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 Access to the Public Clinical Compliance Pathogens with Sequence PABS system and Health Specimens Access shall be with **Pandemic Potential PBAS Materials** information BS governed by Rapid and Timely ACCESS Inter-Emergency What to requirements subject to the Standard Legally andemic grant Materials taken When to grant Prior Informed on biosafety. Any data or 1. Isolated wild--novel (not vet characterized) or period **Binding Contracts** nternationa from humans access / share biosecurity. Consent of the access to information known (including a variant of a type 2. any that define Concern -shareincluding for public health Requirements Party providing risk modified forms 3. generated from known pathogen) (PHEIC) applicable TORs restrictions to for public specimens purposes? such resources assessment, PABS materials potentially highly transmissible anv other (GoE) and health collected from voluntary or grant access / and the Mutually export control through the within human populations materials derived voluntarily binding? purposes? respiratory tract share? Agreed Terms data - can cause PHEIC and/or from, generated application of concluded (EU). **Definitions** (i.e. swabs and between protection. pandemic emergency as defined or prepared using sequence Signed contracts Pandemic Restriction to aspirated fluid). providers and technologies Outbreak in IHR (Indonesia, Malaysia). the materials mply PIC and MA Emergency blood, serum. high'-risk data users of such 1-2 (GoE) (GoE) Definition to draw on WHO to for the purposes plasma, faeces. release (GoE. resources (GoE) establish a Pathogen List (China) specified and tissues (GoE) Russia, China) non-exhaustive list (Brazil) (Malaysia) Monetary or Explicit in Art 12 Who shares benefits? When to Share? What Benefit sharing? To whom do benefits flow? Non Monetary Each Participating Manufacturer Participating Manufacturer: public and/or private entities that Pandemic Minimum 10% donation to WHO of real time production of vaccines, therapeutics and Yes develop and/or manufacture VTDs for pathogens with non monetary diagnostics (VTDs) Emergency pandemic potential including academic institutions. government owned or government subsidized entities, nonprofit organizations or commercial entities (GoE) Additional 10% ≤ of real time production of VTDs reserved at affordable prices to WHO Each Participating Manufacturer, based on nature and capacity Pandemic non monetary Yes of the participating manufacturer Emergency Affordable prices: determined based on the verified cost of production plus a reasonable Rapid, margin not exceeding..%..(Indonesia) Timely, Fair All recipients accessing PABS Materials and/or PABS Sequence and Annual monetary contributions Information when **revenue** is generated from their Incl. inter-pandemic Partially. Proposed Equitable X of total annual revenue for each product or service developed or commercialised using sharing/utilization of PABS Materials and/or PABS Sequence period, PHEIC, monetary modality for annual BENEFIT the PABS system. Annual revenue includes all financial benefits such as income from sales Information. Includes participating database in WCDN if Pandemic Emergency monetary contributions SHARING and rovalties (GoE) generating revenues (GoE) Partially. Proposed Recipients accessing PABS Materials and/or PABS Sequence Incl. inter-pandemic Make available all outcomes from the non-commercial use freely available and accessible non monetary modality for research and Information strictly for non commercial uses - not intended to period, PHEIC, in the public domain. Also reported through the WHO PABS Sequence Database to link to development cooperation generate revenue (GoE) Pandemic Emergency the sequence information accessed (GoE) Partially. Proposed Grant to WHO non-exclusive licenses to sublicense to manufacturers in developing PHEI and/or modality for option for countries for development and/or rapid production of PRHPs. Licence to include providing Participating Manufacturer non monetary Pandemic Emergency on-exclusive licenses to regulatory dossier, technical know-how, any necessary materials, i.e. cell lines (GoE) manufacturers in developing countries Partially. Proposed To prevent, prepare Provide to WHO on request, at non-for-profit prices and on a priority basis, VTDs for modality for option to stockpiling and/or supply to supply affected developing countries. Set asides to be Participating Manufacturers for and respond to non monetary facilitate VTDs PHEIC determined in IGWG (GoE) WHO DG action for breaches of TORs of standard contracts (GoE) Oversight role of COP (GoE, EU) Governance Coordinated and administered by WHO PABS Advisory Group (GoE) 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** oversight Conference of the Partes **WHO Coordinated** onward access granted Recipient **Participating WHO** Laboratory Network (WCLN) Standard **Entities** manufacturers benefit oversight Contract 2 sharing GoE: intl network of NALs coordinated by WHO Terms & Conditions **Parties** further onward access restricted requires signing Standard Contract 2 Distribution of Equitable, timely, rapid. Provide and VTDs to countries safe and affordable **Authorised National** access materials access to in need, dva Laboratories (NAL) pandemic-related health countries, during **WHO** Standard products needed for pandemic Contract GoE: designated by a Party develop policies/ prevention, preparedness emergencies, following criteria and response to pandemic **Facilities** provisions: i.e. Terms & Fund PHEIC. interemergencies to link to non excl licenses. conditions transport pandemic period publications and affordable pricing, Originating laboratory cost to and R&D outputs forego IP royalties, among NALs TOT and K, **Entities to** GoE: NAL that sent the initial Provide and publish licenses WHO develop clinical specimens and/or isolated access Tracking Remove barriers **PRHPs** pathogen with pandemic potential I to Sequence Mechanism **I** Information WHO Role of Record all Originating country Geographically Coordinated transfers product diversified of PABS Materials from which WHO-coordinated Financial allocation Sequence information is production coordinate procurement Global Supply and frameworks Mechanism facilities generated Logistics Network Art 18 Art 10 Art 13 Other Responsibilities transparency Participating of relevant WHO PABS information databases database and raw Facilitate the manufacture Tech and K give transfer, capacity building support materials To define and export of vaccines. access Annual monetary structure, therapeutics and diagnostics **WHO Coordinated** contributions from functions, oversiaht for pathogens covered by the administer **Database Network (WCDN)** Bindina modalities all recipients of Conference PABS instrument **Parties** WHO Contract PABS Materials and of the Partes Sequence Provide support for capacity-Terms & building, speciall to local, Information Conditions **WHO** Registration subregional and/or regional Verify user identity developing country Data Access Agreements manufacturers give access No fees charged to user Guidance for use Risk assessment, biosafety. Note contributions biosecurity, export control, Unique label identifiers / note originating country

Conference

of the Partes

No Intellectual Property

data protection

Align national-regional

applicable ABS measures

Registered

users /

recipients

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	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). All CBD Parties are required to have national legislation governing access to genetic resources. Will need additional national legislation to implement PABS. 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
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	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. 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) 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
International Health Regulations	As amended 2005, Including 2024 amendments	Does not regulate sharing of pathogen information. Definition of pandemic health-related products.