- Modalities and requirements for sharing (including laboratory requirements for handling materials, mechanisms for rapid shipment of materials, etc)

- Provisions to strengthen, facilitate and accelerate research and innovation

- Provisions to ensure "rapid and timely sharing" of PABS Sequence Information (obligations for Parties)

- Modalities and requirements for sharing (including mechanisms to enhance analysis of SI, etc)

- Provisions to strengthen, facilitate and accelerate research and innovation

4. GOVERNANCE ISSUES

Terms for the administration and coordination of the PABS System by the World Health Organization

Collaboration with relevant international organizations and relevant stakeholders

- Modalities for collaboration
- Possible dedicated consultative body

Role of the Conference of the Parties and possible future periodic reviews of the PABS System.

5. GENERAL AND FINAL PROVISIONS

Relationship / consistency of PABS System with other international instruments or with applicable domestic law

- Requirements to ensure that the PABS Annex shall be consistent with, and not run counter to, the objectives of the Convention on Biological Diversity and the Nagoya Protocol
- Requirements to ensure that national and/or regional ABS measures that are contrary to or inconsistent with or duplicative of the PABS System will not be applied
- Consistency 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

- Legal relation with the PIP Framework
- Legal relation with other relevant international access and benefit sharing instruments (in particular the multilateral mechanism for DSI on genetic resources)

Provisions aimed at facilitating and accelerating research and innovation

- Open access to data
- Traceability (including purpose, scope, technical feasibility and cost)

Entry into operation ("All elements of the PABS System shall come into operation simultaneously in accordance with the terms of the PABS Instrument") o Criteria for the entry into operation

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JAPAN

https://apps.who.int/gb/igwg/pdf_files/IGWG2-initial-text-proposals/Japan.pdf

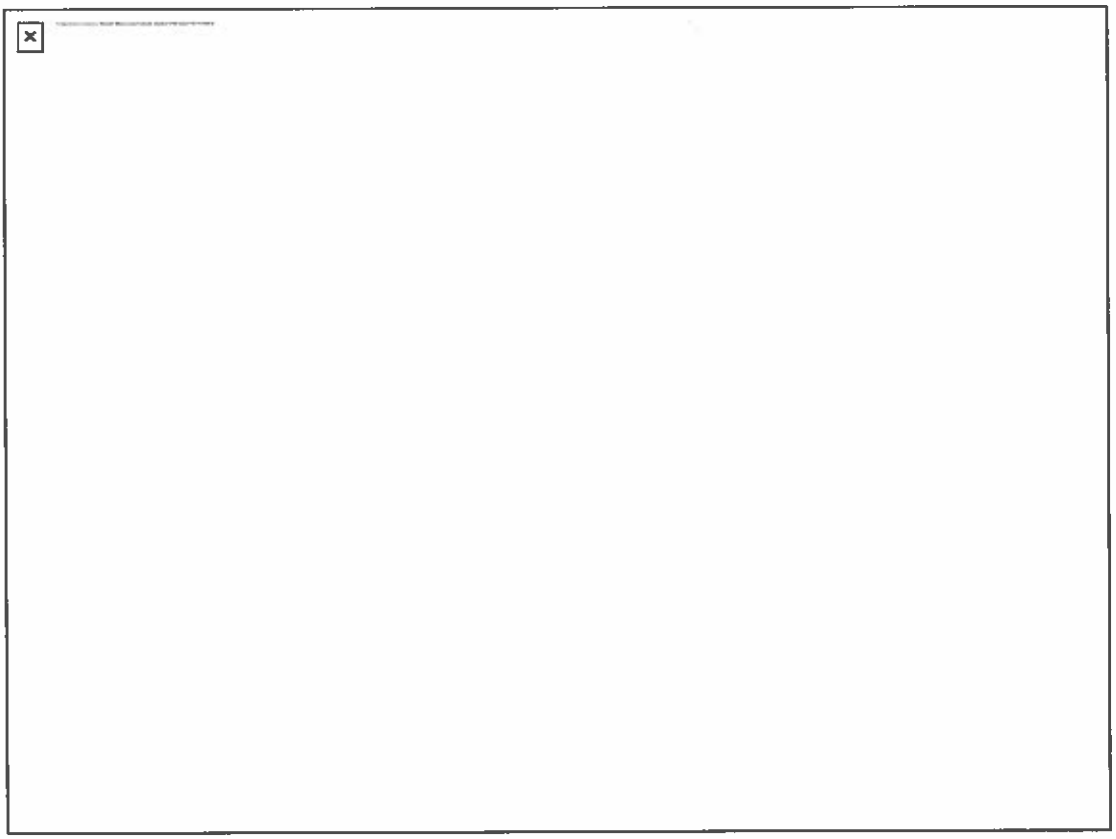
Submission by Japan

August 8, 2025

Key structural issues to be addressed for the PABS system

Based on the discussion at the first and organizational meeting of the IGWG in July 2025 and in pursuance of paragraph 2 of A/IGWG/1/3 Rev.1 ("Timeline and deliverables of the open-ended IGWG"), the Government of Japan hereby submits its initial input aiming to support the IGWG's work to develop an outline of elements to be addressed in the PABS Annex. Our input is in the form of a diagram or chart as attached herewith in Page 2, capturing key elements provided for in Article 12 of the Pandemic Agreement. This input is without prejudice to Japan's further inputs and proposals, and we reserve our right to

make any revisions or new proposals subsequently during the IGWG process. The Government of Japan looks forward to working with other participants in IGWG process on developing an effective PABS system and the PABS Annex.



WHO Pandemic Agreement

Key structural issues to be addressed for the PABS System

To shape the structure of the PABS System, Japan proposes, in the first place, to focus on the basic elements, including those outlined here.

What needs to be shared?

Definitions of:

"Pathogen with pandemic potential"

"PABS Materials"

"PABS Sequence Information"

When should PABS Materials and Sequence Information be shared?

Pandemic Emergency/PHEIC/Outbreak/Inter-pandemic period

Trigger/Timing of sharing PABS Materials and Sequence Information

Who will be involved?

Definition of "participating manufacturer"

When should benefits be shared? Until when?

Where to store PABS Materials?

Where to register Sequence Information?

Whom to distribute"

(Criteria for identifying public health risks and needs?

What countries are in need?

How to share PABS Materials and Sequence Information with WHO?

When to conclude contracts?

(Prior to or during a pandemic?)

What are the benefits to be shared?

Vaccines, Therapeutics and Diagnostics

Monetary contributions

Additional benefits

How to operate/administer the PABS System?

Role of the Secretariat?

Relationship with other ABS instruments

Financing

MALAYSIA

https://apps.who.int/gb/igwg/pdf_files/IGWG2-initial-text-proposals/Malaysia.pdf

Submission of Text Proposal on the Annex on Pathogen Access and Benefits-Sharing (PABS Annex) of the WHO Pandemic Agreement

Submitted by: Government of Malaysia Date: [10 August 2025]

Note: this submission presents elements as requested, however it is without prejudice to any additional proposals on elements or textual suggestions as the discussion progresses.

SECTION 1: OBJECTIVE, SCOPE, AND USE OF TERMS

Article 1: Objective

To establish a safe, transparent and accountable multilateral WHO Pathogen Access and Benefit Sharing System pursuant to Article 12 of the Pandemic Agreement.

Article 2: Scope

The Annex applies to the rapid and timely sharing of "materials and sequence information on pathogens with pandemic potential" (hereinafter "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.

Article 3: Use of Terms

For the purposes of the Annex:

a. "Competent National Authorities (CNAs)" are government ministries, agencies, or other entities formally designated by each State, in accordance with its national laws and regulations, to exercise regulatory, supervisory, and enforcement functions with respect to the implementation of this Annex. CNAs shall be responsible for granting necessary authorizations, overseeing compliance with biosafety, biosecurity, and benefit-sharing requirements, coordinating with the National Focal Point (NFP) and the WHO, and ensuring that all activities involving PABS Materials and Sequence Information within their jurisdiction are conducted in conformity with this Annex, applicable international obligations, and domestic legal frameworks.

b. "Cybersecurity" refers to [placeholder]

c. "Cyberbiosecurity" refers to [placeholder]

d. "Data Access Agreements (DAAs)" refer to legally binding or standardized contractual instruments) from all users of database intending to access PABS Sequence Information established under the PABS System to govern the access, use, sharing, and management of PABS Sequence Information provided by Member States, laboratories, or other authorized entities. DAAs set out the rights, obligations, and conditions for recipients, including safeguards for data security, confidentiality, integrity, availability, and conditions relating to intellectual property; obligations to ensure rapid and transparent sharing of results; and mechanisms for equitable benefit-sharing.

e. "Digital Object Identifiers (DOIs)" are unique, persistent alphanumeric string assigned to a specific digital object, such as a dataset, sequence, publication, or other electronic record, which provides a permanent link to its location on the internet and enables reliable identification, citation, and

tracking of the object over time, even if its underlying location or metadata changes.

f. "National Focal Point (NFPs)" are entities designated by each Provider State, in accordance with national laws and/or domestic laws, policies and regulations, to act as the primary authority responsible for authorizing, coordinating, and monitoring the release, transfer, and reporting of PABS Materials and Sequence Information. NFPs shall serve as the official liaison between the Provider State, WHO, and other relevant stakeholders, ensuring that all transfers and uses of PABS Materials and Sequence Information are conducted in compliance with the provisions of this Annex, applicable international obligations, and national legal requirements.

g. "Pathogen Access and Benefit Sharing System" refers to [placeholder]

h. "Pathogens with pandemic potential" is any pathogen that is novel (not yet characterized) or known (including a variant of a known pathogen), is highly transmissible human to human and can cause a pandemic emergency as defined in the IHR.

i. "PABS Materials and Sequence Information"

i. "PABS Materials" refers to live isolates of pathogens with pandemic potential, and parts thereof, modified pathogens, and any other materials derived from, generated or prepared using the PABS Materials.

ii. "PABS Sequence Information" shall include genetic, genomic, and proteomic data, including full or partial sequences, annotations, synthetic data, and digital sequence information (DSI), necessary for scientific utility.

j. "Participating manufacturer" means public or private entities including academic institutions, government owned or government subsidized entities, non-profit organizations or commercial entities that develop and/or produce vaccines, therapeutics and diagnostics for pathogens with pandemic potential and has entered into legally binding contracts with WHO for accessing PABS Material or Sequence Information.

k. "Standard Material Transfer Agreements (SMTAs)" are standardized, legally binding contracts adopted under the PABS System to regulate the transfer, receipt, and use of Pathogen Materials (including clinical specimens, isolates, and derivatives) between providing entities (such as Member States, laboratories, or biorepositories) and receiving parties (including manufacturers, research institutions, or public health agencies). SMTAs specify the rights and obligations of all parties, including conditions for use, restrictions on onward transfer, intellectual property considerations, requirements for transparency, and benefit-sharing commitments (monetary and non-monetary).

Article 4: Access to PABS System

1. Access to the PABS System shall be governed by Standard Material Transfer Agreements (SMTAs) and Data Access Agreements (DAAs). These agreements ensure traceability, transparency, biosafety and biosecurity, legal certainty, compliance with national laws and/or domestics laws and policies, and fair and equitable benefit-sharing. All access shall be guided by the principles of Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) to respect national sovereignty and ensure fairness. Signed SMTAs and DAAs imply PIC and MAT with respect to specific resources covered under PABS System for PABS purposes specified in those agreements. For PIC and MAT for any other use beyond those specified purposes, the recipients have to approach provider country's competent national authority.

2. Each State Party shall designate National Focal Point (NFP) or other competent national authorities, as appropriate, to authorize the release and facilitate the transfer of PABS Materials and Sequence Information in accordance with the provisions of this Annex. Each State Party shall conduct risk assessment prior to any sharing of PABS Materials and Sequence Information.

3. Access to PABS System shall be subject to the following structure, whereby:

a. Nationally authorized laboratories forming a network coordinated by WHO to provide and access PABS Materials after signing SMTA1.

b. Entities/Persons outside this network of national authorized laboratories may seek access to PABS materials by signing an SMTA2 with WHO. Such SMTAs should specify PABS Materials, purposes and benefits arising therefrom.

c. Access to WHO sequence database shall be available to all registered users, on a non-discriminatory basis subject to acceptance of DAA.

