

PABS Annex: Submission to inform the outline of elements for IGWG2

This submission, provided on behalf of Australia, the United Kingdom, Norway, Canada, and New Zealand is intended to inform the work of the open-ended Intergovernmental Working Group on the WHO Pandemic Agreement (IGWG) to draft and negotiate the Pathogen Access and Benefit-Sharing (PABS) Annex. The submission aims to support the IGWG Bureau to develop a draft outline of elements to be addressed by the PABS Annex. It sets out five key elements expected to be addressed linked to Article 12 of the WHO Pandemic Agreement, issues the IGWG will need to consider and/or address, and expertise needed to inform these considerations (refer **Attachment 1**).

Please note that the input below is without prejudice to further input and proposals, including for legal text, that the abovementioned countries may decide to submit subsequently during the IGWG process to develop the PABS Annex.

1. Scope, principles and definitions

Scope: The “WHO Pathogen Access and Benefit-Sharing System” (“PABS System”) is a “multilateral system” providing for the “rapid and timely sharing of “materials and sequence information on pathogens with pandemic potential” (“PABS Materials and Sequence Information”) and, on an equal footing, the rapid, timely, fair and equitable sharing of benefits arising from the sharing and/or utilization of PABS Materials and Sequence Information for public health purposes.” [12.1]

- Consider and/or address: links as appropriate to existing Access and Benefit-Sharing mechanisms, see “4. Consistency, complementarity and non-duplication”.

Principles underpinning the PABS System:

- Recognition of “the sovereign right of States over their biological resources and of the importance of collective action to mitigate public health risks” [12.1]
- “[S]afe, transparent, and accountable access and benefit-sharing” [12.1] “that provide[s] legal certainty” [12.5(b)] and “strengthen[s], facilitate[s] and accelerate[s] research and innovation, as well as the fair and equitable sharing and distribution of benefits” [12.5(c)], and “facilitate[s] the manufacture and export of vaccines, therapeutics and diagnostics” (VTDs) [12.5(f)]
- Development and implementation to complement and not duplicate access and benefit-sharing (ABS) measures and obligations, including the Pandemic Influenza Preparedness (PIP) Framework and other international instruments [12.5(d)]

Defined terms:

- “Pathogens with pandemic potential” [12.2]
 - Consider and/or address: factors (e.g., transmissibility, geographic spread, virulence, availability of effective countermeasures, origins, and mutation potential) and process to pre-define and/or identify specific pathogens/pathogen families, including to future-proof the term (e.g., capturing pathogen X and synthetic/AI generated sequences)
- “PABS materials” and “PABS sequence information” [12.1]

- Consider and/or address: separate definitions of materials (samples vs. isolates) and sequence information; alignment with other relevant instruments, whilst avoiding new definitions that could impact on those instruments; future proofing to avoid limiting scientific discovery and technological advancements; implications of excluding or including certain materials and information (e.g., associated clinical and epidemiological metadata) in both human, animal and environmentally derived sequences to capture zoonotic pathogens and consider how these different samples/sequence data are managed
- “Participating manufacturer” [12.6(a) and footnote 15]
 - Consider and/or address: link to legally binding contracts per 12.6(a) and 12.7 and any factors the definition should encompass
- Other terms that may need to be defined: e.g., related to institutions, organizations and entities engaged in the PABS system, and potential terms used in “Access” and “Benefit-sharing” provisions, such as “rapid and timely” [12.1 and 12.5(a)]

2. Access

- **Provisions for “rapid and timely sharing of PABS Materials and Sequence Information” [12.1, 12.5(a)] including to “strengthen, facilitate and accelerate research and innovation” [12.5(c)]**
 - Consider and/or address:
 - Current practices, functionality, capacities, and costs associated with sharing/accessing different pathogens with pandemic potential (i.e., databases for sequence data and associated meta-data; and laboratories for materials, including relevant handling and transfer practices to ensure biosafety and biosecurity)
 - Provisions for Parties for “rapid and timely” sharing obtained through routine surveillance and during acute events under the International Health Regulations
 - Accountability, transparency, traceability measures and open access to data [12.3] and legal certainty over data ownership, rights and obligations for institutions, organizations, entities or individuals sharing and accessing data. This should take into account, inter alia:
 - differences in sharing and use of PABS Materials and Sequence Information
 - requirements from regulatory agencies that regulate sharing (including cross-border) and access for laboratories, product developers and manufacturers including for product authorization,
 - lessons learned from other ABS systems’ access and traceability arrangements such as under the International Treaty on Plant Genetic Resources for Food and Agriculture and the Cali Fund,
 - potential use of existing databases (e.g., IP databases, clinical trial registries) to address traceability for use of PABS materials or sequence information for product development, or alternative strategies to address accountability, and
 - incentives for research and innovation
 - Other modalities to ensure access provisions satisfy the objectives of the PABS System, can be effectively operationalised, and are future-proofed (e.g., as genomic sequence data-related analysis shifts to bioinformatic and artificial intelligence approaches)

