Article 12: Vice Chair and Co-Facilitators' proposed PABS design elements
14 February 2024

Background

The proposed design elements were discussed in informal consultations and two subgroup meetings on 31 January and 1 February 2024. This version was revised based on comments and suggestions from the two subgroup meetings. This version was discussed at length with information from experts in the area of GSD databases at the subgroup meeting on 12 February (whole day). There was no general agreement across INB in the subgroup on the design elements. At the closure of the meeting, the subgroup decided to continue dialogue at the subgroup meetings during INB8.

To strengthen pandemic prevention, preparedness and response, the proposed multilateral PABS system should achieve the two objectives of:

1. Rapid, systematic and timely access to pathogens and GSD, which contributes to strengthened global surveillance and risk assessment, and facilitates R&D, innovation and development of health products; and
2. On an equal footing, equitable, fair and rapid sharing of monetary and non-monetary benefits from the use of pathogens and GSD, including timely, effective and predictable access to health products, based on public health risks and needs.

In order to meet the objectives, the system should be consistent with the objectives of the CBD and Nagoya Protocol; provide legal certainty; have the maximum possible participation; and be simple, practicable, and transparent. All Parties will contribute to strengthening and sustaining relevant capacities for the effective operation of the PABS System, towards the global public good and global health security.

Key elements of PABS design

1. PABS coverage

Recognising Member States' sovereign rights over genetic resources, and mindful of the importance of ensuring access to human pathogens for public health preparedness and response purposes, the PABS System will cover biological materials[1] and genetic sequence data (GSD) for *pathogens with pandemic potential*[2].

[1] Possible definition of biological materials (as used for WHO Bio Hub): clinical samples, specimens, isolates, and cultures, either original or processed, of a pathogen.
[2] Possible definition of pathogen with pandemic potential: any pathogen that has been identified to infect a human and that is: novel (not yet characterised); or known (including a variant of a known pathogen), potentially highly transmissible and/or highly virulent and could cause a PHEIC. *(Note: need to consider further in relation to ongoing discussions in the WGIHR and INB on defining a pandemic or pandemic emergency as well as early action alerts)*.

2. Access

2.1 Upon becoming aware of *pathogens with pandemic potential* within its territory, each Party will, using applicable biosafety, biosecurity and data protection standards:

2.1.1 Immediately share with WHO any sequence information known to the Party;[3] and

2.1.2 As soon as biological materials are available, provide the materials to one or more laboratory/ies and/or biorepository/ies participating in *WHO-Coordinated Lab Networks (CLNs)* (any relevant WHO-coordinated laboratory alliances or networks per established ToR and modalities for technical collaboration[4]); and

2.1.3 As soon as pathogen GSD is available, upload the GSD and relevant metadata to one or more *WHO-recommended PABS Sequence Database/s (SDBs)* (publicly accessible databases to be recommended by WHO per established modalities for technical collaboration[5], with arrangements to promote accountability and transparency, including notification that GSD uploaded is covered by the PABS System with applicable benefit sharing requirements).

2.2 The PABS System will promote the sharing of biological materials and GSD through the CLNs and SDBs. Parties consent to the further transfer and use of materials and GSD provided to the CLNs and SDBs, subject to applicable biosafety, biosecurity and data protection standards, modalities for technical collaboration and the benefit sharing requirements below. Intellectual property rights may not be sought on biological materials and GSD provided to the CLNs and SDBs.

3. Benefit sharing

3.1 Manufacturers (including those under licensing agreements) commercially producing vaccines, therapeutic or diagnostic products for *pathogens with pandemic potential* will provide:

3.1.1 Annual monetary contributions, of an amount based on the size and nature of the manufacturer, to support the PABS system and strengthen pandemic prevention, preparedness and response capacities in countries in line with Articles 19 and 20; and

3.1.2 In kind contributions, based on the size and nature of the manufacturer, such as capacity- strengthening activities, arrangements for transfer of

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[3] *Note: need to consider in relation to IHR Article 6 and related discussions.*

[4] Regulations for study and scientific groups, collaborating institutions and other mechanisms for collaboration (https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf#page=170).

