Beko, Michele

From: Robert J. Gargasz <rjgargasz@gmail.com>
Sent: Sunday, August 24, 2025 3:47 AM
To: Jim Jordan; Congressman Jim Jordan; JD Vance; Donald Trump; Congressman Gibbs; Robert; Renz LLC; Congressman Gosar; N. Ana Garner; Larry; Thomas Renz; Phyllis Crespo; Joey Gilbert; Eric Jones; F. R. Jenkins; Jonathan Diener; Michael Hamilton; Tom Niewulis; Congresswoman Kaptur; Ohio Up!; KRAUS STEVEN W; Tom Renz; Mary Team Trump; Mark Pukita; News Daily GOP; Thomas Hach; Joseph Gargasz; andrewgargasz; Mark Campolo; Mike Gargasz; Michael Scherach; Brian Sarvas; Timothy Josoph Gargasz; Pauline Sherry; Kate Zvara; Janice Gargasz; Maggie Kent; Elizabeth Sauer; Wanda Gargasz; M. Elissa Cachon; Terry and Marie Hall; Robby Zsigray; Barb DeFelice; Anne Olsen; Edward Chavez; Dan Plow; Kathy Cucco; Mike Campolo; Garon Petty; jeanne Petty; Aaron Knapp; Wyers; Paul Young; Robert Zvara; Major Steven Scharschmidt; Molly Antill; Charlene Scherach; Jim Dowdell; Sheriff Jack Hall; Tony Cillo; RICHARD ALKIRE; Fran Smith; Patrick Riley; City Council Mail Group; Joe K Auditor; Jack Bradley; Rey Carrion; Joel Arredondo; Don Zaleski; Maggie Partin; Mike Failing; Rocky Radeff; jfr_74 @hotmail.com Jeff Riddel; Teresa Upton; david@yesce.com Moore, David; Patrick Ward; Jacob Morris; David Yost AG; Marty Gallagher; Carissa Woytach; Leigh Prugh; Brian Massie; Christine Mendoza; Darryl Tucker; Mike Brosky; kirsten@totallyengagedamericans.org Hill; Brad Dicken; Julie Wallace; Jamie Lynne Turner; Lindsay Carr; William. Bill Poplar; Tom rodeoh2 Beres; Keely Hall; Lindsay Carr
Subject: Fwd: Stop the PABS Negotiations

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From: James Roguski <jamesroguski@substack.com>
Date: August 24, 2025 at 1:07:49 AM EDT
To: rjgargasz@gmail.com
Subject: Stop the PABS Negotiations
Reply-To: James Roguski <reply+2tth37&gfcn5&&59bf0bdffebd2a240aec3f9a598c88b483b6be9a90fed8c2989b2eabd4c37ee2@mg1.substack.com>

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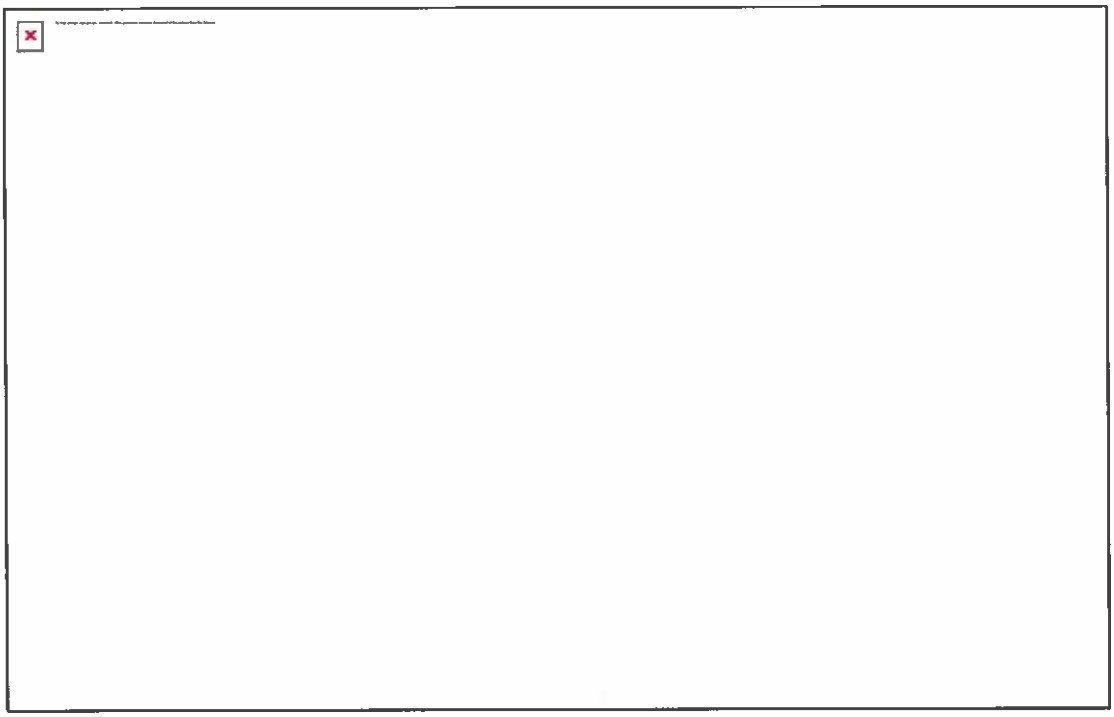
Stop the PABS Negotiations

Pathogen Access and Benefit Sharing (PABS) is an absolutely HORRIBLE idea that must be stopped. We can still STOP the entire Pandemic Agreement by making sure that the PABS negotiations fail.

JAMES ROGUSKI

AUG 24

READ IN APP



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The next meeting of the InterGovernmental Working Group that is guiding the negotiations for the Pathogen Access and Benefit Sharing System Annex is scheduled for September 15-19, 2025.

Regardless of where you live in the world (including the United States), the negotiations for a Pathogen Access and Benefit Sharing (PABS) System will impact your life in the future.