4. WHO Collaborating Centres and designated National Reference Laboratories within a WHO coordinated laboratory network for sharing PABS Material and Sequence Information shall serve as the primary hubs for the receipt, storage, and redistribution of such materials. Sequence Information shall be deposited, managed, and disseminated exclusively through a WHO database, which shall maintain secure, transparent, and auditable systems for access and use, ensuring that such sharing is conducted in a manner that is consistent with the PABS system and traceable.

5. Only authorised national laboratories that agrees to accept the Terms of Reference (ToR), shall be authorized to share PABS Materials under this Annex.

6. PABS Sequence Information shall only be deposited in and accessed through WHO database, operating under governance rules designed to uphold transparency, equity, and the rights of State Parties. Such rules shall include, at a minimum:

a. Mechanisms to protect provider country rights, including acknowledgment and tracking of all downstream uses of the Sequence Information;

b. Mandatory user registration and acceptance of legally binding Data Access Agreement (DAA), including provisions on benefit-sharing obligations arising from the sharing/utilization of the Sequence Information; and

c. Digital traceability through the assignment of persistent identifiers, such as Digital Object Identifiers (DOIs), for each uploaded sequence to ensure accountability and auditable use. Users should be under an obligation not to remove such identifiers.

Article 5: Responsibility of WHO and COP

1. WHO under the guidance and authority of Conference of Parties to the WHO Pandemic Agreement shall provide the infrastructure for the PABS System, ensuring it is functional, transparent, and accessible to all Parties.

2. WHO shall be responsible for managing and maintaining global registries of PABS Materials and Sequence Information; coordinating the collection, allocation, and disbursement of monetary and non-monetary benefit-sharing contributions; and overseeing and verifying compliance with Standard Material Transfer Agreements (SMTAs), Data Access Agreements (DAAs), and benefit-sharing commitments.

3. WHO shall record and monitor all accesses, transfers and uses of PABS Materials and Sequence Information, tracking each item from its source through to final use and disposition. Each material sample and data entry shall be assigned a unique identifier, such as a barcode or Digital Object Identifier (DOI), to enable full traceability.

Article 6: Safe Transfer of PABS Materials

1. All transfers of PABS Materials shall be undertaken in strict compliance with biosafety and biosecurity protocols approved by the WHO, utilizing couriers certified to handle materials at Biosafety Level 2 or 3, as appropriate. Prior to any transfer, the transferring entity shall ensure the use of tamper-proof and secure packaging, and maintain a complete chain-of-custody record to guarantee the integrity and traceability of the materials. The provider and the WHO Collaborating Centre shall be notified, in a timely manner, of the receipt and final disposal of such materials to ensure transparency, oversight, and compliance with applicable provisions of this Annex.

2. All parties involved in the transfer, including the sender, transporter, and recipient, shall maintain adequate liability coverage to address any incidents, accidents, or damages that may arise during the transfer process.

3. WHO should cover the costs of shipment incurred by developing countries.

Article 7: Rapid and Timely Sharing of Benefits

1. Benefits arising from the use of PABS Materials and Sequence Information shall be shared without undue delay at three key stages:

a. At the onset of a disease outbreak having potential to become a pandemic emergency or Public Health Emergency of International Concern (PHEIC): Through the rapid deployment of vaccines, therapeutics, and diagnostics (VTD), accompanied by immediate financial and technical support to affected developing countries to ensure equitable access and timely response as well as licensing for diversification of manufacturing to developing countries, to address shortage of supplies;

b. At all times: regular building and management of national, regional or international stockpiles, and support for strengthening health systems, laboratory capacity and research and development infrastructure, and manufacturing readiness, particularly in developing countries; and

c. Post-pandemic period: Through sustained financial and other support to be identified aimed at building resilient health systems diversifying production and replenishing regional and global stockpiles of VTDs.

2. WHO shall coordinate and oversee the establishment of transparent timelines and mechanisms to track the provision, allocation, and delivery of such benefits, including VTDs, in accordance with this Annex.

3. All recipients of PABS Materials and Sequence Information shall agree to contribute to monetary and non-monetary benefits as detailed in the respective SMTAs and DAAs they sign, depending upon their type of use of PABS Materials and Sequence Information. SMTAs and DAAs should detail out operational aspects of these benefits, for instance, set-asides of VTDs to be shared during Pandemic Emergencies and PHEICs and triggers for such benefit sharing.

Article 8: Monetary Contributions to the PABS System

1. Monetary contributions to the PABS Fund shall be made by recipients of PABS Materials and Sequence Information engaged in generating revenue from the direct and indirect use of PABS Materials and Sequence Information, including laboratories, institutions, researchers, developers and manufacturers of

vaccines, therapeutics, and diagnostics (VTDs). They shall commit to provide such contributions by signing SMTAs and DAAs.

2. Annual monetary contribution is based on the revenue generated from the commercialization of products and services, directly or indirectly, from using the PABS system, in accordance with rates and thresholds to be determined and set out in implementing arrangements.

3. Funds collected pursuant to this Article shall be allocated, in a transparent and equitable manner, based on public health risk and need, with priority to countries most severely affected by the pandemic, to developing countries lacking domestic manufacturing capacity, and to WHO-coordinated mechanisms for stockpiling, logistics, and the equitable global distribution of vaccines, therapeutics, and diagnostics (VTDs) and as further determined.

Article 9: Non-Monetary Contributions

1. Recipients of PABS Materials and Sequence Information shall, through legally binding contracts with WHO, commit to providing non-monetary contributions to support equitable access and pandemic preparedness, including:

a. In case they develop/produce VTDs:

1. [x]% of real-time production to WHO to respond to public health risks and events.
2. [Y]% of real-time production to WHO during PHEICs.
3. [10+10]% to WHO during pandemic emergencies as per Article 12.
4. Granting of non-exclusive licenses to developing country manufacturers through WHO.

b. In case of other users:

1. building new surveillance technologies – to provide affordable access to such technologies;
2. building new prediction softwares in epidemiology – to provide affordable access to such softwares;
3. universities that undertake cutting edge research – to provide partnerships and research collaborations etc.

2. Such contributions shall be monitored, enforced, and reported by WHO to ensure compliance with the provisions of this Annex and to facilitate equitable benefits haring across all participating States.

Article 10: Facilitation of Manufacture and Export

WHO and Member States shall take all necessary measures to facilitate the timely manufacture and global availability of vaccines, therapeutics, and diagnostics (VTDs) produced under the PABS System, including measures that will facilitate export clearances on faster and priority basis.

Article 11: Allocation and Distribution of VTDs

1. WHO shall determine allocation and distribution of VTDs, under guidance of COP, including through the Global Supply Chain and Logistics (GSCL) Network, to ensure that donated and purchased VTDs are distributed equitably based on public health need.

2. Decisions on the allocation and distribution of VTDs under this Article shall be guided by transparent and equitable criteria, including:

a. Epidemiological risk, taking into account the incidence, transmissibility, and severity of the pathogen of concern;

b. Economic vulnerability, with particular priority afforded to developing countries and other resource-limited or marginalized settings; and

c. Proximity to outbreaks and population density in affected or at-risk areas, to ensure timely and proportionate allocation based on public health need.

SECTION 3: GOVERNANCE OF THE PABS SYSTEM

Article 12: Governance Mechanisms

1. The PABS System shall operate under a multi-tiered governance structure designed to ensure transparency, equity, and accountability, comprising the following elements:

2. The Conference of the Parties (COP) to the WHO Pandemic Agreement shall establish a dedicated PABS Secretariat, which shall be responsible for

managing and maintaining global registries of PABS Materials and Sequence Information; coordinating the collection, allocation, and disbursement of monetary and nonmonetary benefit-sharing contributions; and overseeing and verifying compliance with Standard Material Transfer Agreements (SMTAs), Data Access Agreements (DAAs), and benefit-sharing commitments. The PABS Secretariat shall exercise its functions in full respect of national laws, sovereignty, and applicable international obligations, working in partnership with the competent authorities of Provider States.

3. The Conference of the Parties (COP) to the WHO Pandemic Agreement shall inter alia approve strategic priorities, operational policies, and budgetary allocations for the PABS System; ensure the timely and equitable distribution of vaccines, therapeutics, and diagnostics (VTDs) based on public health risk and equity considerations; and review and take decisions on the annual PABS implementation and performance report prepared by the PABS Secretariat.

4. Day-to-day operations of the PABS System shall be coordinated and administered by the WHO, including conducted through WHO-designated laboratories, comprising national and regional reference laboratories responsible for the receipt, handling, and redistribution of PABS Materials; WHO global databases for the secure storage and dissemination of PABS Sequence Information; and distribution centres responsible for the storage and delivery of stockpiled or donated vaccines, therapeutics, and diagnostics (VTDs). All such operational laboratories shall, as a condition of designation and continued participation, comply with internationally recognized biosafety and biosecurity standards, transparency requirements, and reporting obligations as set forth in this Annex.

5. Under the authority of COP, WHO acting as PABS Secretariat, shall ensure the PABS System is functional, transparent, accountable to all Parties. WHO's role will typically include:

a. Establish and maintain the central governance and coordination platform for the PABS System, including oversight of registries, data standards, and compliance mechanisms.

b. Act as the neutral intermediary between Provider (who share PABS Materials and Sequence Information) and Recipients (e.g., manufacturers, research institutions) to ensure equitable access and benefit-sharing.

c. Develop, host, and maintain the WHO PABS Sequence Information Database – a secure, standardized global database for PABS Sequence Information, accessible to Parties and registered users that have accepted DAAs.

d. Manage digital registries and traceability systems, including Digital Object Identifiers (DOIs) for samples and sequence information, to track material and sequence use and enforce benefit-sharing obligations.

e. Provide secure digital platforms for Standard Material Transfer Agreements (SMTAs) and Data Access Agreements (DAAs).

f. Coordinate WHO-led global stockpiling and distribution mechanisms for vaccines, diagnostics, and therapeutics (VTDs) during pandemic emergency or PHEICs and to prevent such occurrences.

g. Support rapid and secure shipment logistics for PABS Materials, especially for emergency response and R&D needs.

h. Provide training, infrastructure funding, and technical support to national laboratories, sequencing centres, and manufacturing hubs (particularly in developing countries).

i. Facilitate technology transfer and local production capacity-building to promote equitable access and self-reliance.

6. WHO shall establish and maintain a publicly accessible roster of all manufacturers participating in the PABS System. This roster shall include, at a minimum:

a. Information on each manufacturer's production capacity for vaccines, therapeutics, and diagnostics (VTDs);

b. Details of their monetary and in-kind contributions, including dose donations and licensing arrangements; and

c. Records of their compliance with the obligations set forth in this Annex, including adherence to benefit-sharing, licensing, and reporting requirements.

7. The PABS System shall undergo independent and periodic monitoring and evaluation to assess the effectiveness and functionality of access and benefit-sharing mechanisms, the equity and timeliness of monetary and non-monetary benefit delivery, and the compliance of all participating manufacturers, laboratories, and databases with the obligations set forth in this Annex. Findings of such evaluations shall be compiled in public reports and shared with all WHO Member States to ensure transparency, accountability and continuous system improvement.

SMTAs and DAAs

1. Ensure compliance with all applicable biosafety and biosecurity standards, and fulfill mandatory reporting obligations, including the notification of the source, characteristics, and movements of PABS Materials and Sequence Information,
2. Cooperate fully with WHO, PABS Secretariat and the National Focal Point (NFP) to ensure the traceability of PABS Materials and Sequence Information, and to facilitate the monitoring, enforcement, including the use of registries, digital object identifiers (DOIs), and other mechanisms for tracking and verification.
3. Ensure full compliance with cyber biosecurity standards, and fulfil mandatory reporting obligations, including disclosure of utilization, and downstream development of PABS Materials and Sequence Information in accordance with the procedures established under the PABS System;
4. Cooperate fully with WHO to fulfill all monetary and non-monetary benefit sharing requirements as stipulated in Standard Material Transfer Agreements (SMTAs), Data Access Agreements (DAAs), or other legally binding instruments under the PABS System.
5. Submit summary reports to WHO detailing their use, transfer, and disposition of such materials and data as specified in SMTAs and

DAA, including reports on analysis, risk assessment and other test results. Non-compliance with reporting or traceability obligations shall trigger enforcement measures as specified under this Annex.