3. *Benefit-sharing*

Provisions for “rapid, timely, fair and equitable sharing of ... monetary and non-monetary [benefits] ... arising from the sharing and/or utilization of PABS Materials and Sequence Information for public health purposes” [12.1, 12.5(a)]

- Pursuant to legally binding contracts between WHO and participating manufacturers including:
 - in pandemic emergencies, rapid access to a 20% target of real time production of safe, quality and effective VTDs for the pathogen causing the pandemic emergency (minimum 10% available to WHO as donation; remaining percentage reserved at affordable prices, with flexibility based on nature and capacity of each participating manufacturer) to be distributed on the basis of public health risk and need, potentially through the Global Supply Chain and Logistics Network [12.6(a) and (b)]
 - during a PHEIC, options regarding access to safe, quality and effective VTDs for the pathogen causing the PHEIC [12.7]
 - additional benefit-sharing provisions, “including options for: capacity building and technical assistance; research and development cooperation; facilitating rapid access to available [VTDs] with a view to responding to public health risks and events ... ; the granting of non-exclusive licences to manufacturers in developing countries, for effective ... production and delivery of [VTDs]; and other forms of transfer of technology as mutually agreed [refer footnote 8 in the WHO Pandemic Agreement], including transfer of relevant knowledge, skills and technical expertise” [12.8]
- Consider and/or address:
 - Provisions regarding the framework for legally binding contracts between WHO and participating manufacturers for benefit-sharing and options for benefit-sharing, including whether model clauses form an appendix or are adopted by the Conference of the Parties
 - Provisions regarding the negotiation of contracts with participating manufacturers that provide legal certainty, consider the manufacturer’s nature and capacity, and increase the likelihood of manufacturers electing options for product access and other benefit-sharing provisions without disincentivizing product development or conclusion of legally binding contracts between WHO and participating manufacturers, and
 - Provisions regarding a framework for the distribution of VTDs, including the process and criteria to determine ‘public health risk and need’, and the role of WHO, other relevant international organizations, and use of the Global Supply Chain and Logistics Network
- **“[A]nnual monetary contributions” [12.5(a)]**
 - Consider and/or address:
 - Provisions regarding the sharing of monetary benefits, including annual monetary contributions, and consider what form non-monetary benefits might take
 - Criteria for quantification and terms of contributions
 - Governance of contributions once received by the PABS system including transparency, reporting, and scope for spending/allocation – linking to “5. *Governance and general provisions*”

- **Overall**

- Consider and/or address:

- Other modalities to ensure benefit-sharing provisions satisfy the objectives of the PABS System, can be effectively operationalised, and are future-proofed (e.g., incentivizing entities' engagement including those entities that would share and/or use PABS Materials and Sequence Information such as for clinical diagnostic purposes and other types of routine medical testing through to R&D)

4. Consistency, complementarity and non-duplication

International ABS instruments: “[T]he PABS [Annex] shall be consistent with, and not run counter to, the objectives of the Convention on Biological Diversity (CBD) and the Nagoya Protocol” [12.4]. It is developed and implemented in a manner “complementary to, and not duplicative of, the [ABS] measures and obligations of the [PIP] Framework and other relevant international [ABS] instruments where applicable” [12.5(d)(i)]

- Consider and/or address:

- Consistency with CBD and Nagoya Protocol objectives, so the PABS Annex can be considered a specialized international instrument for the purposes of Article 4.4 of the Nagoya Protocol
- Complementarity and no duplication with the PIP Framework including to ensure: legal certainty for all who share and access PIP biological materials and PABS Materials and Sequence Information; and complementarity between manufacturers' legally binding contracts for benefit-sharing under the PABS System and SMTA2s under the PIP Framework
- Complementarity, no duplication and legal certainty in relation to other applicable international ABS instruments, including the CBD's Multilateral Mechanism for Digital Sequence Information