I recognize that this issue is extremely complicated and confusing. As of August 24, 2025, the nations involved in the PABS negotiations have submitted 78 pages of proposed text.

I have reviewed all of these documents countless times and summarized them into a 4 page Executive Summary and the 17 minute video below.

GET THE FACTS:

WATCH THE VIDEO BELOW:

Backup videos:

https://www.youtube.com/watch?v=w5v-OmawOvc

https://rumble.com/v6xzwqs-why-the-world-should-oppose-the-who-pathogen-access-and-benefit-sharing-sys.html

https://www.bitchute.com/video/VwcroKPvgQ5z

Seriously. Please watch the video above. It provides a clear and concise summary of vast amounts of information.

READ THE DOCUMENTS:

A 4 page Executive Summary:

Pabs Executive Summary
227KB · PDF file

Download

A 4 page Executive Summary PLUS all the official documents in one place:

Pabs Executive Summary Plus All Document...
1.35MB · PDF file

Download

NOW is the time to raise your voice in opposition to the proposed PABS System and the WHO Pandemic Agreement.

CLICK HERE TO SHARE YOUR OPINION

Your comments may be published in a future article.

If you want to work to oppose the PABS System, then contact me directly:

James Roguski 310-619-3055 (phone, text, Signal, Telegram or WhatsApp)

Executive Summary

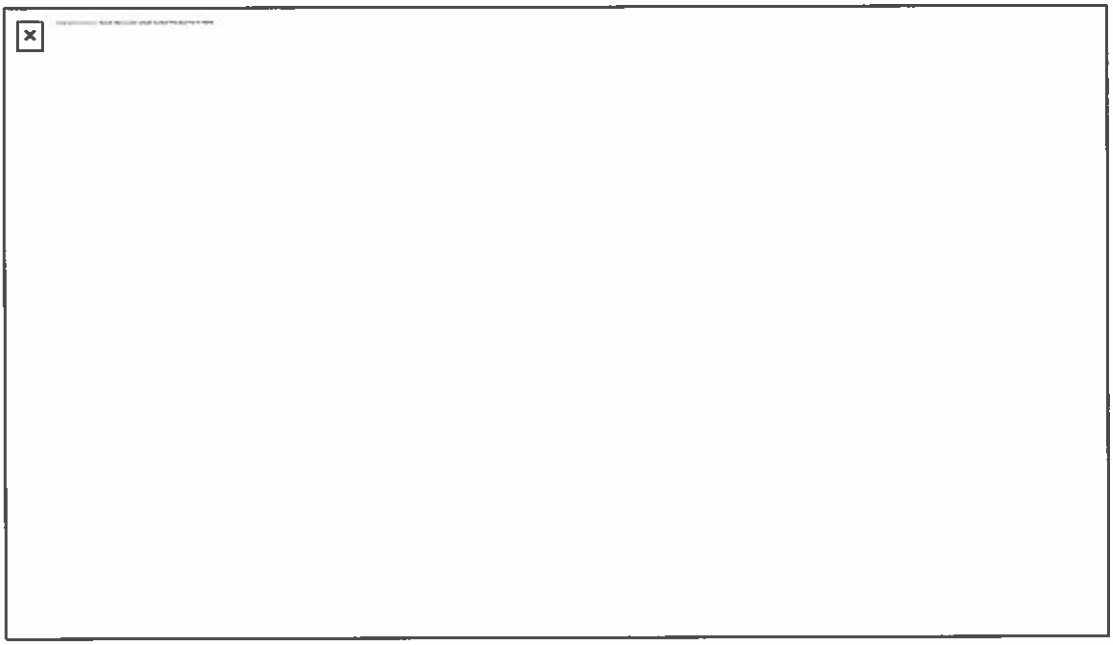
Regardless of where you live in the world (including the United States), the negotiations for a Pathogen Access and Benefit Sharing (PABS) System will impact your life in the future.

The ongoing WHO InterGovernmental Working Group (IGWG) negotiations seek to reach an international agreement to create a global network to isolate "pathogens with pandemic potential," identify their "genetic sequence data," and then send them to a central BIO-HUB in Switzerland.

These pathogens and genetic information will then be shared globally with members of the WHO Collaborating Laboratory Network (WCLN) in order to create Vaccines, Therapeutics and Diagnostics (VTDs). Only those organizations and corporations that are willing to sign contracts in alignment with the details of the PABS System will be permitted to participate.

The PABS System is touted as a way of providing low-income nations with "equitable access" to "pandemic related products." In reality, the World Health Organization seeks to control, manipulate and profit from the discovery, creation, research, development, manufacturing, regulation, distribution and administration of biological weapons-grade "pathogens with pandemic potential."

The proposed PABS system would concentrate all the world's most deadly pathogens into the hands of unelected, unaccountable bureaucrats.



A cartel is a partnership between two or more companies whose goal is to manipulate the market and/or the cost of goods to their advantage.

A cartel is a group of independent corporations, manufacturers, suppliers or other entities that join together to restrict competition, fix prices, rig bids, control or allocate markets, by stockpiling and marketing quotas or conduct other similar illegal activities.

Collusion occurs when entities or individuals work together to influence a market or pricing to their advantage. Acts of collusion can include price fixing and/or sharing insider information.

PABS is the new OPEC cartel:

The Organization of Pandemic Emergency Corporations

The negotiators seem to believe that the only answer is more pharmaceutical products. They want more fake diagnostics, more deadly devices, more

dangerous drugs and more mRNA biological weapons masquerading as "vaccines."

The WHO is ignoring obvious facts about their failed pharmaceutical response to COVID-19:

- Using RT-PCR as a diagnostic test is a fraud.
- Ventilators (along with Midazolam) killed thousands of people.
- Remdesivir (Run-Death-Is-Near) also killed thousands of people.
- The mRNA platform is not a vaccine, it is a biological weapon that has harmed billions of people.

They are ignoring the fact that people in nations of the "Global South" that did NOT have "equitable access" to the pharmaceutical industries' vaccines, therapeutics and diagnostics have actually fared much better and are NOT now suffering the long-term adverse events that have reached pandemic levels among people in the "Global North."

