system that relies exclusively on access to PABS Materials or PABS Sequence Information for leverage, manufacturers cannot readily obtain access to important national markets from alternative sources.

Q3. Can the WHO require registration for PABS digital sequence information and the use of unique persistent identifiers?

Yes, if this proves useful and appropriate, given the context of outbreaks and the continuing evolution of information technologies and research tools. The proposal does not preclude registration, persistent identifiers, tracking or other measures that may improve transparency or the operation of the PABS System. It does, however, avoid making the equity obligations depend exclusively on the ability to trace a particular product to the use of particular PABS Materials or PABS Sequence Information.

Q4. What about technology transfer?

There are measures in Articles 9, 11 and 13 of the Pandemic Agreement that are highly relevant to achieving technology transfer objectives, all of which will depend upon the practical implementation of the agreement, once it comes into force. Elsewhere, KEI has proposed three different novel incentive mechanisms for sharing technologies that can be implemented separately or in connection with the Pandemic Agreement, which we will share on request.