6. Not be used in any activity that may lead to the development, or production of biological agents, toxins, weapons, equipment, or means of delivery specified in Biological Weapons Convention;
7. Acknowledge the contributions of the persons and institutions who submitted the PABS Sequence Information as well as the originating laboratories that first collected the clinical specimen and isolated the pathogen with pandemic potential;
8. Not seek or assert intellectual property over PABS Sequence Information and PABS Materials, or parts thereof, in any form, including any modified forms or for any use;
9. Share full regulatory data for accelerating regulatory approvals in at risk countries.

RUSSIAN FEDERATION

https://apps.who.int/gb/igwg/pdf_files/IGWG2-initial-text-proposals/Russian_Federation.pdf

Draft as of 10 July 2025

Structural elements of Article 12 of the WHO Pandemic Agreement

Note - In general, the paragraphs of Article 12 of the WHO Pandemic Agreement are represented at the section level for ease of cross-reference and transparency.

Section A – Scope (Article 12.1)

The rapid and timely sharing of "materials and sequence information on pathogens with pandemic potential" (hereinafter "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.

Section B bis - Biosafety, biosecurity, risk assessment, export control and data protection (Articles 12.1 and 12.5(e))

The key parameter for the effectiveness of the PABS System is to ensure that it operates in accordance with the highest requirements in the field of biosafety, biosecurity, risk assessment, export control and protection of data related to the exchange of pathogens with pandemic potential.

The PABS System provides for the distribution of pathogens with pandemic potential, which means that the distribution carried out by the PABS System may include threatening pathogens or high threat pathogens that are either already on the lists of states for export control or can be promptly added to such lists by them. In the event of the emergence of a pathogen with pandemic potential, the state (states) may promptly add it to the "List of Microorganisms..." subject to export control, and from the moment this decision comes into force, this microorganism and certain materials and technologies associated with it will become subject to export control requirements, including restrictions on its free transfer to third parties.

Biosafety, biosecurity and risk assessment

– Ensuring that recipient organizations of pathogens with pandemic potential have the necessary certified laboratory facilities, equipment, personnel, and have the appropriate national licenses and permits to carry out research work with the received pathogenic materials of the corresponding pathogenicity group.

– Laboratory work with and storage of received pathogens with pandemic potential should be carried out in strict compliance with national biosafety and biosecurity regulations and guidelines or in accordance with international regulations and guidelines (e.g. Laboratory Biosafety Manual, 4th edition. World Health Organization (2020)), if these are used as a basis for national regulations.

– In the absence of national biosafety and biosecurity regulations and certified laboratory facilities and personnel in the recipient country, pathogens with pandemic potential should not be transferred to such a country. This decision is made on the basis of a comprehensive risk assessment conducted by the country exporting pathogens with pandemic potential.

Export control

– Export control is a set of measures ensuring the implementation of the procedure established by national legislation for the implementation of foreign economic activity in relation to goods, information, works, services, results of intellectual activity (rights to them), which can be used in the creation of weapons of mass destruction, their delivery vehicles, other types of weapons and military equipment, or in the preparation and (or) commission of terrorist acts.

– The main objectives of export control are:

- Protecting the interests of the country exporting controlled goods and technologies.
- Implementation of the requirements of international agreements of the country-exporter of controlled goods and technologies in the area of nonproliferation of weapons of mass destruction, their means of delivery, as well as in the area of control over the export of military and dual-use products.
- Counteracting international terrorism.

– Requirements and restrictions in the area of export control apply to controlled goods and technologies - raw materials, materials, equipment, scientific and technical information, works, services, results of intellectual activity (rights to them), which, due to their characteristics and properties, can make a significant contribution to the creation of weapons of mass destruction, their delivery vehicles, other types of weapons and military equipment, as well as products that are particularly dangerous in terms of the preparation and (or) commission of terrorist acts.

– In the context of Article 12 of the WHO Pandemic Agreement and this PABS Instrument (Annex), controlled goods include pathogens with pandemic

potential that are included in the "Lists of Microorganisms, Toxins, Equipment and Technologies Subject to Export Control" adopted by countries that are party to the WHO Pandemic Agreement and countries that are party to the BTWC in accordance with their applicable national export control legislation.

In the event of transfer of pathogens with pandemic potential, that are not subject to export control, their exchange within the framework of the PABS System shall be carried out in accordance with other national legislation regulating the import and export of pathogenic microorganisms. –

The following restrictions apply to controlled pathogens with pandemic potential:

- Export from the exporting state to foreign states of controlled pathogens with pandemic potential is permitted for purposes not prohibited by the BTWC.

- Foreign economic transactions with controlled pathogens with pandemic potential, involving their transfer to foreign persons, are carried out on the basis of one-time or general licenses issued by the national agency responsible for export control.

- The decision to issue or refuse to issue a one-time license or permit is made on the basis of the results of the state examination of the foreign economic transaction, conducted in accordance with the established procedure by the national agency responsible for export control, together with other interested national agencies, as determined by national legislation in the field of export control.

- The agreement (contract, agreement) providing for the transfer of controlled pathogens with pandemic potential to a foreign party shall specify:

- the purpose and place of use of controlled pathogens with pandemic potential,

- end user of controlled pathogens with pandemic potential,

- obligations of a foreign person providing that the controlled pathogens with pandemic potential received by it:

1. will be used only for the stated purposes, not related to the creation of bacteriological (biological) weapons or the implementation of other activities prohibited by the BTWC;
2. will not be re-exported or transferred to anyone without the written permission of the participant in foreign economic activity from the exporting country, agreed upon with the national agency responsible for export control.

– If a foreign person is an intermediary, the obligations specified in subparagraphs a) and b) above shall also be assumed by the end user of controlled pathogens with pandemic potential, and the obligations may be drawn up in the form of a separate document.

– When transferring controlled pathogens with pandemic potential to states that are not parties to the BTWC, the obligations of the foreign person specified above in subparagraphs a) and b) must be confirmed by a document from the authorized body of the state in which the controlled pathogens with pandemic potential will be used.

– In the event of a violation by a foreign person of the obligations specified in subparagraphs a) and b) above, the national authority responsible for export control shall suspend the validity of issued and the issuance of new one-time licenses for the transfer of controlled pathogens with pandemic potential to that foreign person until the violation is corrected.

– Participants in foreign economic activity from the exporting country - licensees are obliged to immediately inform the national agency responsible for export control of the violation by a foreign person of the obligations provided for in paragraphs a) and b) above.

– A permit for re-export (transfer to a third party) of controlled pathogens with pandemic potential exported from the exporting country shall be issued to a foreign person by a participant in foreign economic activity from the exporting country in agreement with the national agency responsible for export control, or in accordance with another procedure established by national legislation in the field of export control.

– The decision to approve or refuse to approve re-export (transfer to a third party) is made by the national agency responsible for export control, based on the results of the state examination of the foreign economic transaction. The state examination of the foreign economic transaction is conducted in accordance with the established procedure by the national agency responsible for export control, together with other interested national bodies and agencies that previously participated in the state examination of the foreign economic transaction, based on the results of which a one-time license (permit) was issued to a participant in foreign economic activity from the exporting country.

Data protection

– Access to and protection of genetic sequence information on pathogens with pandemic potential contained in national genetic information databases shall be regulated in accordance with the national legislation of the countries that are party to the WHO Pandemic Agreement.

– Access to and protection of genetic sequence information on pathogens with pandemic potential contained in international genetic information databases shall be governed by the terms and conditions of such databases.

– In the absence in a country/territory of a national database of genetic information, including information on genetic sequences for pathogens with pandemic potential, access to such information shall be provided through the agreement on the terms of transfer between the country that is a party to the WHO Pandemic Agreement and the PABS System, taking into account the provisions of the PABS System.

Section B – Elements to be developed in the PABS System (Article 12.2 and 12.5)

(1) Definitions (Article 12.2) Pathogens with pandemic potential; (Article 12.2)

«Pathogen with pandemic potential» is a new (not yet characterized) or known (including variants) infectious agent (virus, bacterium or other microorganism) that possesses a set of biological characteristics that significantly increase its

likelihood of causing a global outbreak of disease (pandemic)/PHEIC. These characteristics include:

1. **High transmissibility** - the ability to be transmitted with high efficiency from person to person (for example, by airborne droplets, contact, fecal-oral route, etc.) under conditions of normal social interaction.
2. **Population vulnerability:** the ability to infect people who lack significant preexisting immunity (natural or vaccine-derived), making a large proportion of the population susceptible.
3. **Ability to spread widely:** potential for rapid and uncontrolled spread across international borders using modern transportation networks and globalized societies.
4. **Potential to cause high levels of morbidity and mortality:** potential to cause severe disease leading to serious health consequences (prolonged hospitalization, disability, death), creating excessive financial and social burden on health systems and society as a whole.
5. **Difficulties in control:** lack or limited availability of effective and widely applicable countermeasures (specific vaccines, effective treatments in the early stages of an outbreak).

PABS Materials and Sequence Information; (Article 12.2)

«Materials and information on the genetic sequences of the PABS» – pathogens with pandemic potential in the form of samples from people or animals (in the case of zoonotic or zooanthroponotic pathogens) or in the form of isolated cultures and information on the genetic sequences of these pathogens, received by the PABS System in the established manner.

«Genetic sequence (information)» – a sequence of nucleotides in nucleic acid polymers.

«Genetic data» – information on the genetic information of various biological objects, presented in a form suitable for obtaining (collecting), systematizing, accumulating, storing, clarifying (updating, changing), using, distributing (including transferring) and destroying such information.

Participating manufacturer (Article 12.6(a))

Other technical terms

1. blank
2. Modalities, terms and conditions on access and benefit sharing that provide legal certainty (Article 12.5(b))
3. Legal nature (Article 12.2)
4. Coordination and operation of the PABS System, in collaboration with relevant international organizations and relevant stakeholders (Article 12.2)
5. Administration and coordination of the PABS System by WHO (Article 12.2)
6. Sharing of material and sequence information and of benefits, both monetary and nonmonetary, including annual monetary contributions and vaccines, therapeutics and diagnostics (Article 12.5(a))
7. Facilitation and acceleration of research and innovation (Article 12.5(c))
8. Complementarity with the PIP Framework and other relevant ABS instruments (Article 12.5(d)(i))
9. Review and alignment of national and/or regional ABS measures (Article 12.5(d)(ii)) National and/or regional access and benefit-sharing measures are not identical to and do not replace export control legislation for controlled pathogens with pandemic potential.
10. Consistency with applicable law related to risk assessment, biosafety, biosecurity and export control of pathogens, and data protections (Article 12.5(e))
11. Facilitation of manufacture and export of vaccines, therapeutics and diagnostics (Article 12.5(f))

Section C – Traceability and open access to data (Article 12.3)

The provision of pathogens with pandemic potential is carried out in accordance with international rules (BTWC) and national legislation in the field of export control, with priority given to national norms and rules (in the case of the

transfer of controlled pathogens with pandemic potential) or other national legislation regulating the import and export of pathogenic microorganisms (in the case of the transfer of pathogens with pandemic potential that are not subject to export control).

The provision of information on the genetic sequences of PABS is carried out in accordance with international rules (in the case of international databases) and national legislation in relation to national databases of genetic information – with priority given to national norms and rules.

The free transfer of materials and information on the genetic sequences of the PABS is permitted only for scientific purposes. Commercial use of these materials and information requires a benefit-sharing agreement as defined in the PABS Instrument.

Section D – Consistency with Nagoya Protocol (Article 12.4)

The PABS instrument does not replace the Nagoya Protocol, but complements it in the event of pandemic emergencies and PHEICs, with the understanding that nothing in this paragraph creates obligations for States that are not parties to the Convention on Biological Diversity and/or the Nagoya Protocol.

Section E – Provisions in the event of pandemic emergency (Article 12.6)

1. Rapid access to real-time production of vaccines, therapeutics and diagnostics (Article 12.6(a))
2. Distribution of vaccines, therapeutics and diagnostics based on public health risks and needs, with particular attention to the need of developing countries (Article 12.65(b))

In distributing vaccines, medicines and diagnostics received by the PABS System, priority should be given to countries that have provided a pathogen with pandemic potential on the basis of or using which certain pandemic countermeasures have been developed. Further distribution of such resources is carried out depending on the level of risk to public health and public health needs, with particular attention to the needs of developing countries.