The proposed Pathogen Access and Benefit Sharing (PABS) System is essentially a multinational trade deal to establish a WHO controlled infrastructure for obtaining biological weapons grade pathogens, research (Gain Of Function?), development, manufacturing, and distribution of dangerous products that only benefit the Pharmaceutical Hospital Emergency Industrial Complex (PHEIC).

Participating pharmaceutical manufacturers must agree to share financial and in-kind benefits with the nations that provided the access to the pathogens and their genetic sequence data.

THIS INCENTIVIZES THE SEARCH FOR, AND THE CREATION OF, "PATHOGENS WITH PANDEMIC POTENTIAL."

Natural remedies and pre-existing essential medications that are used by intelligent and creative health care practitioners who work outside the Pharmaceutical Hospital Emergency Industrial Complex (PHEIC) are more than adequate to prevent any and all pandemics.

The diagnostics, devices, drugs, "vaccines" and gene-altering therapies that they believe to be the way to prevent, prepare for and respond to the next

pandemic, have actually caused the current pandemic of VAIDS, myocarditis, stroke, turbo cancer and sudden death.

These negotiations are not designed to prevent, prepare for, or respond to the next pandemic. The PABS negotiations are designed to incentivize the search for deadly pathogens, so that pathogens with pandemic profiteering potential can be circulated through the WHO Coordinated Laboratory Network, not for the benefit of mankind, but for the benefit of those who would profit from the diseases that they would spread through the very system that they are claiming would prevent the next pandemic.

During COVID-19, the denial of such early treatment using existing options was a crime against humanity. Now they want to reward those who find or create "pathogens with pandemic potential."

This is NOT a path to prevent, to prepare for, or to respond to "pandemics."

This is an attempt to create an evil cartel that will profit from the fear generated by propaganda surrounding the never-ending threat of man-made "pandemic emergencies."

QUESTIONS:

1. Why is the WHO ignoring the most obvious reality, that existing natural healing solutions must be employed as soon as possible and faith in dangerous, UNTESTED, high-tech, gene-altering technologies is FRAUDULENT AND MISGUIDED.
2. Why in the world would we allow the WHO, which has diplomatic immunity, to be in control of all the world's most deadly pathogens?
3. Who (WHO?) will be held liable for harm caused by rapidly developed, poorly tested and widely deployed "Vaccines, Therapeutics and Diagnostics?"
4. What defines a pathogen as being a novel "pathogen with pandemic potential?"
5. Why is gain-of-function research NOT being outlawed?
6. Will organizations and corporations be permitted to participate in the PABS System even though the country in which they are based is

NOT a party to the "Pandemic Agreement?" Won't that actually hinder research and development, rather than help it?

THE PABS NEGOTIATIONS MUST BE STOPPED.

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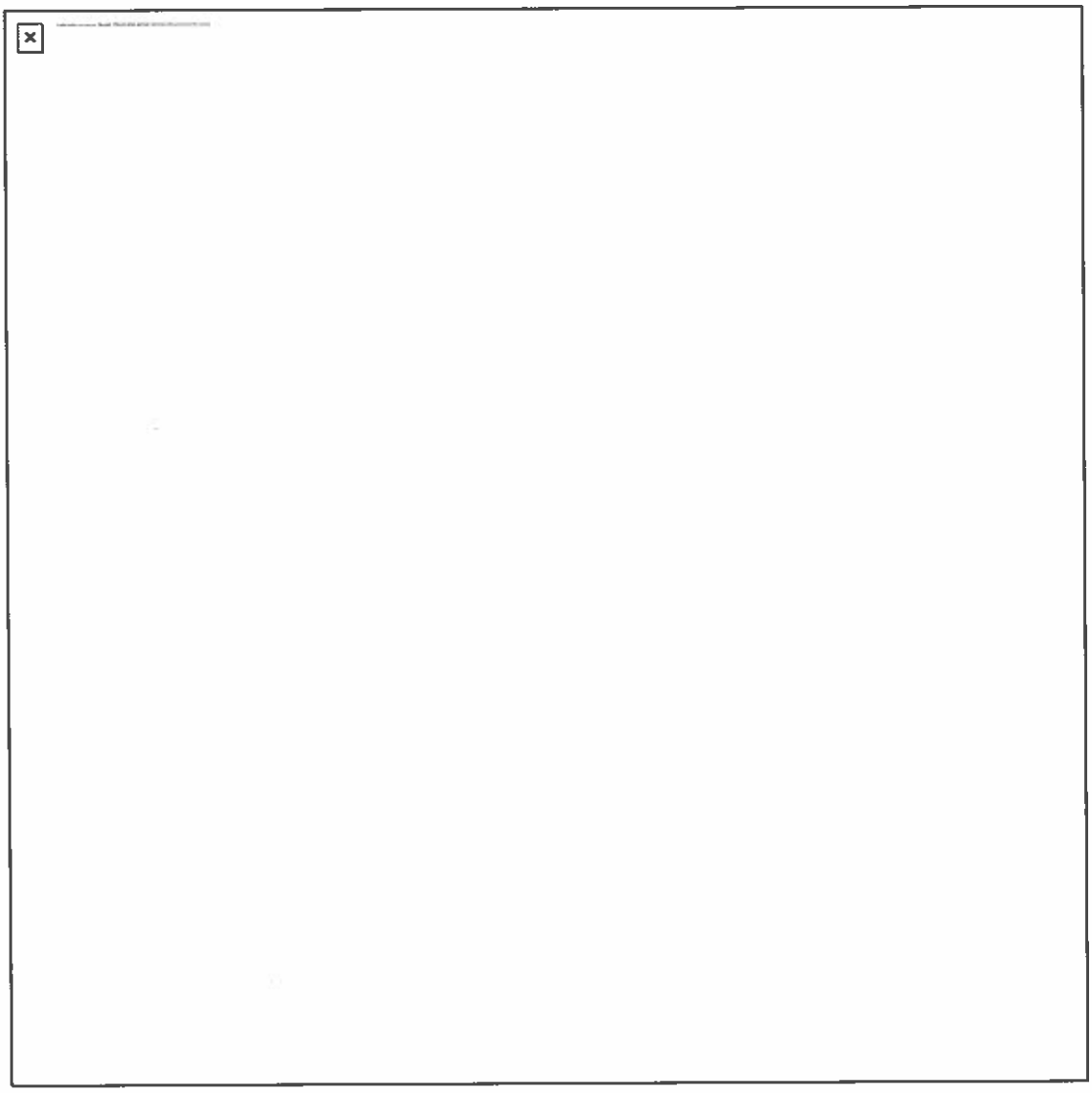
"THE COBRA EFFECT"



As of August 23, 2025, a number of nations have submitted their initial text proposals for the Pathogen Access and Benefit Sharing System.

