

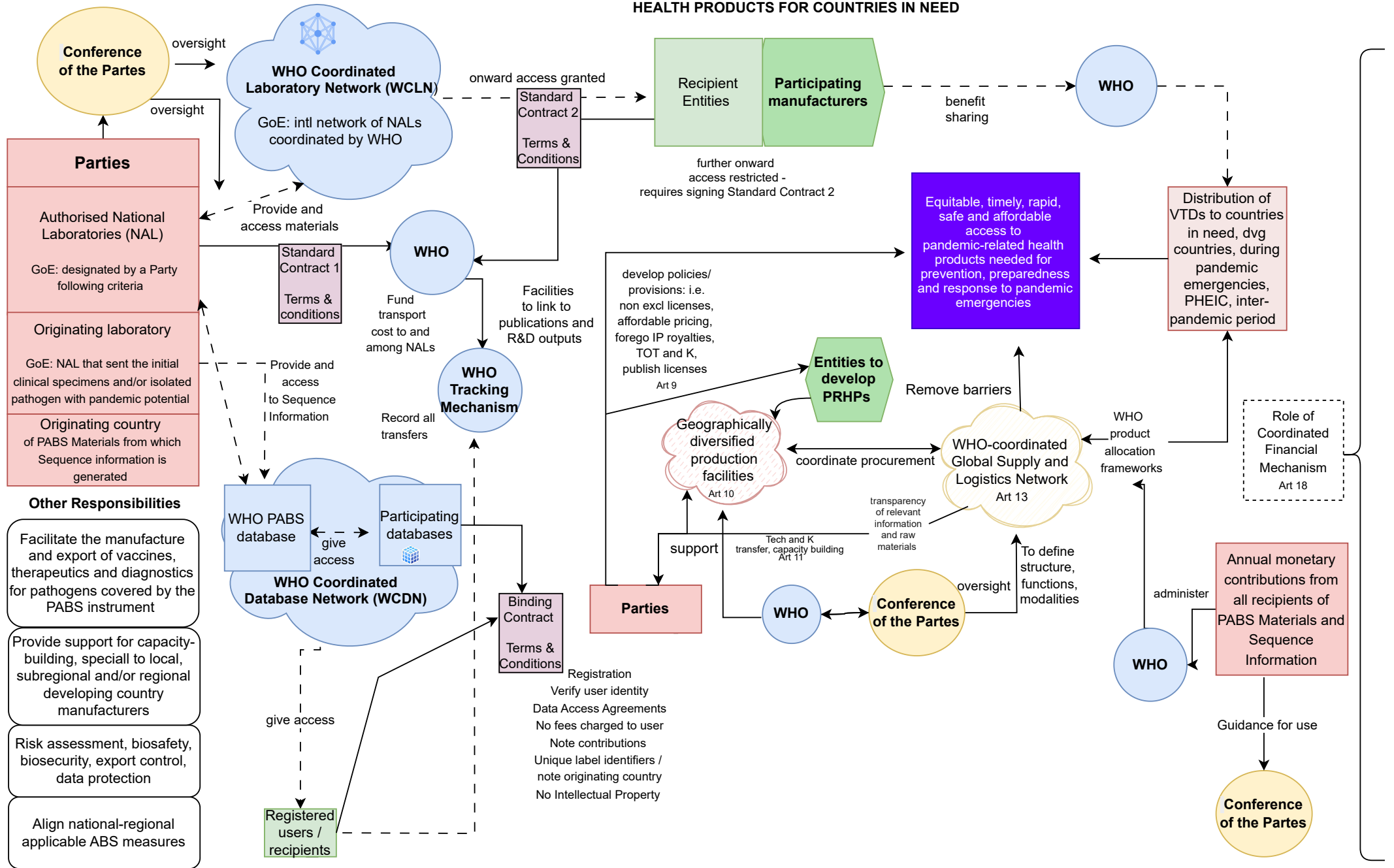
# ANNEX TO THE WHO PANDEMIC AGREEMENT ON A MULTILATERAL PATHOGEN ACCESS AND BENEFIT SHARING SYSTEM (PABS SYSTEM)

