

**The Global Healthcare Innovation Alliance Accelerator (GHIAA)
remarks to be presented at the first informal dialogue in the intersessional
period of the IGWG on the PABS Annex, 24 November 2025**

Thank you for the opportunity to make these remarks representing GHIAA - The Global Healthcare Innovation Alliance Accelerator, a not-for-profit organization that creates resources, curates information, collaborates with stakeholders and provides consulting support related to policies and agreement provisions that aim to achieve equitable, global access to medical products

The following comments are for the consideration of Member States in respect of the issue of pathogen access and benefit sharing, including contracts / agreements that would need to be established for this purpose.

Our comments focus on some of the types of contracts which will be necessary to operationalize the sharing of pathogen materials from identification to product manufacture and supply.

As an example of how a chain of contracts could work together to achieve access, clarity of obligations and tracking of ownership, we invite Member States to consider the following:

Upon receipt by a WHO coordinated lab network of PABS materials (pursuant to a material transfer agreement or assignment) WHO would license such materials primarily to two types of licensee organizations: those with manufacturing capacity and those without, such as universities or small biotech companies. Those licenses would differ in several fundamental ways:

First, the original transfer from WHO will need to include in its license to a non-manufacturing entity a requirement that the organization without manufacturing capacity will need to grant a sublicense, including for foreground intellectual property (improvements), during development to one or more third party manufacturers. A sublicense must require that a potential manufacturer will need to have signed an agreement with WHO to be a Participating Manufacturer, with the rights and obligations that entails. The form of such a sublicense could be standardized and attached to the original license agreement, and used for all sub-licenses to potential Participating Manufacturers.

Secondly, licenses directly from WHO to Participating Manufacturers would need to include the right and obligation to sublicense to regional Participating Manufacturers if they are unable to, in a timely manner, fully satisfy the need in all countries impacted by the outbreak /pandemic,

and/or if the original manufacturer is blocked by its own country from exporting any or adequate doses of product.

An additional suggestion for Member States to consider is that aligning incentives and agreement terms for potential Participating Manufacturers could increase the number of manufacturers who would become Participating Manufacturers as well as Member States' leverage and negotiating strength in subsequent agreement negotiations.

These comments draw on GHIAA's technical expertise and lessons learned from its extensive experience of analyzing and negotiating such R&D and commercialization agreements for medical products. with the aim of demonstrating practical pathways to help members of the Intergovernmental Working Group (IGWG) engage meaningfully in the upcoming negotiations. GHIAA stands ready to provide further technical expertise and practical guidance to support the IGWG in this process.

Thank you.