INITIAL TEXT PROPOSALS

https://apps.who.int/gb/IGWG/

https://apps.who.int/gb/igwg/e/e_igwg2-initial-text-proposals.html

1. Africa Group (3 pages)
2. Australia, the United Kingdom, Norway, Canada, and New Zealand (6 pages)
3. Brazil (6 pages)
4. Central African Republic (French version) (2 pages)
5. China (Chinese version) (4 pages)
   China (English version) (4 pages)
6. Colombia (4 pages)
7. European Union (3 pages)
8. Japan (2 pages)
9. Malaysia (11 pages)
10. Russian Federation (Russian version) (10 pages)
    Russian Federation (English version) (8 pages)
11. South Africa (10 pages)
12. Switzerland (5 pages)
13. Tunisia (French version) (13 pages)
14. Turkiye (1 page)

I have collected all of the text of the initial documents and I have machine translated some of the documents that were only available in French (Central African Republic and Tunisia).

The information below is provided as a go-to resource for those people around the world who really want to comprehend the details of what the WHO negotiations for the Pathogen Access and Benefit Sharing System are really all about.

CLICK HERE TO SHARE YOUR OPINION

Below are some excerpts from the documents submitted by the many nations:

PATHOGEN ACCESS

1. Access to PABS Materials and Sequence Information shall be *subject to terms and conditions defined in a contract between the recipient and the WHO.* [Africa Group]
2. "Pathogens with pandemic potential" [12.2] - Consider and/or address:... synthetic/AI generated sequences) [Australia, UK, Norway, Canada and New Zealand]
3. PABS Materials: isolated wild-type pathogens with pandemic potential, and parts thereof, ***modified pathogens, and any other materials derived from, generated or prepared using the PABS Materials*** **(GAIN-OF-FUNCTION).** [Brazil]
4. All transfers of PABS Materials within the network are subject to Standard Contract 1, which establishes the terms and conditions for sharing. [Brazil]
5. Sharing of Sequence Information occurs via a WHO-managed database. [Brazil]
6. Users of PABS Materials and revenue-generating sequences *must make financial contributions.* [Central African Republic]
7. **Only individuals/entities accepting benefit-sharing commitments through legally binding contracts should have access to PABS Materials and Sequences. [Central African Republic]**
8. **In accordance with Article 12, the scope of the PABS system must be limited to "pathogens with pandemic potential." [Central African Republic]**

9. **Access to the PABS System shall be governed by Standard Material Transfer Agreements (SMTAs) and Data Access Agreements (DAAs). [Malaysia]**
10. 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. [Malaysia]
11. Only authorised national laboratories that agrees to accept the Terms of Reference (ToR), shall be authorized to share PABS Materials under this Annex. [Malaysia]
12. PABS Sequence Information shall only be deposited in and accessed through WHO database. [Malaysia]
13. WHO should cover the costs of shipment incurred by developing countries. [Malaysia]
14. 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. [South Africa]
15. 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. [South Africa]
16. 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"). [South Africa]

17. 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. [South Africa]
18. 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. [Tunisia]

BENEFIT SHARING

1. *Each participating manufacturer shall make available to the World Health Organization, pursuant to legally binding contracts signed with the World Health Organization, rapid access targeting 20% of their real time production of safe, quality and effective vaccines, therapeutics, and diagnostics for the pathogen causing the pandemic emergency, provided that a minimum threshold of 10% of their real time production is made available to the World Health Organization as a donation, and the remaining percentage, with flexibility based on the nature and capacity of each participating manufacturer, is reserved at affordable prices to the World Health Organization.* [Article 12]
2. *Annual monetary contributions* [Article 12]
3. Facilitate the manufacture and export of vaccines, therapeutics and diagnostics for pathogens [Article 12]
4. The granting of non-exclusive licenses to manufacturers in developing countries, for the effective production and delivery of vaccines, therapeutics and diagnostics [Article 12]
5. Other *recipients of PABS Materials and Sequence Information must also enter into legally binding contracts with the WHO* to ensure full compliance with the terms and conditions of the contracts. [Africa Group]

6. Access to PABS Materials and Sequence Information is contingent upon agreement to share benefits. Those benefits will be listed in the legally binding contracts as alternatives for different categories of users, and will include:

   a) Annual financial contributions by commercial users based on revenues generated from pandemic-related health products developed using PABS Materials or Sequence Information;

   b) Capacity-building and technical assistance;

   c) Research and development cooperation;

   d) Open and timely access to research data and results. Includes scientific findings, analyses, and outcomes derived from PABS use.

   e) The granting of non-exclusive licenses to manufacturers in developing countries, for the effective production and delivery of vaccines, therapeutics and diagnostics; and

   f) Other forms of transfer of technology as mutually agreed, including transfer of relevant knowledge, skills and technical expertise. [Brazil]
7. Parties shall facilitate the rapid manufacture and export of vaccines, therapeutics, and diagnostics, and ensure compliance with benefit-sharing obligations. [Brazil]
8. Users must report their analyses and publications to WHO, and agree to terms ensuring compliance and benefit-sharing, including contributions from revenue. [Brazil]
9. When revenue arises from commercialization of products which were developed thanks to the sharing or utilization of Materials or Sequence Information, participating manufacturers shall contribute a percentage of the income to benefit-sharing; [Brazil]
10. To ensure sufficient production during an emergency, *manufacturers using PABS materials and sequences must grant manufacturing licenses to the WHO*, which can then sublicense them to manufacturers in developing countries. [Central African Republic]
11. A fundamental element of the PABS system is that benefit sharing must ensure equitable and guaranteed access to VTDs from the initial stages of outbreaks, to prevent their development into PHEICs, and during PHEICs to prevent pandemics. *This guarantee*

should be materialized in the form of mandatory stockpiles for developing countries. [Central African Republic]