[5] Regulations for study and scientific groups, collaborating institutions and other mechanisms for collaboration (https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf#page=170).

technology and know-how in line with Article 11, and/or scientific and research collaborations; and

3.1.3 During a PHEIC or a pandemic,[6] real time contributions of relevant diagnostics, therapeutics and/or vaccines (X% free of charge and X% at not-for-profit prices), to be made available upon request by WHO and delivered, through the mechanisms set out in Article 13, for equitable allocation on the basis of public health risk, need and demand.

These contributions will be set out in legally binding *standard PABS contracts*.

3.2 Those who use shared biological materials and GSD for commercial purposes that are not manufacturers will be expected to consider voluntary contributions to support management and implementation of the PABS System.

3.3 Those who use shared biological materials and GSD for non-commercial purposes will be required to appropriately acknowledge, in presentations and publications, the laboratories/Parties providing biological materials and GSD; and expected, as appropriate, to actively engage in scientific and academic collaborations, training and capacity strengthening activities, contribute to public dissemination and transparency of research results, and consider voluntary contributions to support management and implementation of the PABS System.

3.4 Additional to relevant diagnostics, therapeutics and/or vaccines provided by manufacturers as set out above, during a pandemic or a PHEIC, Parties in a position to do so will make relevant products available for equitable allocation on the basis of public health risk, need and demand.[7]

3.5 All Parties will benefit from strengthened surveillance, risk assessment, and early warning information, services, coordination and cooperation.

4. Implementation and governance

4.1 Implementation of the PABS System will begin when the WHO CA+ is adopted. The access and benefit sharing provisions will come into full effect simultaneously when the WHO DG, in consultation with the *PABS Advisory Committee* (an independent committee of recognised experts reflecting regional representation, gender balance, and balanced representation between developed and developing countries) determines that the CLNs and SDBs are ready as outlined in sections 2.1.2 and 2.1.3, and the coverage of legally binding standard PABS contracts as outlined in section 3.1 is sufficient to ensure large-scale and continuous benefit sharing. The PABS System is intended as a specialized international access and benefit-sharing instrument within the meaning of Article 4.4 of the Nagoya Protocol, and the Parties will implement it as such at the domestic level through the necessary legislative, administrative or policy measures.

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[6] *Note: need to consider further in relation to ongoing discussions on defining a pandemic or pandemic emergency as well as early action alerts.*

[7] *Note: need to consider further in relation to ongoing discussions on defining a pandemic or pandemic emergency as well as early action alerts.*

4.2 The Parties will cooperate and take appropriate measures to encourage and facilitate as many manufacturers as possible to enter into standard PABS contracts as early as possible, and to encourage and facilitate benefit sharing through other means until a standard contract is signed, such as conditions in public procurements or on public financing of research and development, prepurchase agreements, regulatory procedures or other appropriate measures.

4.3 The Parties will cooperate to support the effective operation of the PABS System, including by taking all necessary steps to facilitate the sharing of biological materials, and the export of necessary health products during a PHEIC or pandemic[8], in accordance with applicable international law

4.4 The governing body will oversee the implementation of the PABS System, and will regularly review its operation, performance, relevance and effectiveness. The WHO DG, supported by the PABS Advisory Committee, will report regularly to the governing body for this purpose.