National and/or regional ABS measures: “[E]ach Party reviews and, as it deems appropriate, aligns its national and/or regional [ABS] measures applicable to PABS Materials and Sequence Information within the scope of the PABS [Annex], so that measures that are contrary to, or inconsistent with, or duplicative of, the PABS [Annex] will not be applied upon entry into operation of all elements of the PABS System” [12.5(d)(ii)]

- Consider and/or address:

- How national and/or regional ABS measures could be considered inconsistent with, or duplicative of, the PABS Annex
- Time limitations and/or reporting requirements for Parties to share the outcomes of their review and any non-application of measures, taking into account all elements of the PABS System coming into operation simultaneously
- Other arrangements for identification of contrary, inconsistent or duplicative measures

Applicable international, national and/or domestic law: The PABS System shall be “implement[ed] consistent with applicable international law and with applicable national and/or domestic law, regulations

and standards related to risk assessment, biosafety, biosecurity and export control of pathogens, and data protection” [12.5(e)]

- Consider and/or address:
 - o Applicable laws, regulations and standards and how they apply to PABS Materials and Sequence Information (e.g., to ensure efficient and safe exchange of pathogen material)
 - o Provisions that need to be included in the PABS Annex to ensure consistency with applicable laws, regulations and standards

5. Governance and general provisions

Administration and coordination of the PABS System: “The PABS [Annex] shall define the terms for the administration and coordination of the PABS System by the [WHO]” [12.2], and in “coordination and operation of the PABS System, the [WHO] shall collaborate with relevant international organizations and relevant stakeholders” [12.2]

- Consider and/or address:
 - o Provisions regarding the WHO Secretariat’s responsibilities, terms of administration, and operational dimensions including how the PABS System will be situated within the WHO Secretariat, and resourcing considerations compatible with WHO’s reprioritization efforts
 - o Provisions to ensure complementarity and non-duplication with the administration and coordination of the PIP Framework, the Cali Fund and other relevant ABS instruments
 - o Provisions regarding the development, review and amendment of terms of reference with laboratories and databases that are in line with the principles of the PABS System
 - o Provisions regarding the development, review and amendment of terms of reference between the WHO and relevant international organizations and relevant stakeholders, including forms for collaboration, and the relevant international organizations and relevant stakeholders that should be involved based on their respective mandates, interests and capacities

The role of the Conference of the Parties (COP) and monitoring and review of the PABS System

- Consider and/or address:
 - o Provisions regarding COP’s role in providing oversight, the Secretariat’s role in reporting to the COP (linked to Article 22), and mechanisms for monitoring and review to ensure the PABS System’s good functioning (e.g., access, contracts being negotiated and signed, vaccines, therapeutics and diagnostics distributed, and other benefits shared, as well as overall assessment of the System’s performance), including frequency and scope

Entry into operation: “All elements of the PABS System shall come into operation simultaneously in accordance with the terms of the PABS [Annex]” [12.2]

- Consider and/or address:
 - o How all elements of the PABS System come into operation simultaneously and if any criteria or clarifications regarding operationalization are required

Attachment 1: Expertise required to develop the PABS Annex

Expertise required	Headline elements
<p>Scientific and technical experts e.g., virologists / microbiologists genomic scientists bioinformaticians epidemiologists clinical infectious disease specialists biosecurity and biosafety specialists laboratory technicians/managers</p>	<ul style="list-style-type: none"> • Scope, principles and definitions • Access • Consistency, complementarity and non-duplication
<p>Legal and regulatory experts e.g., pharmaceutical regulators international health law specialists intellectual property (IP) lawyers and/or specialists access and benefit-sharing (ABS) lawyers and/or specialists (including those leading work across other forums, such as the CBD and Cali Fund Secretariats) bioethics experts trade and export control policy experts, customs and regulatory specialists (including biosecurity/biosafety specialists) health systems analysts and evaluation experts contract law specialists health economists</p>	<ul style="list-style-type: none"> • Scope, principles and definitions • Access • Benefit-sharing • Consistency, complementarity and non-duplication • Governance and general provisions
<p>Policy and governance professionals e.g., global health policy advisors data governance/data innovation specialists and scientists AI and blockchain experts data governance/security/privacy specialists (including owners of relevant data repositories) bio/public health ethicists</p>	<ul style="list-style-type: none"> • Scope, principles and definitions • Access • Consistency, complementarity and non-duplication • Governance and general provisions
<p>Industry and innovation stakeholders e.g., vaccine, therapeutic and diagnostic (VTD) researchers, developers and manufacturers biomanufacturing specialists, biotech company representatives innovation policy experts and researchers</p>	<ul style="list-style-type: none"> • Scope, principles and definitions • Benefit-sharing