12. This commitment should be applicable not only during emergency periods, but also during non-emergency periods, to build up WHO stockpiles and allow rapid access in the event of outbreaks with pandemic potential. [Central African Republic]
13. Ensure that benefits flow to the providing party. [China]
14. Benefits arising from the use of PABS Materials and Sequence Information shall be shared without undue delay... 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; [Malaysia]
15. Benefits arising from the use of PABS Materials and Sequence Information shall be shared without undue delay... 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; [Malaysia]
16. Benefits arising from the use of PABS Materials and Sequence Information shall be shared without undue delay... 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. [Malaysia]
17. *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. [Malaysia]

18. *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. [Malaysia]
19. *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. [Malaysia]
20. 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. [Russian Federation]
21. **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; [South Africa]
    (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; [South Africa]
    (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 [South Africa]

(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;[South Africa]

(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; [South Africa]

(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); [South Africa]

22. **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; [South Africa]

(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; [South Africa]

23. **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;[South Africa]

(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; [South Africa]

(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 [South Africa]

(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; [South Africa]

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

(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); [South Africa]

24. **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; [South Africa]

(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; [South Africa]

25. **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). [South Africa]

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: [South Africa]

(a) set-asides of real-time pandemic emergencies and PHEICs; [South Africa]

(b) support to WHO stockpiles and outbreak response; [South Africa]

(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 [South Africa]

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

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. [South Africa]

26. 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. [South Africa]
27. 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. [South Africa]
28. *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.* [Tunisia]

29. A multilateral funding mechanism should be established within the PABS system, funded in particular by mandatory or voluntary contributions from beneficiary private entities. [Tunisia]
30. *Any manufacturer that has accessed pathogens must commit to returning a portion of the products developed or profits to the country of origin.* [Tunisia]
31. *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. [Tunisia]
32. *Expected benefits include: Funding for P3-level national laboratories* [Tunisia]
33. Expected benefits include: Preferential access to health products (vaccines, tests, treatments) (details: percentage, free of charge) [Tunisia]
34. 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. [Tunisia]
35. Any entity benefiting from the PABS system, whether public or private, is required to include in the Standard Material Transfer Agreements (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. [Tunisia]

36. ***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]

GOVERNANCE (BUREAUCRACY)

1. 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; [Article12]
2. Administration and coordination of the PABS System shall be undertaken by the World Health Organization under the guidance of the Conference of the Parties, including review by a subsidiary body established by it. [African Group]
3. WHO Coordinated Laboratory Network (WCLN) is an international network of authorized laboratories managed by WHO, governed by the PABS System under the supervision of the Conference of the Parties (COP). Membership requires meeting designated criteria and compliance with contractual terms. [Brazil]
4. The WHO Coordinated Laboratory Network (WCLN) will be established under WHO coordination, linking authorized national laboratories that meet the criteria and agree to abide by the Terms of Reference (ToR), which are legally binding. [Brazil]
5. The PABS System shall be coordinated and administered by WHO, under the authority of the Conference of Parties (COP) [Brazil]
6. WHO shall coordinate and administer the PABS system, under the supervision of the Conference of the Parties. [Central African Republic]
7. The PABS System shall operate under a multi-tiered governance structure. [Malaysia]
8. 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. [Malaysia]
9. 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. [Malaysia]

10. 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. [Malaysia]
11. 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. [Malaysia]
12. 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. [Malaysia]
13. 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. [Malaysia]
14. 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. [Malaysia]
15. 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. [Malaysia]

16. 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. [Malaysia]
17. 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. [Malaysia]
18. 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. [Malaysia]

19. 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. [Malaysia]

20. 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. [South Africa]

21. 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. [South Africa]

22. 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. [South Africa]
23. 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. [South Africa]
24. **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; [South Africa]
25. 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 WHO coordinated laboratory network (WHO lab network), national authorised

laboratories shall meet Conference of the Parties (COP)-adopted criteria, accept specific Terms of Reference detailing tasks, and execute the standard WHO-Lab Standard Materials Transfer Agreement SMTA (and the DAA where PABS Sequence Information (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). PABS Sequence Information (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. [South Africa]

26. To achieve these objectives, it is essential to establish a WHO PABS Sequence Information (PSI) Repository and authorise other repositories or databases to host and disseminate PSI, under contracts with WHO and accountable to the COP. [South Africa]
27. The WHO PSI Repository shall ensure that PABS Sequence Information (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. [South Africa]
28. 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. [South Africa]
29. Compliance of the WHO Lab Network with the SMTA shall be monitored by the Director General. 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. [South Africa]

30. The PABS system is coordinated by WHO, in collaboration with relevant international organizations and stakeholders, in accordance with their respective mandates. [Tunisia]
31. Partner international organizations are selected based on objective criteria defined by a PABS Governance Committee. [Tunisia]
32. The WHO and its partners coordinate logistics, including transportation, distribution, and technical support for recipient countries. [Tunisia]
33. 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: Temporary *exemption from any export restriction* or health protectionism that undermines equity of access. [Tunisia]
34. 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. [Tunisia]
35. The World Health Organization shall establish a permanent PABS coordination unit, responsible for:
    a. the centralized management of Standard Material Transfer Agreements (SMTAs);
    b. monitoring the circulation of pathogens and their associated data;
    c. overseeing the PABS digital platform;
    d. coordinating with the Parties and relevant stakeholders. [Tunisia]
36. A secure digital platform is established and administered by the WHO to:
    a. facilitate the registration, signing, and monitoring of SMTAs;
    b. ensure the traceability of PABS resources and derived products;
    c. ensure transparency of user commitments and accountability;

d. enable public access to non-sensitive scientific data, in compliance with national data protection and biosafety legislation. [Tunisia]