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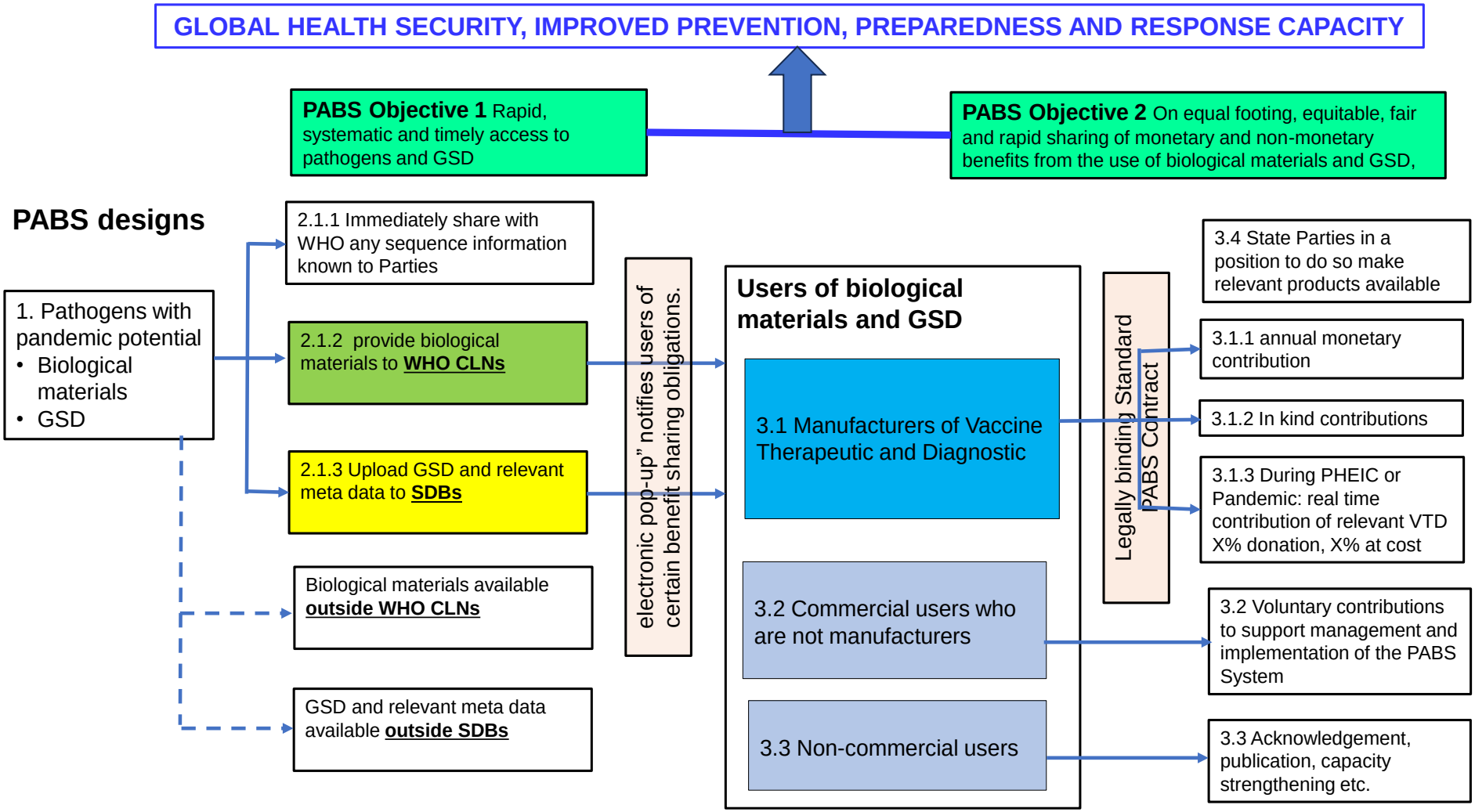
[8] *Note: need to consider further in relation to ongoing discussions on defining a pandemic or pandemic emergency as well as early action alerts.*


GLOBAL HEALTH SECURITY, IMPROVED PREVENTION, PREPAREDNESS AND RESPONSE CAPACITY
PABS Objective 1 Rapid, systematic and timely access to pathogens and GSD
PABS Objective 2 On equal footing, equitable, fair and rapid sharing of monetary and non-monetary benefits from the use of biological materials and GSD,
PABS designs
1. Pathogens with pandemic potential
• Biological materials
• GSD
2.1.1 Immediately share with WHO any sequence information known to Parties
2.1.2 provide biological materials to WHO CLNs
2.1.3 Upload GSD and relevant meta data to SDBs
Biological materials available outside WHO CLNs
GSD and relevant meta data available outside SDBs
electronic pop-up" notifies users of certain benefit sharing obligations.
Users of biological materials and GSD
3.1 Manufacturers of Vaccine Therapeutic and Diagnostic
3.2 Commercial users who are not manufacturers
3.3 Non-commercial users
Legally binding Standard PABS Contract
3.4 State Parties in a position to do so make relevant products available
3.1.1 annual monetary contribution
3.1.2 In kind contributions
3.1.3 During PHEIC or Pandemic: real time contribution of relevant VTD X% donation, X% at cost
3.2 Voluntary contributions to support management and implementation of the PABS System
3.3 Acknowledgement, publication, capacity strengthening etc.