Section F – Provisions in the event of a public health emergency of international concern (Article 12.7)

In emergency situations involving the occurrence or risk of outbreaks of infectious diseases, in order to take measures to implement protective measures, a decision to issue a one-time license for the import of controlled pathogens with pandemic potential may be taken by the national agency responsible for export control, subject to the written consent of the federal executive body authorized to exercise functions for the control and supervision of infectious diseases.

Section G – Additional benefit-sharing provisions (Article 12.8)

Section H – Other elements for effective operationalization of the PABS System (Article 12.9)

The national agency responsible for export control, based on the results of the state examination of a foreign economic transaction, has the right to establish as a mandatory condition for the transfer of controlled pathogens with pandemic potential to a foreign person the acceptance by the end user of obligations to provide the participant in foreign economic activity from the exporting country with:

- The right to verify the use of obtained controlled pathogens with pandemic potential.
- Delivery confirmation certificate or other document issued by the authorized body of the state of end use, certifying the import of controlled pathogens with pandemic potential into the territory of its state.

SOUTH AFRICA

https://apps.who.int/gb/igwg/pdf_files/IGWG2-initial-text-proposals/South_Africa.pdf

10 August 2025

Draft Outline and Elements for the Pathogen Access and Benefit Sharing System Submission made by South Africa to the Intergovernmental Working Group

This submission is without prejudice to any further elements and textual proposals and/or modifications that may be placed from time to time.

I. Institutional/Structural Elements of PABS

I.1. Conference of Parties

The Conference of Parties (COP) to the World Health Organisation (WHO) Pandemic Agreement is the ultimate decision-making authority with respect to the Pathogen Access and Benefit Sharing (PABS) system. WHO coordinates and administers the PABS System under the authority and guidance of the COP.

The COP adopts, amends and periodically reviews the instruments and agreements used to implement the PABS System, including SMTAs/DAAs, Technical Standards (e.g., lab safety, transport of biological materials, cyber-biosecurity and persistent identifiers), a Revenue Calculation Annex and a Procurement Policy. The COP may complement, amend or replace instruments to improve implementation.

For legal certainty, the PABS Instrument forms an integral part of the Agreement and shall not weaken essential elements, namely: scope including DSI/derivatives; conditional access via standard agreements with flow-down obligations; minimum non-monetary and monetary benefit-sharing floors; transparency; and compliance/enforcement. The COP establishes and oversees a PABS Equity Fund.

I.2. WHO Secretariat serving as PABS Secretariat [PIP Framework Model]

Just as in the case of the PIP framework model, the WHO Secretariat acts as the PABS Secretariat. The staffing and other resources are to scaled up stage by stage, taking into account the development and unfolding of functionalities within the PABS system, as well as the scale of transactions and the revenue available for such purposes.

Core operational functions include: (a) coordinating the WHO Laboratory Network and operating the WHO Repository for PABS Sequence Information (WHO PSI Repository) with a first-deposition rule and controlled mirroring; (b) maintaining public dashboards on setasides, deliveries, prices and monetary contributions, and a public roster of participating manufacturers; (c) administering standard SMTAs/DAAs and ensuring flow-down to affiliates and contractors; (d) implementing the Procurement Policy; (e) arranging shipment and last-mile logistics support for deliveries to developing countries as approved by the COP; (f) conducting independent/regular monitoring and evaluation and supporting an operational simulation exercise for continuous improvement;

I.3. WHO Laboratory Network accountable to COP

Currently, various WHO-coordinated networks are addressing different aspects of infectious pathogens. Some of these networks entail the sharing of clinical specimens and pathogens, subject to acceptance of specific Terms of Reference and principles that set out the specific purposes and uses of the biological materials by the receiving laboratory. They also accept terms and conditions contained in a material transfer agreement that contains the terms and conditions for the handling and use of such materials.

The GISRS network of laboratories under Pandemic Influenza Preparedness Framework (PIP Framework) use a "Standard Material Transfer Agreement (SMTA 1)". They also have terms of reference and guiding principles that set out the specific tasks to be conducted with respect to PIP biological materials. Similarly, in the case of Biohub, Standard Material Transfer Agreements (SMTAs) govern the transfer of biological materials, accompanied by guiding principles. The SMTA has to be signed by the Provider, WHO Biohub facility and the WHO. In the case of WHO Coronavirus Network (CoViNet), to be a part of the reference laboratory, the laboratory has to meet certain criteria and accept specific Terms

of Reference that list the various tasks of the laboratory and the uses of materials received.

From these approaches, and especially that of the PIP Framework, an instrument negotiated by Member States, a laboratory has to meet specific criteria, accept specific terms of reference detailing specific tasks and accept the terms and conditions that sets out the rights and responsibilities of the laboratories in the network, as providers and recipients in order to become part of WHO. At the same time dealing with pathogens, including transporting them outside the borders has serious implications for national sovereignty and security, and therefore only authorized laboratories become part of such international network.

Accordingly, it is proposed that a network of national laboratories authorised by their governments or by their Competent National Authority (CNA) be set up for the sharing of pathogens with pandemic potential (PPP), coordinated by WHO. To be a part of the WHOcoordinated laboratory network (WHO lab network), national authorised laboratories shall meet COP-adopted criteria, accept specific Terms of Reference detailing tasks, and execute the standard WHO-Lab SMTA (and the DAA where PSI access is sought) as a pre-condition to access, with flow-down to affiliates, contractors, CROs/CMOs and any downstream recipients (one-time execution unless a Party requires a signed agreement). PSI generated shall be deposited first in the WHO PSI Repository pursuant to the DAA; onward sharing within the Network is recorded in a COP-mandated tracking system using persistent identifiers.

Existing WHO networks or laboratories from networks may also become part of the WHO network, provided the laboratories have authorization from their respective governments. In doing this, establishment of a PABS system also provides an opportunity to streamline and standardise existing approaches that currently exist with respect to handling of pathogens with pandemic potential by laboratories coordinated by WHO.

The WHO lab network may also have laboratories with different capacities such as WHO Collaborating Centres and WHO Reference laboratories with specific terms of reference, although the same SMTA shall apply. It is important to ensure that each region and subregion has sufficient laboratory capacity to

undertake the needed assessments and activities for prevention, preparedness and response of a health emergency. The COP and Secretariat shall support regional capacity development and periodic operational simulations to validate timelines, logistics and data workflows.

I.4. WHO PSI Repository and other authorised repositories (databases) accountable to COP

Another crucial issue in the PABS system is the sharing of PABS Sequence Information (PSI) generated from PABS Materials. Under the Convention on Biological Diversity and the Nagoya Protocol on Access and Benefit Sharing, sequence information generated from the genetic materials shall be regulated by the respective national legislations. There is also recognition of the need to share fair and equitable benefit sharing arising from the use of sequences.

In the case of the PABS system, there are five important pressing requirements: (i) to ensure that there is transparency and accountability to Parties providing the PSI and thus to the COP; (ii) to ensure PSI is made accessible without any form of discrimination, consistent with eligibility conditions and data-protection requirements; (iii) entities or persons accessing PSI have to agree (prior to access), to identify themselves and to use the PSI based on terms and conditions set out including to provide fair and equitable benefit-sharing; (iv) PSI remains comprehensively accessible via a WHO-designated point of first deposition with controlled mirroring (WHO PSI repository) and (v) to ensure PSI is not used in violation of national ABS laws, PABS instruments or for purposes beyond the PABS system, including by prohibiting removal of provenance tags and re-upload to non-authorised repositories.

To achieve these objectives, it is essential to establish a WHO PSI Repository and authorise other repositories or databases to host and disseminate PSI, under contracts with WHO and accountable to the COP.

The WHO PSI Repository shall ensure that PSI generated from PABS Materials is shared through a single WHO-designated point of first deposition and made accessible in accordance with COP-adopted instruments, rather than at the discretion of individual repositories or databases. Accessibility is provided through registered user accounts subject to a COP-approved Data Access

Agreement (DAA). The WHO PSI Repository and authorised repositories shall implement certain requirements in particular user registration, acceptance of the DAA (See III.3 below) as well as ensure the PSI is sufficiently labelled as PABS sequence information, using persistent unique identifiers (e.g., DOIs), which shall be tracked via audit logs.

Authorised repositories or databases may mirror PSI from the WHO PSI Repository only under WHO contracts that enforce the DAA, preserve provenance tagging, prohibit detagging and re-upload to non-authorised databases, and ensure interoperability via WHO brokered connectors to external registries (e.g., IP, regulatory and clinical-trial registries). The COP shall adopt the mandatory fields with respect to the metadata, including any provenance data such as origin or source etc. mentioned above and minimum cyber biosecurity controls and audit requirements;

I.5. Advisory Group

Advisory group comprising experts from Parties (fair representation from developed and developing countries) shall be established to advise WHO regarding the operations of the PABS System and make recommendations for decision-making by the COP. The Advisory Group shall have a mix of relevant expertise and operate in an open and transparent manner. Members shall disclose and manage conflicts of interest; meetings and recommendations shall be published. Terms of reference on the functions of the advisory group shall be established by the COP.

To align with operational needs, the Advisory Group shall: (a) review and advise on technical standards for PSI stewardship (first deposition, controlled mirroring, persistent identifiers, cyber-biosecurity); (b) review and recommend updates to SMTAs/DAAs and to the Procurement Policy; (c) review and advise on metadata schemas and interoperability connectors; and (d) review findings from independent M&E and operational simulations, making recommendations to the COP.

II. Definitions and The Scope

II.1. Definition of PABS Materials

The scope of PABS System as per Article 12 of WHO PA shall remain pathogens of pandemic potential i.e. pathogens that can cause a pandemic emergency. Further criteria for determination of pathogen with pandemic potential may be defined by COP.

PABS Materials means isolates of PPP, parts thereof, and any materials derived from, generated or prepared using such pathogens or their parts, including attenuated strains, vectors, cell lines, reference standards, and synthetic or computationally-generated constructs arising from PABS inputs, shared by laboratories authorised by the Competent National Authority (CNA) within the WHO Laboratory Network.

If clinical specimens are being shared, their use is limited to isolation of PPP necessary for public-health response covered under the SMTA. Any other use requires prior written consent of the Provider Party's CNA, and compliance with national law, ethics approvals and privacy protections.

II.2. Definition of PABS Sequence Information

PABS Sequence Information means digital sequence information and related data derived from PABS Materials or PSI, including information generated from the PABS Materials by using sequencing technologies, such as nucleotide (DNA/RNA) and amino-acid sequences, multi-omics (transcriptomic/proteomic), annotations, variant calls, consensus sequences, design files and associated metadata (including provenance), together with any computational outputs based on PABS inputs. Access to PSI is non-discriminatory but conditional on registration and execution of a Data Access Agreement (DAA); PSI is subject to first deposition in the WHO PSI Repository, controlled mirroring under WHO contracts, use of persistent identifiers (e.g., DOIs), and prohibitions on de-tagging and re-upload to non-authorised repositories.

II.3. Other definitions necessary for operational certainty inter alia

"Competent National Authority (CNA)" – the national authority designated to implement PABS, authorise participation in the WHO Laboratory Network, and liaise with WHO.

"Data Access Agreement (DAA)" – the COP-approved agreement governing access to and use of PSI, including user identification, traceability, preservation of provenance tags, flowdown obligations and benefit-sharing.

"Digital Object Identifier (DOI)" – a globally unique persistent identifier assigned to PSI records to enable interoperable traceability across repositories and registries.

"Cyber-biosecurity" – technical and organisational measures to protect the integrity, confidentiality and availability of biological data/systems; minimum controls adopted by the COP.

"Vaccines, therapeutics, and diagnostics for the pathogen causing the pandemic emergency," includes repositioned medicines, and related ancillary supplies used for prevention, preparedness and response

Clarify 'Participating manufacturer': include any entity that accesses or benefits from PABS inputs, directly or indirectly (affiliates, CROs/CMOs, licensees) involved in research, development or manufacturing VTDs, to close the "voluntary" loophole.