37. 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. [Tunisia]
38. 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. [Tunisia]

Article 12 of the "Pandemic Agreement"

https://apps.who.int/gb/ebwha/pdf_files/WHA78/A78_R1-en.pdf

Article 12 Pathogen Access and Benefit-Sharing System

Section A – Scope (Article 12.1)

1. Recognizing the sovereign right of States over their biological resources and the importance of collective action to mitigate public health risks, and underscoring the importance of promoting 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, the Parties hereby establish a multilateral system for safe, transparent, and accountable access and benefit-sharing for PABS

Materials and Sequence Information, the "WHO Pathogen Access and Benefit-Sharing System" (hereinafter the "PABS System"), to be developed pursuant to paragraph 2 of this Article.

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

2. The provisions governing the PABS System, including definitions of pathogens with pandemic potential and PABS Materials and Sequence Information, modalities, legal nature, terms and conditions, and operational dimensions, shall be developed and agreed in an instrument in accordance with Chapter III (hereinafter the "PABS Instrument") as an annex. The PABS Instrument shall also define the terms for the administration and coordination of the PABS System by the World Health Organization. For the purposes of the coordination and operation of the PABS System, the World Health Organization shall collaborate with relevant international organizations and relevant stakeholders. All elements of the PABS System shall come into operation simultaneously in accordance with the terms of the PABS Instrument.

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

3. Taking into account the differences in the use of PABS Materials and Sequence Information, the development of a safe, accountable and transparent PABS System shall address traceability measures and open access to data.

Section D – Consistency with Nagoya Protocol (Article 12.4)

4. Having regard to Article 4.4 of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their utilization to the Convention on Biological Diversity (hereinafter the "Nagoya Protocol"), the PABS Instrument shall be consistent with, and not run counter to, the objectives of the Convention on Biological Diversity and the Nagoya Protocol, recognising that nothing in this paragraph creates obligations under these instruments for non-Parties thereto.

5. The PABS Instrument referred to in paragraph 2 of this Article, shall contain provisions regarding, inter alia, the following:

(a) the rapid and timely sharing of PABS Materials and Sequence Information and, on an equal footing, the rapid, timely, fair and equitable sharing of benefits, both monetary and non-monetary, including annual monetary contributions, vaccines, therapeutics and diagnostics arising from the sharing and/or utilization of PABS Materials and Sequence Information for public health purposes;

(b) modalities, terms and conditions on access and benefit sharing that provide legal certainty;

(c) implementation in a manner to strengthen, facilitate and accelerate research and innovation, as well as the fair and equitable sharing and distribution of benefits;

(d) development and implementation in a manner:

(i) complementary to, and not duplicative of, the access and benefit sharing measures and obligations of the Pandemic Influenza Preparedness Framework and other relevant international access and benefit sharing instruments, where applicable; and

(ii) to ensure that each Party reviews and, as it deems appropriate, aligns its national and/or regional access and benefit sharing measures applicable to PABS Materials and Sequence Information within the scope of the PABS Instrument, so that measures that are contrary to, or inconsistent with, or duplicative of, the PABS Instrument will not be applied upon entry into operation of all elements of the PABS System.

(e) implementation consistent with applicable international law and with applicable national and/or domestic law, regulations and standards related to risk assessment, biosafety, biosecurity and export control of pathogens, and data protection; and

(f) implementation in a manner to facilitate the manufacture and export of vaccines, therapeutics and diagnostics for pathogens covered by the PABS Instrument.

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

6. The PABS System, as set out in the Annex referred to in paragraph 2 of this Article, shall provide, inter alia, that in the event of a pandemic emergency, as determined in accordance with Article 12 of the International Health Regulations (2005):

(a) each participating manufacturer shall make available to the World Health Organization, pursuant to legally binding contracts signed with the World Health Organization, rapid access targeting 20% of their real time production of safe, quality and effective vaccines, therapeutics, and diagnostics for the pathogen causing the pandemic emergency, provided that a minimum threshold of 10% of their real time production is made available to the World Health Organization as a donation, and the remaining percentage, with flexibility based on the nature and capacity of each participating manufacturer, is reserved at affordable prices to the World Health Organization; and

(b) the distribution of these vaccines, therapeutics, and diagnostics shall be on the basis of public health risk and need, with particular attention to the needs of developing countries, and the Global Supply Chain and Logistics Network referred to in Article 13 may be used to this end.

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

7. The PABS Instrument shall also include benefit sharing provisions, in the event of a public health emergency of international concern as determined in accordance with Article 12 of the International Health Regulations (2005), including options regarding access to safe, quality and effective vaccines, therapeutics, and diagnostics for the pathogen causing the public health emergency of international concern, pursuant to legally binding contracts signed by participating manufacturers with the World Health Organization.

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

8. The PABS Instrument shall also include additional benefit sharing provisions to be set out in legally binding contracts signed with the World Health Organization, including options for:

(a) Capacity-building and technical assistance;

(b) research and development cooperation;

(c) facilitating rapid access to available vaccines, therapeutics and diagnostics with a view to responding to public health risks and events in the context of Article 13.3 of the International Health Regulations (2005);

(d) the granting of non-exclusive licences to manufacturers in developing countries, for the effective production and delivery of vaccines, therapeutics and diagnostics; and

(e) other forms of transfer of technology as mutually agreed, including transfer of relevant knowledge, skills and technical expertise.

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

9. This Article is without prejudice to consideration of other elements for the effective operationalization of the PABS System in a fair, transparent, accountable and equitable manner.

