

Tunisian Delegation proposal for the Annex to the PABS system

Section A: Purpose and scope (Section A – Article 12.1)

This annex aims to clarify the operational provisions of the PABS system to ensure

- 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;
- The 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 System” refers to any biological material (isolates, strains, clinical samples) and genetic data associated with a pathogen identified as having pandemic potential.

Pathogen with pandemic potential: any biological agent that could cause rapid international spread with major impacts on public health.

Participating manufacturer: any pharmaceutical or industrial entity with access to a pathogen through the PABS system.

Relevant international organizations: include, in particular, multilateral institutions with a mandate in the areas of public health, international trade, and intellectual property.

Monetary benefits: Financial benefits, including monetary contributions to the PABS Multilateral Fund, user fees, or any payment agreed upon in SMTAs related to the exploitation of shared resources.

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

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

II. Access and sharing conditions (Section B.2, B.6)

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

- Authorized uses (public health only);
- The transfer schedule and volume transferred
- The terms of use (scope and details of use, purposes, etc.)
- The obligation to provide feedback (results, sequencing data, use)
- The commitment and terms of benefit sharing in the event of commercialization (vaccines, treatments and diagnostic products, health products, patents, etc.).
- The obligation to transfer technologies
- Protection against deliberate misuse (storage and access security)
- Post-pandemic use

States Parties shall 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 defined in its annex, have legal force equivalent to those of the main treaty.

Tunisia recommends that:

- The PABS Annex be explicitly recognized as an integral and 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 the States Parties, following a transparent and equitable governance procedure;
- The annex contain firm provisions on traceability, benefit sharing, transfer conditions (SMTAs), and technological cooperation, in order to ensure a fair balance between access to pathogens and effective health benefits for contributing countries.

Such a legal architecture is essential for building trust among Parties, preventing acts of biopiracy, and ensuring a fair, coordinated, and sovereign global response to future pandemics.

IV. Coordination and operations 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 the clear supervision of 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.

International partner organizations are chosen based on objective criteria set by a PABS Governance Committee and participate in areas such as public health, research, financing, intellectual property, or data sharing. Any formal collaboration between WHO and an external party must be made public, documented, and reviewed for compliance by States Parties. Operational platforms may be decentralized and assigned to national or regional institutions, as long as they meet 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 for 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 WHO establish a governance body dedicated to the PABS system, with a balanced and multi-stakeholder composition. This body shall include representatives from each WHO region, with equal representation, and a rotating chairmanship alternating between a high-income and a low- or middle-income country.

It should include equitable representation of pathogen-providing countries and user countries, as well as independent experts in ethics, human rights, biosecurity, equity, and open science.

This body would be responsible for reviewing SMTAs, accrediting 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 application of the PABS system. It is composed of experts appointed by the States Parties. This mechanism may be invoked in the event of disputes over access to pathogen resources, breaches of contractual commitments, or failure to fulfill obligations for the equitable sharing of benefits.

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

The coordination led by the WHO 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 participate effectively in the PABS system. It supports the transformation of national institutions into approved 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 performance of the PABS system is being established. The evaluation is conducted every two years, using indicators that measure equity, transparency, responsiveness, and contractual compliance. The results of this evaluation are made public.

Tunisia recommends that any substantial revision of the rules of the PABS system, including 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 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 facilitates local or regional production, enabling more efficient manufacturing of medicines and vaccines. This benefit is not solely financial.
- Funding for national P3-level laboratories;

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

The Parties undertake to ensure fair, equitable, and binding sharing of benefits resulting 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 share 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 SMTAs, manufacturers' declarations, and feedback from States Parties.

Contractual transparency *via* a public database of manufacturers' commitments is a powerful tool for improving trade relations, building trust, and promoting a more equitable and competitive environment.

VII. Facilitating and accelerating research and innovation:

Tunisia believes that the ABS system should not be limited to ensuring access to pathogens for other countries, 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 beneficiary to involve, to the extent possible, institutions in 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 financing mechanism will need to be established within the PABS system, funded in particular by mandatory or voluntary contributions from private beneficiary entities. This fund supports collaborative research projects involving institutions in provider countries. Projects are selected through a competitive application process based on criteria of scientific excellence, public health impact, and geographical relevance. Priority is given to research on endemic pathogens, 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 derivative innovations—must be shared with the WHO within a reasonable time frame and made available in an open, equitable, and non-discriminatory manner for the benefit of public research institutions in the country of origin.

SMTAs also include specific clauses relating to the transfer of technology, know-how, and equipment essential to research, including reagents, cell lines, bioinformatics software, and validated protocols. These transfers will be accompanied, to the extent possible, by technical training and capacity-building activities, at the expense of the beneficiary, for researchers and technicians from institutions in the supplying country.

Once more, the WHO's collaborative digital platform, developed and administered as part of the PABS system, will facilitate the networking of the Parties' research teams. This will enable the sharing of protocols, data, and publications resulting from the system. It will also 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 Framework) 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 should 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 review 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 shall be conducted in a sovereign and progressive manner, respecting existing commitments, in particular 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, including through guidelines, training, legal templates, and exchange platforms.

Tunisia, as a State Party, is committed to coordinating efforts at the national and regional levels to strengthen the consistency of ABS measures in 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 legislation, in particular those relating to biosafety, biosecurity, biological risk assessment, control of exports of pathogenic material, and data protection, including sensitive genetic data.

Tunisia, in accordance with its full sovereignty, will commit to making access to pathogens or associated data subject to compliance with national security frameworks.