II.4. Scope of the PABS system

The scope of the PABS system **covers PPP and their PABS Materials and sequence information as defined above.**

PABS Materials and PSI are governed under the PABS system for the specific purposes set out in the standard agreements SMTA/DAA, i.e. for pandemic prevention, preparedness and response. Access is conditional on execution of the applicable SMTA/DAA with flow-down to affiliates, contractors, CROs/CMOs and downstream recipients ("no access without obligations"), and on compliance with first deposition, traceability and transparency requirements. Minimum benefit-sharing floors (real-time set-asides and revenue-linked contributions) apply as provided elsewhere in this submission. For any

purposes beyond PABS or outside the specified scope, national laws and regulations of the Provider Party shall apply.

III. Access to PABS Materials and Sequence Information

III.1. Transfer of PABS Materials with and within WHO Lab Network

III.1.1. Events Triggering Transfers

Nationally authorised laboratory within the WHO Lab Network may share PABS Materials with the WHO Lab Network, with immediate notification to the Provider CNA and the WHO Secretariat, based on its risk assessment of a disease causing pathogen as to whether such pathogen is of pandemic potential as defined.

III.1.2. Legally Binding Obligations applicable to transfer of PABS Materials with and within WHO Lab Network and Benefit-Sharing (signing of WHO-Lab Network SMTA required once)

The transfer of PABS Materials to a laboratory within the WHO Lab Network is subject to the standard WHO-Lab SMTA terms and conditions accepted upon enrollment and as updated by the COP/WHO. Execution of the WHO-Lab SMTA (and, where PSI access is sought, the DAA) is a pre-condition to access and applies with flow-down to affiliates, contractors, CROs/CMOs and any downstream recipients.

Compliance of the WHO Lab Network with the SMTA shall be monitored by the DirectorGeneral. In the event of non-compliance with the SMTA and the relevant ToR, appropriate action will be taken, including suspension or revocation of the WHO designation from the laboratory.

The WHO-Lab SMTA shall contain legally binding provisions including the following: ♣

1. compliance with the tasks and activities set out in the laboratory ToR; uses beyond the ToR are prohibited and the national laws of the Provider Country shall apply in such cases. ♣

2. benefit-sharing appropriate to laboratory functions, including non-monetary benefits (e.g., access to results, reference materials, training and technology packages) for Provider Countries, and cooperation to enable downstream monetary benefit-sharing where commercialisation occurs through the PABS Equity Fund. ♣
3. clarity that any further sharing of PABS Materials within the Network is subject to the same terms and conditions as applicable to WHO Lab Network and recorded in the tracking system described below. ♣
4. commitment not to share PABS Materials outside of the Network, unless the prospective recipient has signed the applicable material transfer agreement and, where PSI access is sought, the DAA; no onward transfer without flow-down of obligations. ♣
5. commitment to share sequence information only through the WHO PSI Repository with first deposition in that repository; agreement to comply with the Data Access Agreement (DAA) (see element III.3), including preservation of provenance tags, prohibition of detagging and re-upload to non-authorised databases, and use of persistent identifiers (e.g., DOIs) for traceability.
6. commitments with regard to intellectual property i.e. that there will be no IP claims on the shared materials, or on any other modified forms or uses of the materials as well as any of the outcomes ♣
7. commitment to record the receipt and any onward transfer of the PABS Materials in a tracking mechanism to be established. The tracking system shall use persistent identifiers and audit logs, and be interoperable with WHO-brokered connectors to external registries, as applicable. ♣
8. to abide by any additional requirements of the PABS system, including WHO cyberbiosecurity and biosafety standards, reporting obligations and audit rights as adopted by the COP.

III.2. Transfer of PABS Materials to entities outside the Network

III.2.1. All prospective recipients (persons/entities) seeking access to PABS Materials, including for research and/or for development, manufacture, authorisation or supply of vaccines, therapeutics and diagnostics (VTDs) shall execute a WHO Standard Material Transfer Agreement (SMTA) approved by the

COP as a pre-condition to access ("no access without obligations"). The SMTA flows down to affiliates, contractors, CROs/CMOs, collaborators and sublicensees. Obligations cover handling and use of PABS Materials and PSI, traceability, transparency and benefit-sharing arising from sharing/utilisation of PABS inputs.

The Standard Template for the Material Transfer Agreement shall, at a minimum, contain legally binding provisions on: ♣

1. permitted specific uses of PABS Materials and PSI. These uses shall be only for pandemic prevention, preparedness and response (PPR) purposes. Uses beyond the SMTA scope require prior written authorisation by the Provider Country (via CNA) and compliance with national law, ethics and privacy requirements; ♣
2. prohibition of onward transfer outside the PABS system without mandatory flow-down: no transfer to partners, collaborators, CROs/CMOs or any third party unless such party is registered and has executed the applicable SMTA (and, where applicable, DAA); all onward transfers are recorded in the COP-mandated tracking system; ♣
3. commitment to generate and share PSI with first deposition in the WHO PSI Repository, with controlled mirroring only under WHO contracts; compliance with the DAA, preservation of provenance tags, use of persistent identifiers (e.g., DOIs), and a prohibition on de-tagging or re-upload to non-authorised repositories; ♣
4. commitments with regard to intellectual property i.e. that there will be no IP claims on the shared materials, or on any other modified forms or uses of the materials as well as on any of the outcomes. ♣
5. biosafety, biosecurity and cyber-biosecurity: prohibition/regulation of research of concern (e.g., enhanced PPP/GoF/DURC) consistent with WHO guidance and national law; prior review/authorisation where applicable; adherence to COP-adopted technical standards.

▪ **Benefit Sharing obligations of the participating manufacturer:**

(i) Annual Monetary contributions to the PABS Equity Fund calculated on global revenues from PABS-enabled products/services: [XX%] during a

PHEIC/Pandemic and [YY%] interpandemic, as defined in the Revenue Calculation Annex;

(ii) 20% or more set aside of real-time production for WHO allocation by public-health need (with at least 10% donation and the balance at affordable prices) during pandemic emergency, with delivery commencing ≤ 30 days after WHO EUL or first national authorisation;

(iii) 15% or more set aside of real time production for WHO allocation by public-health need (with at least half as donation and the balance at affordable prices) during PHIEC, with delivery commencing ≤ 30 days after WHO EUL or first national authorisation

(iv) Supply to WHO stockpiles and outbreak response on request; WHO may arrange and, where appropriate, cover shipment and last-mile logistics for deliveries to developing countries;

(v) Pandemic emergency and PHEIC set-asides may be updated consistent with Article 12 and COP decisions; floors may be raised by COP but not lowered;

(vi) Licence to WHO (worldwide, non-exclusive, royalty-free) with sub-licensing to developing countries manufacturers covering background/foreground IP, regulatory data waivers/sharing, cell lines/seeds, process parameters and tacit know-how; time-bound transfers (30-day package; 60–90-day on-site support);

- **Benefit Sharing obligations of all other recipients**

(i) Annual Monetary contributions: where revenues arise from PABS-enabled services/tools, apply the inter-pandemic rate above; otherwise, provide non-monetary benefits (reference materials, training, method transfer, data/tools) as specified by COP;

(ii) Other fit-for-purpose benefits according to recipient type (e.g., sharing validated methods, QC panels, analytics scripts), as well as cooperation to enable downstream monetary benefit-sharing where commercialisation later occurs;

▪ Other contractual terms including duration of the agreement, termination, dispute resolution etc.; transparency (publication of SMTA; public dashboards on PABS usage, benefit sharing, deliveries and contributions); monitoring and implementation, consistent with national law and COP-adopted policies.

III.3. Access to PABS Sequence Information

III.3.1. User Registration and Data Access Agreement (DAA) signed as a part of Registration, as a pre-condition to access.

WHO PSI Repository and other authorised databases/repositories provide access only to users with verified identities, who have registered and have signed the DAA, as part of registration. Access is non-discriminatory but conditional on eligibility, user identification, and acceptance of COP-approved terms (including flow-down to affiliates, contractors, CROs/CMOs and downstream recipients), and on compliance with minimum cyber biosecurity controls and audit requirements.

III.3.2. The DAA is legally binding between WHO and each PSI user and commits users to at least the following terms: ♣

1. PSI may be used only for specified PPR purposes; any other use requires prior written authorisation of the Provider Country (via CNA/NFP) and compliance with applicable national law, ethics and privacy protections. ♣
2. commitments with regard to intellectual property i.e. that no IP to be claimed on the sequence information in any form and use as well as on the outcomes of the research activities. ♣
3. biosafety, biosecurity and cyber-biosecurity requirements, including prohibition/regulation of research of concern (e.g., enhanced PPP/GoF/DURC) consistent with WHO guidance and national law; prior review/authorisation where applicable. ♣
4. commitment with regard to persistent unique identifiers including the use of persistent identifiers (e.g., DOIs), preservation of provenance metadata/tags, and a prohibition on removal or alteration of such identifiers; ♣

5. no onward sharing of PSI with any person or entity that has not executed a DAA and been registered by WHO; all onward access is recorded in repository audit logs; ♣
6. commitment not to upload PSI to non-authorised repositories and not to re-upload mirrored PSI; interoperability with external registries (e.g., IP, regulatory and clinical-trial) shall occur only via WHO-brokered connectors that preserve PABS tagging and obligations;

III.4. Benefit Sharing obligations of the participating manufacturer, accessing PSI:

(i) Annual Monetary contributions to the PABS Equity Fund based on global revenues from PABS-enabled products/services: [XX%] during a PHEIC/Pandemic and [YY%] interpandemic, as defined in the Revenue Calculation Annex;

(ii) 20% or more set aside of real-time production for WHO allocation by public-health need (with at least 10% donation and the balance at affordable prices), during pandemic emergencies, with delivery commencing ≤ 30 days after WHO EUL or first national authorisation;

(iii) 15% or more set aside of real-time production for WHO allocation by public-health need (with at least half as donation and the balance at affordable prices) during PHIEC, with delivery commencing ≤ 30 days after WHO EUL or first national authorisation

(iv) Supply to WHO stockpiles and outbreak response on request; WHO may arrange and, where appropriate, cover shipment and last-mile logistics for deliveries to developing countries;

(v) Pandemic emergency set-asides may be updated consistent with Article 12 and COP decisions; floors may be raised by COP but not lowered;

(vi) Licence to WHO (worldwide, non-exclusive, royalty-free) with sub-licensing to designated developing countries manufacturers covering background/foreground IP, regulatory data waivers/sharing, cell lines/seeds,

process parameters and tacit know-how; time-bound transfers (30-day package; 60–90-day on-site support);

III.5. Benefit Sharing obligations of all other persons/entities accessing PSI:

(i) Annual Monetary contributions: where revenues arise from PABS-enabled services/tools, apply the inter-pandemic rate above; otherwise, provide non-monetary benefits (reference materials, training, method transfer, data/tools) as specified by COP;

(ii) Other fit-for-purpose benefits according to recipient type (e.g., sharing validated methods, QC panels, analytics scripts), as well as cooperation to enable downstream monetary benefit-sharing where commercialisation later occurs;

▪ Other contractual terms including duration, termination, dispute resolution, transparency (publication of DAA; public dashboards on PSI use, monitoring and implementation, consistent with national law and COP-adopted policies

IV. Fair and Equitable Sharing of Benefits

IV.1. All recipients of PABS Materials and/or PSI that generate revenue (directly or indirectly) from PABS-enabled products or services shall contribute annual monetary benefit-sharing to the PABS Equity Fund, calculated on global revenues in accordance with a COP-adopted Revenue Calculation Annex. Rates shall be [XX%] during a PHEIC/Pandemic and [YY%] inter-pandemic, as applicable. Recipients shall report revenues to WHO (with audit-light verification).

IV.2. All recipients shall provide non-monetary benefits appropriate to their role, in addition to monetary contributions. Manufacturers accessing PABS Materials and/or PSI shall, as a condition of the SMTA/DAA, provide at minimum:

(a) set-asides of real-time pandemic emergencies and PHEICs;

(b) support to WHO stockpiles and outbreak response;

(c) licences to WHO with sub-licensing to designated developing countries manufacturers, including transfer of cell lines/seeds, regulatory data, process parameters and tacit knowhow with time-bound milestones; and

(d) training, method transfer and access to reference standards/QC panels.

Non-manufacturing recipients (e.g., academic labs, repositories, service providers) shall provide fit-for-purpose non-monetary benefits (e.g., validated methods, analytics scripts, data tools, training) and cooperate to enable downstream monetary benefit-sharing where later commercialisation occurs. All obligations flow down to affiliates, contractors, CROs/CMOs and sublicensees and are recorded in COP-mandated tracking systems.