AFRICA GROUP

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

DRAFT – CONFIDENTIAL

Initial Submission of the Africa Group on the Pathogen Access and Benefit-Sharing (PABS) Instrument August 2025

In response to the invitation by the Bureau of the IGWG to submit initial text proposals, in particular the elements to be addressed by the Pathogen Access and Benefit Sharing (PABS) Annex, the Africa Group submits preliminary input to support the work of the Bureau to develop a draft outline of elements to be addressed by the PABS Annex. This preliminary input is without prejudice to the position of the Africa group in future negotiations. The Africa Group reserves its rights to change, nuance, amend these proposals as it sees fit, and to submit new proposals.

The Africa Group reaffirms its strong commitment to the timely and effective conclusion of the PABS Annex to enable entry into force of the Pandemic Agreement. Recognizing the need to safeguard public health while upholding the sovereign rights of States over their genetic resources, as reflected in the Common African Position on Pandemic Prevention, Preparedness and Response (PPPR). The Africa Group supports a multilateral system that ensures equitable, transparent, and predictable benefit-sharing and underscores the importance of legal coherence with existing international frameworks, including PIP Framework, the Convention on Biological Diversity, and the Nagoya Protocol.

The elements set out below derive from Article 12 of the Pandemic Agreement and are essential to develop a well-functioning PABS System.

General

1) Object and Purpose: The provision on object and purpose seeks to establish the functional scope and legal intent of the Annex. Since the PABS System is central to ensuring equity under the WHO Pandemic Agreement (Article 12), the object and purpose must clearly reflect its dual mandate, namely: i) rapid, safe and timely access to PABS Materials and Sequence Information, and on equal footing, ii) the rapid, timely, fair and equitable sharing of benefits, especially with developing countries that are the main source of these materials.

2) Use of Terms: The following key terms must be defined to prevent ambiguity and provide operational clarity, legal certainty and enforceability: i) "PABS

Materials and Sequence Information"; ii) "Pathogens with Pandemic Potential"; iii) "Provider" and "Recipient" of PABS Materials and Sequence Information; iv) "Participating Manufacturer", "User", "Commercial DSI User"; v) "Standard Material Transfer Agreement".

3) Scope: This Annex applies i) to all PABS Materials and Sequence Information shared through the PABS System for public health purposes related to pandemic prevention, preparedness, and response, as well as to all benefit-sharing obligations and entitlements arising from the access, use or transfer of PABS Materials and Sequence Information under the PABS System; ii) to all state parties to the Pandemic Agreement, Providers and Recipients of such PABS Materials and Sequence Information, Participating Manufacturers, the WHO Secretariat, and relevant regional health governmental institutions; and iii) during inter-pandemic periods, PHEICs, and pandemic emergencies as defined under the IHR.

Fundamental Principles

The proposed foundational principles which form the normative basis of the entire PABS System are the following:

1) Sovereign rights of States over their biological resources: Principles of sharing would be based on the sovereign rights of Member States over their biological resources and in a coordinated manner through designation of national focal point.

2) Rapid and timely access to PABS Materials and Sequence Information, and on an equal footing, the rapid, timely, fair and equitable sharing of benefits arising therefrom (nonmonetary and monetary benefits, including annual contributions).

3) Primacy of mutual trust and cooperation, accountability, and transparency in the PABS System.

4) Ethical use, integrity, and traceability of PABS Materials and Sequence Information.

Access and Use

1) Access to PABS Materials and Sequence Information shall be subject to terms and conditions defined in a contract between the recipient and the WHO.

2) Contracts between the WHO and a Participating Manufacturer shall be public and shall contain provisions relating to the rapid, timely, fair and equitable sharing of benefits arising from the sharing and/or utilization of such materials/information.

3) Other Recipients of PABS Materials and Sequence Information must also enter into legally binding contracts with the WHO to ensure full compliance with the terms and conditions of the contracts.

Traceability measures of PABS Material

The WHO shall establish a tracing and tracking mechanism and rules of procedures governing access to PABS materials and Sequence Information, guaranteeing transparency and traceability.

Metadata and identifiers associated with PABS Sequence Information, including unique labels that trace sequences to their country of origin and the PABS System, shall not be removed or altered, to ensure traceability, scientific utility, and transparency in the use of pathogen resources.

Benefit Sharing

Pandemic emergency

In the event of a pandemic emergency, each participating manufacturer shall make available to the World Health Organization, pursuant to legally binding contracts, rapid access targeting 20% of their real time production of safe, quality and effective vaccines, therapeutics, and diagnostics for the pathogen causing the pandemic emergency, provided that a minimum threshold of 10% of their real time production is made available to the World Health Organization as a donation, and the remaining percentage, with flexibility based on the nature and capacity of each participating manufacturer, is reserved at affordable prices to the World Health Organization. Distribution of benefits shall be on the basis of public health risk and need, with particular attention to the needs of developing countries, and within strict time limits.

Public health emergency of international concern

Contracts between the WHO and Participating Manufacturers shall include benefit sharing provisions guaranteeing that, in the event of a public health emergency of international concern (PHEIC) as determined in accordance with International Health Regulations (2005), they shall provide rapid access to safe, quality and effective vaccines, therapeutics, and diagnostics for the pathogen causing the public health emergency of international concern.

Additional benefits

Contracts between the WHO and Participating Manufacturers shall also include provisions regarding the sharing of the following additional benefits by the Participating Manufacturer, including: i) annual monetary contributions to the PABS system to support initiatives for transfer of technology and know-how, research and development, scientific and research collaborations, and laboratory capacity strengthening; ii) provision of vaccines, therapeutics and diagnostics arising from the sharing and/or use of PABS Materials and Sequence Information for public health purposes, 10% free of charge and 10% at not-for-profit rate during the public health emergency of international concern; iii) technology transfers, co-development, and R&D.

Governance, Compliance, Accountability and Enforcement

Administration and coordination of the PABS System shall be undertaken by the World Health Organization under the guidance of the Conference of the Parties, including review by a subsidiary body established by it.

Others

1) Settlement of Disputes: There shall be a dispute settlement mechanism under this Annex pursuant to the provisions of the WHO Pandemic Agreement.