To be developed pursuant to Article 12

Dr. Viviana Munoz Tellez, munoz@southcentre.int

Rapid and Timely ACCESS	What to grant access to -share- for public health purposes? Definitions	Pathogens with Pandemic Potential  -novel (not yet characterized) or known (including a variant of a known pathogen) - potentially highly transmissible within human populations - can cause PHEIC and/or pandemic emergency as defined in IHR (Indonesia, Malaysia). Definition to draw on WHO to establish a Pathogen List (China) non-exhaustive list (Brazil)	PBAS Materials  1. Isolated wild-type 2. any modified forms 3. any other materials derived from, generated or prepared using the materials 1-2 (GoE)	Sequence information  Any data or information generated from PABS materials through the application of sequence technologies (GoE)	Clinical Specimens  Materials taken from humans including specimens collected from respiratory tract (i.e. swabs and aspirated fluid), blood, serum, plasma, faeces, and tissues (GoE)	When to grant access / share for public health purposes? voluntary or binding?	Inter-pandemic period	Public Health Emergency of international Concern (PHEIC)	Requirements - restrictions to grant access / share?	Access shall be subject to the Prior Informed Consent of the Party providing such resources and the Mutually Agreed Terms between providers and users of such resources (GoE)	Access to the PABS system and BS governed by Standard Legally Binding Contracts that define applicable TORs (GoE) and voluntarily concluded (EU). Signed contracts imply PIC and MAT for the purposes specified (Malaysia)	Compliance with requirements on biosafety, biosecurity, risk assessment, export control, data protection. Restriction to high'-risk data release (GoE, Russia, China)
							Outbreak	Pandemic Emergency				
Rapid, Timely, Fair and Equitable BENEFIT SHARING	Who shares benefits?			When to Share?	What Benefit sharing? To whom do benefits flow?					Monetary or Non Monetary	Explicit in Art 12	
	Each Participating Manufacturer			Pandemic Emergency	Minimum 10% donation to WHO of real time production of vaccines, therapeutics and diagnostics (VTDs)					non monetary	Yes	
	Participating Manufacturer: public and/or private entities that develop and/or manufacture VTDs for pathogens with pandemic potential including academic institutions, government owned or government subsidized entities, nonprofit organizations or commercial entities (GoE)											
	Each Participating Manufacturer, based on nature and capacity of the participating manufacturer			Pandemic Emergency	Additional 10% ≤ of real time production of VTDs reserved at affordable prices to WHO Affordable prices: determined based on the verified cost of production plus a reasonable margin not exceeding..%..(Indonesia)					non monetary	Yes	
	All recipients accessing PABS Materials and/or PABS Sequence Information when <b>revenue</b> is generated from their sharing/utilization of PABS Materials and/or PABS Sequence Information. Includes participating database in WCDN if generating revenues (GoE)			Incl. inter-pandemic period, PHEIC, Pandemic Emergency	Annual monetary contributions X of total annual revenue for each product or service developed or commercialised using the PABS system. Annual revenue includes all financial benefits such as income from sales and royalties (GoE)					monetary	Partially. Proposed modality for annual monetary contributions	
	Recipients accessing PABS Materials and/or PABS Sequence Information strictly for <b>non commercial uses</b> - not intended to generate revenue (GoE)			Incl. inter-pandemic period, PHEIC, Pandemic Emergency	Make available all outcomes from the non-commercial use freely available and accessible in the public domain. Also reported through the WHO PABS Sequence Database to link to the sequence information accessed (GoE)					non monetary	Partially. Proposed modality for research and development cooperation	
	Participating Manufacturer			PHEI and/or Pandemic Emergency	Grant to WHO non-exclusive licenses to sublicense to manufacturers in developing countries for development and/or rapid production of PRHPs. Licence to include providing regulatory dossier, technical know-how, any necessary materials, i.e. cell lines (GoE)					non monetary	Partially. Proposed modality for option for non-exclusive licenses to manufacturers in developing countries	
Participating Manufacturers			To prevent, prepare for and respond to PHEIC	Provide to WHO on request, at non-for-profit prices and on a priority basis, VTDs for stockpiling and/or supply to supply affected developing countries. Set asides to be determined in IGWG (GoE)					non monetary	Partially. Proposed modality for option to facilitate VTDs		
Governance	Coordinated and administered by WHO		PABS Advisory Group (GoE)	WHO DG action for breaches of TORs of standard contracts (GoE)			Oversight role of COP (GoE, EU)		Possible future period reviews (EU)			

# PABS SYSTEM AS PART OF BROADER SYSTEM FOR EQUITABLE AND TIMELY ACCESS TO PANDEMIC RELATED HEALTH PRODUCTS FOR COUNTRIES IN NEED



Relationship with other ABS agreements		
Convention of Biological Diversity and the Nagoya Protocol	consistent with, and not run counter to, the objectives of CBD. No obligations created for non-Parties	<p>Principle that States have rights over their biological resources (GoE, China). Access subject to PIC of the Providing Party and MATs between providers and users (GoE).</p> <p>All CBD Parties are required to have national legislation governing access to genetic resources. Will need additional national legislation to implement PABS.</p> <p>Ensure consistency in design of PABS, though it is formally up to CBD/Nagoya COP to determine if PABS is a specialized instrument under Art 4.4</p>
WHO Pandemic Influenza Preparedness Framework	complementary to, not duplicative of, ABS	PABS system shall not regulate the sharing of influenza virus material or sequence information (Brazil)
Other relevant international ABS instruments	where applicable to Parties	<p>Multilateral mechanism for PABS SI is distinct and separate from DSI on genetic resources. Will not be duplicative as BS depends on specific use. Voluntary contributions to the CBD's Multilateral Mechanism For Digital Sequence Information (Cali Fund) is not optimal for PABS system. Cali Fund remains empty to date.</p> <p>Lessons learned from other ABS systems' access and traceability arrangements, such as International Treaty on Plant Genetic Resources for Food and Agriculture and the Cali Fund (Australia, UK, Norway, Canada, NZ)</p> <p>Lessons learned should also include the WHO PIP Framework, and Agreement on the Conservation and Sustainable Use of Marine Genetic Diversity of Areas Beyond National Jurisdiction (BBNJ)s' standard batch identifiers for digital sequence information</p>
International Health Regulations	As amended 2005, Including 2024 amendments	<p>Does not regulate sharing of pathogen information.</p> <p>Definition of pandemic health-related products.</p>