IV.3. The distribution and use of monetary and non-monetary benefits shall occur under COP direction, administered by the WHO Secretariat. The COP establishes allocation principles prioritising public-health needs with particular attention to developing countries, regional balance and surge capacity.

IV.4. PABS Compliance should be taken into account when Parties promote or incentivize R&D activities or manufacturing.

V. Accountability

The governance chain—from COP to the WHO Secretariat, and Advisory Group, to providers, repositories, laboratories and participating manufacturers—shall be established and published, including roles, reporting lines and escalation paths. Any issues of non-performance of obligations, and infringements of rights, should be addressed promptly through various dispute settlement processes, including negotiations, mediations and arbitration. Pending disputes settlement processes should not hinder the delivery of committed VTDs during the time of outbreaks or emergencies.

VI. Transparency

Mechanisms are established to ensure full transparency in the functioning of the PABS system. This includes for:

- recording all transfers of PABS Materials as well as clinical specimens;

- identifying and making available the list of registered users of PABS Sequence Information;
- making available all signed SMTAs especially with entities outside the WHO Lab Network
- making available all information with respect to benefit sharing received.

SWITZERLAND

https://apps.who.int/gb/igwg/pdf_files/IGWG2-initial-text-proposals/Switzerland.pdf

Federal Department of Home Affairs FDHA Federal Office of Public Health FOPH Division of International Affairs

Submission by Switzerland 6 August 2025

Structured List of Questions to be Addressed by the IGWG for Focused Discussions on the PABS Mechanism

Following the adoption of the WHO Pandemic Agreement by the World Health Assembly (WHA) in May 2025, Member States are now engaged in the negotiation of the annex establishing the Pathogen Access and Benefit-Sharing (PABS) System. In view of the initial commitment to finalize the annex by WHA79 in May 2026, Switzerland would like to support the Bureau and Member States in this process by proposing a structured list of questions to be addressed and the organization of a simulation exercise. The questions stem from Switzerland's efforts to visualize how a future PABS System could be operationalized, based on the text (Art. 12) adopted by the WHA on 20 May 2025. The flow chart included on the last page of this document provides an illustration of this conceptual framework which aims to ensure that all important elements to be considered are taken into account. Furthermore, Switzerland proposes to organize a simulation exercise in collaboration with the WHO Collaborating

Centre at the Spiez Laboratory, which we believe will meaningfully support Member States in further developing the annex.

1. Structured list of questions to be addressed

The questions below, stemming from the flowchart on the last page of this document, are both related to definitions and processes, the governance of the PABS System as well as the functioning of the access and benefit sharing of pathogens with pandemic potential. Grouped into four thematic areas, the list aims to support focused and constructive discussions, and to contribute to the coherent and effective development of the PABS Mechanism and its associated elements. In this regard, these questions would need to be discussed at different stages of the PABS negotiation process:

1. Cross-Cutting Issues

Definitions o "PABS Material"

- "Pathogens with Pandemic Potential"
- "Participating Manufacturer"

Interaction with Other Instruments or Mechanisms

- How can overlap and duplication be avoided? (Art. 12.5.d)
- What is the relationship with:
- The PIP Framework?
- The Nagoya Protocol?
- National or regional ABS measures?

Agreements and Contracts

- Will there be standardized contracts?
- Could existing models serve as references (e.g., SMTA 1, SMTA 3)?
- What elements are essential in the contracts?

2. Governance

Role of WHO

- What is WHO's role in the governance of the PABS System?

- What is the mandate of the coordinating and administrative body under Art. 12.2?
- Which departments or existing WHO mechanisms are implicated?
- Is WHO financially and structurally equipped to fulfill these tasks?

Operationalization of the System

- Who are the eligible participants (e.g., states, laboratories, universities, private sector, WHO)?
- How will simultaneous implementation of all system elements be ensured? (Art. 12.2)
- Will a compliance or oversight mechanism be established? Where?
- What are the consequences of non-compliance?

Financing

- How will the mechanism be financed in the long term?
  - In "peace time"?
  - During a "public health crisis"?
- What role does the Coordinating Financing Mechanism play (Art. 18)?
- What do the "annual monetary contributions" cover (Art. 12.5.a)?

Role of the Conference of the Parties (COP)

- What is the COP's role in governance?
- Will there be reporting obligations?
- Will monitoring and evaluation mechanisms be established?
- How will the COP coordinate with WHO?

3. Access

Access Governance & Procedures

- Who decides if and when access is granted?
- What data will be shared ("PABS Materials")?
- How will sensitive data be protected?
- Are States Parties obligated to share pathogens in certain situations (e.g., PHEIC)?
- Can only Parties share pathogens? What happens if relevant pathogens are found in non-Parties?
- How will the sovereignty over biological resources be respected?

- Who bears the costs of collection, storage, sequencing, and sharing?

Channels and Infrastructure

- What channels will be used to share material:
    - Existing WHO laboratories (e.g., BioHub)?
- How quickly must material be shared?
- Can this system function effectively during crises?
- Will training be provided to increase the number of BSL-4 labs globally?

4. Benefit-Sharing

Definition and Scope

- What is the scope and definition of "benefits"
- What is the scope of the different types of benefits?
    - "set asides"
    - "real time production"
    - "donation"
    - "affordable prices"
- Optional benefits (Art. 12.8), including:
    - Capacity building and technical assistance
    - Research and development collaboration
    - Licensing of technologies to manufacturers in developing countries
    - Other forms of technology transfer
- What is the scope of "medical countermeasures" in the PABS Mechanism?
    - Is it limited to novel countermeasures? What about repositioned medications?

Triggers and Timing

- What triggers the sharing of benefits?

Distribution and Delivery

- What are the conditions and criteria for distribution of medical countermeasures?
- What legal frameworks govern the delivery and distribution of medical countermeasures?

- What is the role of WHO and national/regional authorities in regulatory approval?
- How will legal risks related to novel pandemic vaccines be managed? (WHA78.1, OP15.10)

2. Proposal for a simulation exercise

Switzerland, in collaboration with the WHO Collaborating Centre at the Spiez Laboratory, proposes to organize a simulation exercise to support the negotiations of the annex. This simulation exercise will ideally be co-hosted by a Member State from the Global South and coordinated by the WHO with the WHO Biohub.

We suggest holding the simulation exercise between the third and fourth meetings of the IGWG, as a one-day event on the premises of the Spiez Laboratory in Switzerland.

Objective

This simulation exercise aims to test the practical feasibility and operational functionality of a potential PABS Mechanism by simulating a realistic pandemic emergency scenario. The focus is on exploring the existing draft and on identifying procedural, legal, and political challenges that may arise during the implementation of the system in a time-sensitive context. The key objectives include:

- Assess how quickly and effectively pathogens and/or sequence data can be shared under the PABS framework.
- Evaluate how benefit-sharing obligations are triggered and implemented.
- Identify bottlenecks, ambiguities, and coordination challenges.
- Generate insights to inform negotiation and design of the PABS mechanism.

The outcome of the exercise will be a report summarizing the findings and lessons learned, intended to support Member States in the further negotiation and refinement of the annex.

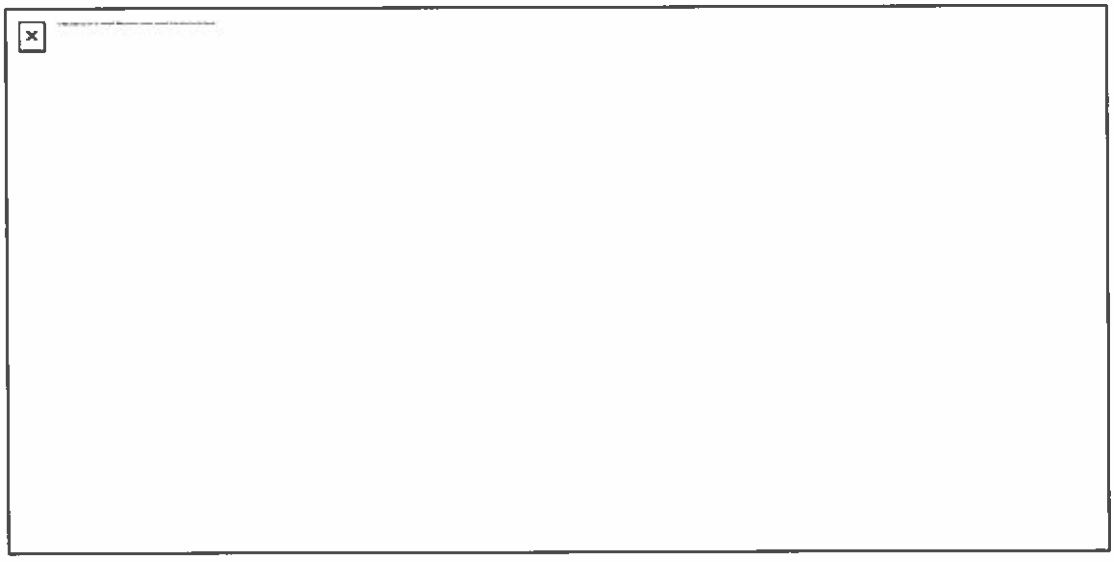
Exercise Format

We propose a tabletop simulation, similar to a role play, based on the available draft of the PABS Annex and on the adopted text of the Pandemic Agreement. The Exercise will simulate real-time decisions and processes that States Parties, WHO, Reference Laboratories, participating manufacturers and stakeholders would face when responding to an emerging disease threat related to a pathogen with pandemic potential.

Participants

To ensure a comprehensive discussion, we propose involving stakeholders across the PABS process. Alongside Member States, WHO, and the WHO BioHub, we foresee including industry partners, and civil society.

Switzerland welcomes the opportunity to work collaboratively with Member States, WHO, and relevant stakeholders to ensure the relevance of this simulation exercise.



TUNISIA

https://apps.who.int/gb/igwg/pdf_files/IGWG2-initial-text-proposals/Tunisia.pdf

The text below was machine translated from the French version.

Tunisian Draft Proposal for the PABS System Annex

Section A: Objective and Scope (Section A – Article 12.1)

This annex aims to specify the operational provisions of the PABS system in order to guarantee

- Rapid, equitable, and traceable access to pathogens with pandemic potential and their genetic sequences;
- Fair, transparent, and binding sharing of monetary and non-monetary benefits resulting from their use;
- Protection of the sovereign rights of countries of origin, in accordance with the Nagoya Protocol.

It applies to all stakeholders involved in the transfer, analysis, exploitation and distribution of these biological resources, including commercial entities.

Section B: Elements to be developed in the PABS system:

I. Definitions (Section B.1 – Article 12.2):

PABS Materials and Sequence Information: "WHO Pathogen Access and Benefit-sharing Scheme" means any biological material (isolates, strains, clinical samples) and genetic data associated with a pathogen identified as having pandemic potential.

Pandemic Pathogen: Any biological agent that could cause rapid international spread with major public health impacts.

Participating Manufacturer: Any pharmaceutical or industrial entity that has access to a pathogen through the PABS.

Relevant International Organizations: Includes multilateral institutions with mandates in the areas of public health, research, biosafety, intellectual property, and health development financing.

Pecuniary Benefits: Financial benefits, including monetary contributions to the PABS Multilateral Fund, user fees, or any payments agreed upon in the SMTAs related to the use of shared resources.

Non-monetary benefits: Non-financial advantages, such as equitable access to health products, technology transfer, participation in research, training, and open sharing of scientific data and sequences.

In-kind benefits: Direct provision of health products (vaccines, treatments, diagnostics) to supplier countries, free of charge or at reduced cost, particularly in the event of a public health emergency.

II. Access Terms and Sharing Conditions (Section B.2, B.6)

All transfers of pathogens must be made via a signed SMTA (Standard Material Transfer Agreement), specifying:

- Authorized uses (public health only);
- Transfer schedule, volume transferred
- Terms of use (scope and details of use, purposes, etc.)
- Obligation to provide feedback (results, sequencing data, use)
- Commitment and terms of benefit sharing in the event of exploitation (vaccines, treatment and diagnostic products, health products, patents, etc.).
- Obligation to transfer technologies
- Protection against deliberate misuse (storage and secure access)
- Post-pandemic use

States Parties will maintain a national registry interconnected with the WHO and the designated platform.