Tunisia, in accordance with its full sovereignty, will undertake to make access to pathogens or associated data subject to compliance with national frameworks for biological safety, privacy protection through personal data protection, and technology transfer regulations.

Standard material transfer agreements (SMTAs) concluded under the PABS system must include a clause whereby the user undertakes to:

- Comply with the legal requirements of the supplying country in terms of biosafety, export control, and data confidentiality;
- Immediately notify any security breach, traceability breach, or non-compliant 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 manufacture and export of vaccines, treatments, and diagnostic tools

The Parties, including Tunisia, undertake to facilitate rapid, equitable, affordable, and public health-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 the 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 South, in distribution strategies in the event of a pandemic.

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, or 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 supports the fact 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);
- To be included in manufacturing partnerships, based on its national or regional industrial capacities;
- To 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 movement 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 non-confidential summary accessible to the public.

Beneficiary users are required to report:

- The use made of the 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 supplier countries, unless otherwise specified and justified.

Section D: Alignment with the Nagoya Protocol

Tunisia, as a Party to the Nagoya Protocol, which it ratified in 2021, is committed 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 from their utilization.

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

Section E: Provisions in the event of a pandemic emergency declaration (Art. 12.6)

Supplier countries must have rapid, effective, equitable, and immediate 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,
- means of diagnosis and rapid detection,
- as well as protection and response tools developed from biological resources shared through the PABS system.

The distribution of these products is organized under the coordination of the WHO and its partners, based on:

- 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, solidarity, and equitable access.

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

Tunisia, as a State Party, undertakes to:

- not apply export restrictions or protectionist measures on these products for the duration of the pandemic,
- facilitate the issuance of compulsory or voluntary licenses where necessary to accelerate global production and distribution.

The WHO coordinates with international partner agencies on logistical, financial, and technical aspects to ensure effective, equitable, and free or low-cost delivery, particularly in 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 obligations of the PABS system are activated automatically and without preconditions:

- Immediate and effective access for all parties to health products developed from shared resources through PABS (vaccines, treatments, diagnostics).
- A systematic approach to determining priorities, informed by a comprehensive evaluation of public health risks and evidenced-based health requirements, with a focus on the needs of least developed countries, island states, and countries with a high prevalence of pathogens.
- SMTA beneficiaries are obligated to implement accelerated delivery and effective product sharing arrangements in accordance with contractual commitments.
- Temporary exemption from any export restrictions or health protectionism that undermines equitable 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 WHO.

The WHO and its partners will provide logistical coordination, including transportation, distribution, and technical support for recipient countries.

The WHO will maintain a public database that will include:

- The countries that have received the products,
- The quantities delivered,
- And the contractual commitments fulfilled.

In case of non-compliance with commitments during a USPPI, several measures may be considered, including: suspension of access to the PABS system, public disclosure of identified breaches, and recourse to the dispute settlement mechanism provided for in the instrument.

Section G: Additional provisions on benefit sharing (Art. 12.8)

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

Tunisia plans to put in place enhanced, flexible but binding sharing mechanisms, particularly in

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

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

Recipients of PABS resources shall share the protocols, results, and analyses of preclinical and clinical trials with interested Parties, within a timeframe compatible with public health interests.

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

Any scientific results published based on resources from the PABS system must explicitly mention the origin of the resource and, where possible, associate the institutions or researchers from the provider countries as co-authors or collaborators.

A percentage of the mandatory monetary contributions paid by users will be allocated to a fund intended to finance research, development, or manufacturing projects in the provider countries.

Any commercial exploitation of a product derived from PABS resources must be notified in advance to the supplying country and include a negotiated sharing of profits or royalties, in accordance with the SMTA.

Section H: Other elements for the 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 operationalization elements that guarantee:

- its rapid implementation upon the treaty's entry into force,
- its technical and logistical effectiveness,

- its accessibility to 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 time frame from the entry into force of this instrument.

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

- a) centralized management of standard material transfer agreements (SMTAs);
- b) monitoring the movement of pathogens and associated data;
- c) oversight of the PABS digital platform;
- d) coordination with Parties and relevant stakeholders.

A secure digital platform shall be established and administered by WHO in order to:

- a) facilitate the registration, signing, and monitoring of SMTAs;
- b) ensure the traceability of PABS resources and derivative products;
- c) guarantee the transparency of user commitments and accountability;
- d) allow public access to non-sensitive scientific data, in compliance with national legislation on data protection and biosafety.

The Parties may designate, in consultation with the WHO, approved national and/or regional laboratories to collect, store, sequence, and where appropriate, transfer pathogens under the PABS system. These laboratories must meet harmonized biosafety, biosecurity, and quality standards.

A harmonized and legally binding model for SMTA shall be developed by WHO, in consultation with the Parties. This model shall include:

- a) the terms and conditions for the transfer of pathogens and their use
- b) the terms and conditions for the fair and equitable sharing of benefits, both pecuniary and non-pecuniary;
- c) specific obligations applicable in pandemic emergencies;
- d) clauses on traceability, prohibition of unauthorized re-export, and non-reverse engineering;
- e) conditions for notification, transparency, and contractual liability.

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

- a) biosafety and biosecurity;
- b) legal and technical management of SMTAs;
- c) use of the digital platform;
- d) mastery of tools for sequencing, storing, and analyzing pathogens.

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

- a) the number and nature of shared PABS resources;
- b) SMTAs signed and implemented;
- c) the amounts and terms of benefit sharing;
- d) 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 designated by the Conference of the Parties. This review will enable the adaptation of the system's operational tools without altering the instrument's substantive provisions.