III. Legal nature of the annex:

As a Party fully committed to the responsible governance of pathogens with pandemic potential, the Republic of Tunisia reaffirms the importance of ensuring that the obligations relating to the PABS system, including those set out in its annex, have legal force equivalent to those of the main treaty.

Tunisia recommends that:

- The PABS Annex be explicitly designated as an integral, legally binding part of the treaty adopted under Article 19 of the WHO Constitution;
- Any amendment to this Annex be subject to formal approval by States Parties, through a transparent and equitable governance process;
- The Annex contain strong provisions on traceability, benefit sharing, transfer conditions (SMTAs), and technological cooperation, to ensure a fair balance between access to pathogens and effective health benefits for contributing countries.

Such a legal architecture is essential to build trust between Parties, prevent biopiracy, and ensure a fair, coordinated, and sovereign global response to future pandemics.

IV. Coordination and Operation of the PABS System in Collaboration with Relevant International Organizations and Stakeholders (Art. 12-2)

Collaboration must not be vague or unbalanced. It must be:

- Inclusive
- Geographically and functionally balanced
- Under clear supervision of the States Parties
- And transparent

The PABS system is coordinated by WHO, in collaboration with relevant international organizations and stakeholders, in accordance with their respective mandates.

Partner international organizations are selected based on objective criteria defined by a PABS Governance Committee and operate in the areas of public health, research, funding, intellectual property, or data sharing.

Any formalized collaboration between WHO and an external party must be made public, documented, and subject to compliance review by State Parties.

Operational platforms may be decentralized and entrusted to national or regional institutions, subject to compliance with PABS standards.

V. Coordination and Administration of the PABS System By the WHO

The Parties recognize the World Health Organization (WHO) as the central coordinating authority of the PABS system, responsible for its operational management, monitoring, strategic oversight, and support to the Parties, in accordance with the principles of transparency, equity, inclusive participation, and accountability.

Tunisia recommends that the WHO establish a dedicated governance body for the PABS system, composed in a balanced and multi-stakeholder manner. This body includes representatives from each WHO region, with equal representation, with a rotating chair alternating between high-income countries and low- and middle-income countries. It includes equitable representation from pathogen-supplying and user countries, as well as independent experts in ethics, human rights, biosafety, equity, and open science. This body is responsible for reviewing SMTAs, approving designated platforms, overseeing the implementation of benefit sharing, and recommending any necessary corrective measures.

An independent arbitration mechanism is established to resolve disputes related to the implementation of the PABS system. It is composed of experts appointed by the States Parties. This mechanism may be consulted in the event of disputes relating to access to pathogen resources, breached contractual commitments, or non-fulfilment of equitable benefit-sharing obligations.

The WHO ensures full transparency in the administration of the PABS system. All decisions related to approvals, access, distribution, or contractual commitments are made public via an online platform. Commitments made by private entities under the SMTAs are also published, including those relating to the production, distribution, price, and quotas of derived health products.

The WHO-led coordination includes an active mission to build capacity and reduce structural inequalities. As such, the WHO supports low- and middle-income countries in developing their scientific, regulatory, and logistical capacities to enable them to effectively participate in the PABS system. It supports the transformation of national institutions into accredited PABS platforms and promotes the systematic inclusion of technology and know-how transfer clauses in SMTAs.

A mechanism for periodic and independent evaluation of the PABS system's performance has been established. The evaluation is conducted every two years, based on indicators relating to equity, transparency, speed of response, and contractual compliance. The results of this evaluation are made public.

Tunisia recommends that any substantial revision of the PABS rules, including the SMTA models, be subject to formal and inclusive consultation with the States Parties. The latter have a collective right to oppose any change that would compromise the fundamental principles of the system or the interests of the supplier countries.

VI. Benefit Sharing (Section B.6, Section G – Article 12.5(a), 12.8)

Expected benefits include:

- Preferential access to health products (vaccines, tests, treatments) (details:
  percentage, free of charge)
- Technology transfer enabling local or regional production enabling more efficient production of medicines and vaccines, also considered as benefits, even if not purely financial
- Funding for P3-level national laboratories;

Contractual transparency is ensured through a public database of manufacturers' commitments.

The Parties undertake to ensure a fair, equitable, and binding sharing of benefits arising from access to biological resources provided under the PABS system.

This sharing includes benefits:

- Monetary (pecuniary): mandatory annual contributions to the PABS Fund, proportional royalties in the event of commercialization;
- Non-monetary (non-pecuniary): priority access to health products, technology transfer, scientific co-development, and national capacity building.

Any manufacturer that has accessed pathogens must:

- Commit to returning a portion of the products developed or profits to the country of origin;
- Enter into an SMTA detailing these obligations;
- Report annually on its deliveries, transfers, and contributions.

The WHO will then publish an annual report on compliance with sharing obligations, based on the SMTAs, manufacturer declarations, and feedback from State Parties.

Contractual transparency through a public database of manufacturer commitments is a powerful tool for improving commercial relations, building trust, and fostering a fairer and more competitive environment.

VII. Facilitation and acceleration of research and innovation:

Tunisia believes that the PABS system should not be limited to providing other countries with access to pathogens, but should also serve as a lever for scientific cooperation, skills transfer, and strengthening R&D sovereignty in middle-income countries.

Any access to biological resources or associated genetic data under the PABS system entails an obligation for the recipient to integrate, to the extent possible, the institutions of the provider country in research, product development, and scientific publication activities related to the analysis of the materials.

This obligation is formalized in the SMTAs and reflects the principles of co-development and co-publication.

A multilateral funding mechanism should be established within the PABS system, funded in particular by mandatory or voluntary contributions from beneficiary private entities. This fund supports collaborative research projects involving institutions in provider countries, based on competitive calls for proposals and criteria of scientific excellence, public health impact, and geographic relevance. Priority is given to research on endemic pathogens, the local production of diagnostic tools, and epidemiological surveillance systems.

Scientific data produced from resources obtained through the PABS system—including genetic sequences, experimental results, publications, potential patents, or derived innovations—must be shared with the WHO within a

reasonable timeframe and made available, in an open, equitable, and non-discriminatory manner, for the benefit of public research institutions in the country of origin.

Since the SMTAs also include specific clauses relating to the transfer of technologies, know-how, and equipment essential for research, including reagents, cell lines, bioinformatics software, and validated protocols, these transfers will be accompanied, to the extent possible, by technical training and skills-building activities, at the beneficiary's expense, for researchers and technicians in the institutions of the provider country.

Also through the collaborative digital platform developed and administered by WHO as part of the PABS system, the networking of research teams from the Parties will enable the sharing of protocols, data, and publications from the system, and ensure transparent and accessible monitoring of research projects funded or derived from shared resources.

VIII. Complementarity between the PABS system and the WHO Pandemic Influenza Preparedness Framework (PIP) and other relevant ABS (Access and Benefit-Sharing) instruments,

The PABS system is designed to work in synergy with other relevant international access and benefit-sharing regimes, including:

- The WHO Pandemic Influenza Preparedness Framework (PIP Framework);
- The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits;
- The International Treaty on Plant Genetic Resources (FAO);
- Sequencing databases (GISAID, GenBank).

Nothing in this annex limits the sovereign rights of States under the Nagoya Protocol, without binding Member States that have not ratified this Protocol.

Tunisia strongly supports the idea that the SMTAs of the PABS system must be compatible with sharing agreements under other regimes. The WHO must ensure operational coordination, regulatory consistency, and the prevention of legal conflicts between instruments.

IX. Review and Alignment of National and Regional Access and Benefit-Sharing Measures

The Parties undertake to undertake a review of their national or regional legal frameworks relating to access to biological resources and benefit-sharing (ABS), to ensure their compatibility with this PABS system.

This review must be conducted in a sovereign, progressive manner, and in compliance with existing commitments, particularly those under the Nagoya Protocol.

The WHO, in collaboration with relevant partner organizations, will provide technical and legal support to assist States in this process, notably through guides, training, legal templates, and exchange platforms.

Tunisia, as a State Party, commits to coordinating efforts at the national and regional levels to strengthen the coherence of ABS measures within the framework of the international response to pandemics.

X. Consistency with Applicable Laws on Risk Assessment, Biosafety, Biosecurity, Export Control, and Data Protection

The provisions of the PABS system must be interpreted and applied in accordance with applicable national, regional, and international laws, including those relating to biosafety, biosecurity, biological risk assessment, export control of pathogenic material, and data protection, including sensitive genetic data.

Tunisia, in full respect of its sovereignty, will undertake to make access to pathogens or associated data subject to compliance with national frameworks on biosafety, privacy protection through the protection of personal data, and technology transfer regulations.

Standard Material Transfer Agreements (SMTAs) entered into under the PABS systemmust include a clause requiring the user to:

- comply with the legal requirements of the supplier country regarding biosecurity, export control, and data confidentiality;

- immediately notify the supplier of any security breach, traceability breach, or improper use;
- not exploit for commercial purposes or transfer to a third party the data or materials received without the prior written consent of the country of origin.

XI. Facilitation of the Manufacturing and Export of Vaccines, Treatments, and Diagnostics

The Parties, including Tunisia, undertake to facilitate rapid, equitable, affordable, and public health-needs-based access to vaccines, treatments, and diagnostics developed from biological materials or data obtained through the PABS system.

Any entity benefiting from the PABS system, whether public or private, is required to include in the SMTA a clause stipulating:

- the provision of a specified share of final products (vaccines, treatments, diagnostics) to supplier countries, free of charge or at an affordable cost, particularly in the event of a public health emergency;
- the prioritization of low- and middle-income countries, particularly those in the Global South, in distribution strategies during pandemic situations.

Beneficiaries are encouraged, and in some cases required, to enter into local or regional manufacturing partnerships, including activities such as packaging, filling and finishing, distribution, and quality assurance.

They also commit to sharing production protocols, critical tools, validated cell lines, and quality validation processes. In exceptional circumstances, the Parties agree to temporarily lift certain legal barriers to access to essential technologies, including through the use of compulsory licenses, voluntary access mechanisms, or other flexibilities provided for in the TRIPS Agreement, in accordance with WTO decisions.

Tunisia maintains that any country that has contributed to the PABS system by sharing biological resources or genetic data has the right to:

- receive a guaranteed minimum quota of products developed from these resources (in kind or otherwise);

- be included in manufacturing partnerships, based on its national or regional industrial capabilities;
- request technical or financial support to upgrade its pharmaceutical production capacities.

Section C: Traceability and Open Access to Data (Article 12.3)

Traceability and open access to data are technical but highly strategic elements of the PABS system: they determine its transparency and effectiveness.

A centralized digital traceability system, managed by the WHO, enables real-time tracking of the movements of pathogen resources or their sequences within the PABS system.

All SMTAs concluded within this framework must be registered with the WHO in a secure registry, with a publicly accessible non-confidential summary.

Beneficiary users are required to declare:

- The use made of resources,
- The research results obtained,
- The health products developed,
- Any patent or license applications.

The scientific data resulting from this research must be shared on open, interoperable platforms accessible to provider countries, unless otherwise justified.

Section D: Alignment with the Nagoya Protocol

Tunisia, as a Party to the Nagoya Protocol, which it ratified in 2021, commits to ensuring consistency between the provisions of the PABS system and its international obligations relating to access to genetic resources and the fair and equitable sharing of benefits arising therefrom.

The State Party shall be supported through the designated national focal point for the Nagoya Protocol in developing these measures and aligning them with relevant multilateral frameworks, including this instrument and its annex.

Section E: Provisions in the Event of a Declaration of a Pandemic Emergency (Art. 12.6)

Providing countries must benefit from rapid, effective, equitable, and undelayed access to health products (vaccines, treatments, diagnostics).

In the event of a pandemic emergency declaration by the World Health Organization, a mechanism for accelerated and coordinated access to health products derived from the PABS system is automatically activated, without delay.

The products concerned include, but are not limited to:

- vaccines,
- therapeutic treatments,
- diagnostic and rapid detection means,
- as well as protection and response tools developed from biological resources shared through the PABS system.

The distribution of these products is coordinated by the WHO and its partners, based on:

- a real-time scientific assessment of epidemiological risks,
- the urgent health and humanitarian needs of populations,
- national response capacities.

Particular attention is paid to least developed countries (LDCs), small island developing states (SIDS), and low-income countries to ensure priority, inclusive, and equitable access.

Countries that have provided a pathogen or its genetic data that caused the pandemic emergency benefit from a priority quota of health products, equivalent to at least 10% of the available global production of each type of derived product, delivered within 30 days of their operational availability.

Tunisia, as a State Party, undertakes to:

- not apply export restrictions or protectionist measures to these products throughout the duration of the pandemic,

- facilitate the issuance of compulsory or voluntary licenses, if necessary, to accelerate production and distribution worldwide.

The WHO, with partner international agencies, coordinates logistical, financial, and technical aspects to ensure effective, equitable, and free or low-cost delivery, particularly to vulnerable countries.

Section F: Provisions Applicable in the Event of a Public Health Emergency of International Concern (PHEIC):

In the event of a declaration by the WHO of a Public Health Emergency of International Concern (PHEIC), the following PABS obligations are automatically activated and without preconditions:

- Immediate and effective access by Parties to health products developed from resources shared through PABS (vaccines, treatments, diagnostics);
- Prioritization based on an assessment of public health risks and proven health needs, with particular attention to least developed countries, island states, and pathogen-supplying countries;
- The obligation for SMTA beneficiaries to implement expedited delivery and effective sharing of products in accordance with contractual commitments;
- Temporary exemption from any export restriction or health protectionism that undermines equity of access.

The cost of products allocated under this framework must be covered by the PABS Multilateral Fund, or offered at an affordable, non-profit price, determined in consultation with the WHO.

The WHO and its partners coordinate logistics, including transportation, distribution, and technical support for recipient countries.

A public database is maintained by the WHO, listing:

- the countries that received the products,
- the quantities delivered,
- and the contractual commitments fulfilled.

In the event of non-compliance with commitments during a PHEIC, several measures may be considered, including: suspension of access to the PABS

system, publicity of the breaches observed, and recourse to the dispute settlement mechanism provided for by the instrument.

Section G: Additional Provisions on Benefit-Sharing (Art. 12.8)

These are additional provisions, to be included in the PABS Annex, to ensure that benefit-sharing is not merely symbolic or minimal, but supports a sustainable transformation of national capacities.

Tunisia plans to implement strengthened, flexible, yet binding benefit-sharing mechanisms, particularly in:

- training,
- technology transfer,
- regional co-production,
- intellectual property ownership,
- sharing of preclinical and clinical knowledge.

The Parties undertake to include in the SMTAs a clause for the progressive transfer of technology, particularly for the production, formulation, or packaging of vaccines, diagnostics, or treatments, to supplier countries or their regional partners.

Recipients of PABS resources must share protocols, results, and analyses of preclinical and clinical trials with interested parties, within a timeframe consistent with the interests of public health.

When technically and legally justified, the institutions that provided the biological material or associated data may be recognized as co-owners of the intellectual property or granted non-exclusive access, under a free or preferential license.

Any scientific results published using resources from the PABS system must explicitly acknowledge the source of the resource and, where possible, include institutions or researchers from the providing countries as co-authors or collaborators.

A percentage of the mandatory monetary contributions paid by users will be allocated to a window intended to finance research, development, or

manufacturing projects in the providing countries. Any commercial exploitation of a product derived from PABS resources must be subject to prior notification to the supplier country and include a negotiated sharing of profits or royalties, in accordance with the SMTA.

Section H: Other elements for effective operationalization of the PABS system (Art. 12.9)

For the PABS system to be fully functional and not remain an abstract framework, the annex should include clear, concrete, and measurable operational elements that guarantee:

- its rapid implementation upon entry into force of the treaty,
- its technical and logistical efficiency,
- its accessibility for all countries, including Tunisia.

The Parties recognize that the effectiveness of the PABS system depends on the rapid, equitable, and coordinated implementation of its institutional, technical, digital, and logistical components. Accordingly, the Parties agree to establish the following mechanisms within a specified timeframe, commencing upon the entry into force of this instrument.

The World Health Organization shall establish a permanent PABS coordination unit, responsible for:

1. the centralized management of Standard Material Transfer Agreements (SMTAs);
2. monitoring the circulation of pathogens and their associated data;
3. overseeing the PABS digital platform;
4. coordinating with the Parties and relevant stakeholders.

A secure digital platform is established and administered by the WHO to:

1. facilitate the registration, signing, and monitoring of SMTAs;
2. ensure the traceability of PABS resources and derived products;
3. ensure transparency of user commitments and accountability;
4. enable public access to non-sensitive scientific data, in compliance with national data protection and biosafety legislation.

Parties may designate, in consultation with the WHO, accredited national and/or regional laboratories to ensure the collection, storage, sequencing, and,

where appropriate, transfer of pathogens under the PABS system. These laboratories must meet harmonized biosafety, biosecurity, and quality standards.

A harmonized and legally binding SMTA model is being developed by the WHO, in consultation with the Parties. This model must include:

1. modalities for pathogen transfer and use;
2. modalities for the fair and equitable sharing of pecuniary and non-pecuniary benefits;
3. specific obligations applicable in pandemic emergencies;
4. clauses on traceability, prohibition of unauthorized re-export, and non-reverse engineering;
5. conditions for notification, transparency, and contractual liability.

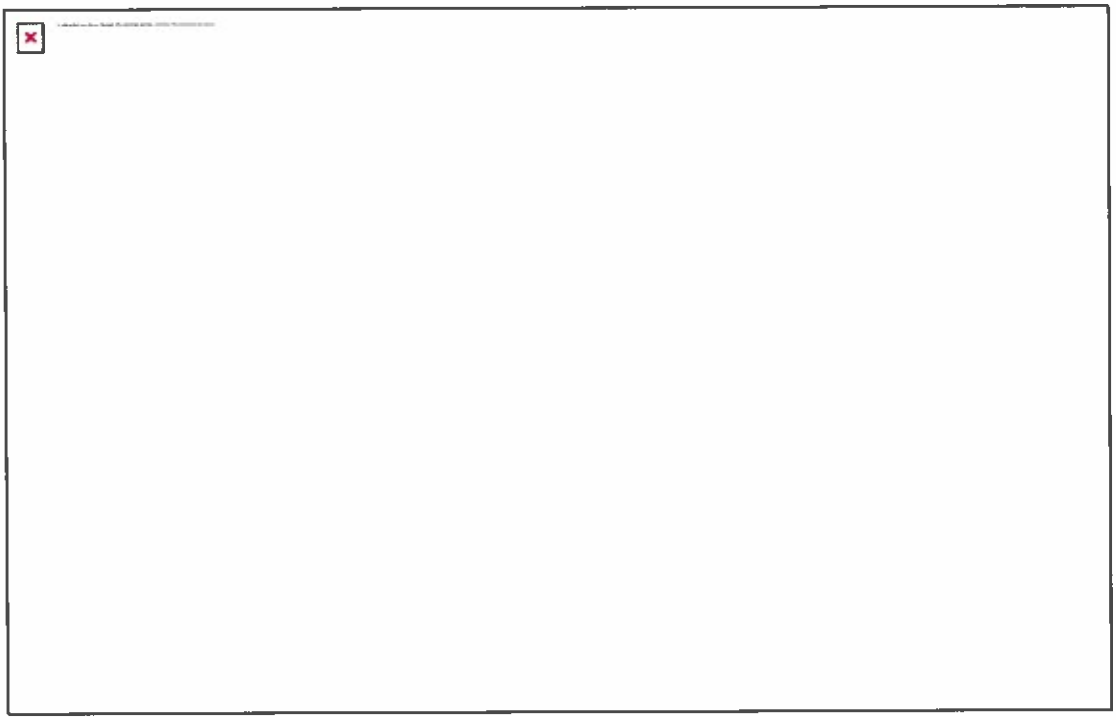
An international capacity-building program is being implemented under the aegis of the WHO to support States Parties with limited capacity, particularly in:

1. biosafety and biosecurity;
2. legal and technical management of SMTAs;
3. use of the digital platform;
4. mastery of tools for sequencing, storage, and analysis of pathogens.

The WHO shall ensure the establishment of an annual or periodic monitoring and evaluation system, including public and verifiable indicators relating to:

1. the number and nature of shared PABS resources;
2. SMTAs signed and implemented;
3. the amounts and modalities of benefit sharing;
4. the effective distribution of medical countermeasures during public health emergencies.

The Parties agree to conduct, every two (2) years, a technical evaluation and review of the PABS system, conducted by an independent body appointed by the Conference of the Parties. This review shall allow for the adaptation of the system's operational tools without modifying the substantive provisions of this instrument.



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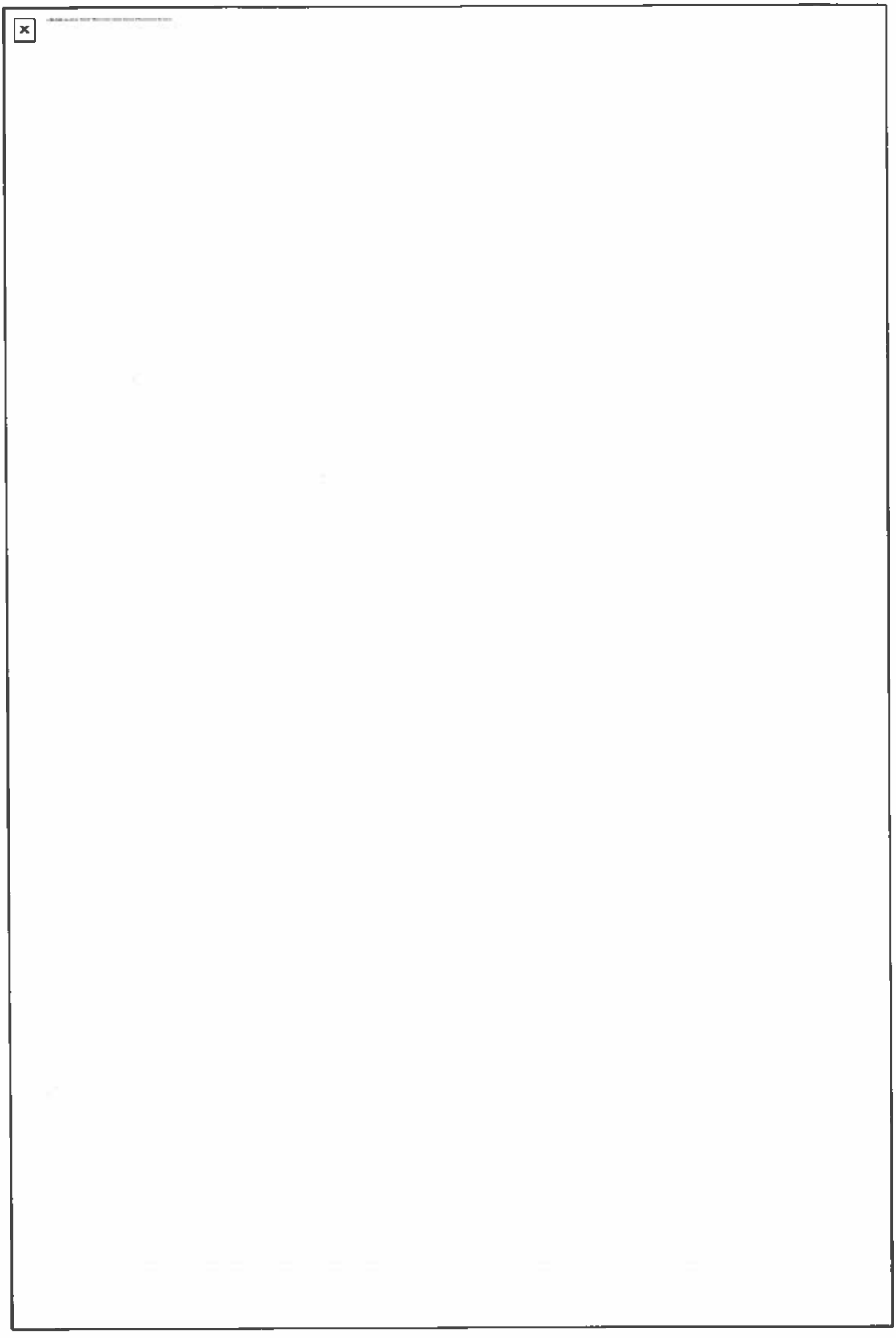

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