2) Entry into force: The Annex shall enter into force simultaneously with the WHO Pandemic Agreement as an Integral part thereof.

3) Cross referencing provisions of the Nagoya Protocol relevant to traditional knowledge associated with PABS Materials and Sequence Information. ***

AUSTRALIA, THE UNITED KINGDOM, NORWAY, CANADA AND NEW ZEALAND

https://apps.who.int/gb/igwg/pdf_files/IGWG2-initial-text-proposals/AUS-UK-NOR-CAN-NZ.pdf

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

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

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

1. Scope, principles and definitions

Scope: The "WHO Pathogen Access and Benefit-Sharing System" ("PABS System") is a "multilateral system" providing for the "rapid and timely sharing of "materials and sequence information on pathogens with pandemic potential" ("PABS Materials and Sequence Information") and, on an equal footing, the

rapid, timely, fair and equitable sharing of benefits arising from the sharing and/or utilization of PABS Materials and Sequence Information for public health purposes." [12.1] -

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

Principles underpinning the PABS System:

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

Defined terms:

- "Pathogens with pandemic potential" [12.2] - Consider and/or address: factors (e.g., transmissibility, geographic spread, virulence, availability of effective countermeasures, origins, and mutation potential) and process to pre-define and/or identify specific pathogens/pathogen families, including to future-proof the term (e.g., capturing pathogen X and synthetic/AI generated sequences) • "PABS materials" and "PABS sequence information" [12.1]
    - Consider and/or address: separate definitions of materials (samples vs. isolates) and sequence information; alignment with other relevant instruments, whilst avoiding new definitions that could impact on those instruments; future proofing to avoid limiting scientific discovery and technological advancements; implications of excluding or including certain materials and information (e.g.,

associated clinical and epidemiological metadata) in both human, animal and environmentally derived sequences to capture zoonotic pathogens and consider how these different samples/sequence data are managed

- "Participating manufacturer" [12.6(a) and footnote 15]
  - Consider and/or address: link to legally binding contracts per 12.6(a) and 12.7 and any factors the definition should encompass
- Other terms that may need to be defined: e.g., related to institutions, organizations and entities engaged in the PABS system, and potential terms used in "Access" and "Benefit-sharing" provisions, such as "rapid and timely" [12.1 and 12.5(a)]

2. Access

Provisions for "rapid and timely sharing of PABS Materials and Sequence Information" [12.1, 12.5(a)] including to "strengthen, facilitate and accelerate research and innovation" [12.5(c)]

Consider and/or address:

Current practices, functionality, capacities, and costs associated with sharing/accessing different pathogens with pandemic potential (i.e., databases for sequence data and associated meta-data; and laboratories for materials, including relevant handling and transfer practices to ensure biosafety and biosecurity)

Provisions for Parties for "rapid and timely" sharing obtained through routine surveillance and during acute events under the International Health Regulations

Accountability, transparency, traceability measures and open access to data [12.3] and legal certainty over data ownership, rights and obligations for institutions, organizations, entities or individuals sharing and accessing data. This should take into account, inter alia:

- differences in sharing and use of PABS Materials and Sequence Information ▪ requirements from regulatory agencies that regulate sharing (including cross border) and access for laboratories, product developers and manufacturers including for product authorization,

- lessons learned from other ABS systems' access and traceability arrangements such as under the International Treaty on Plant Genetic Resources for Food and Agriculture and the Cali Fund,
- potential use of existing databases (e.g., IP databases, clinical trial registries) to address traceability for use of PABS materials or sequence information for product development, or alternative strategies to address accountability, and
- incentives for research and innovation

Other modalities to ensure access provisions satisfy the objectives of the PABS System, can be effectively operationalised, and are future-proofed (e.g., as genomic sequence data related analysis shifts to bioinformatic and artificial intelligence approaches)

3. Benefit-sharing

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

Pursuant to legally binding contracts between WHO and participating manufacturers including: - in pandemic emergencies, rapid access to a 20% target of real time production of safe, quality and effective VTDs for the pathogen causing the pandemic emergency (minimum 10% available to WHO as donation; remaining percentage reserved at affordable prices, with flexibility based on nature and capacity of each participating manufacturer) to be distributed on the basis of public health risk and need, potentially through the Global Supply Chain and Logistics Network [12.6(a) and (b)] - during a PHEIC, options regarding access to safe, quality and effective VTDs for the pathogen causing the PHEIC [12.7]

- additional benefit-sharing provisions, "including options for: capacity building and technical assistance; research and development cooperation; facilitating rapid access to available [VTDs] with a view to responding to public health risks and events ... ; the granting of non-exclusive licences to manufacturers in developing countries, for effective production and delivery of [VTDs]; and other forms of transfer of technology as mutually agreed [refer footnote 8 in the WHO

Pandemic Agreement], including transfer of relevant knowledge, skills and technical expertise" [12.8]

- Consider and/or address:

- Provisions regarding the framework for legally binding contracts between WHO and participating manufacturers for benefit-sharing and options for benefit-sharing, including whether model clauses form an appendix or are adopted by the Conference of the Parties
- Provisions regarding the negotiation of contracts with participating manufacturers that provide legal certainty, consider the manufacturer's nature and capacity, and increase the likelihood of manufacturers electing options for product access and other benefit-sharing provisions without disincentivizing product development or conclusion of legally binding contracts between WHO and participating manufacturers, and
- Provisions regarding a framework for the distribution of VTDs, including the process and criteria to determine 'public health risk and need', and the role of WHO, other relevant international organizations, and use of the Global Supply Chain and Logistics Network

"[A]nnual monetary contributions" [12.5(a)] - Consider and/or address:

- Provisions regarding the sharing of monetary benefits, including annual monetary contributions, and consider what form non-monetary benefits might take
- Criteria for quantification and terms of contributions
- Governance of contributions once received by the PABS system including transparency, reporting, and scope for spending/allocation – linking to "5. Governance and general provisions

Overall - Consider and/or address:

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

4. Consistency, complementarity and non-duplication

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

- Consider and/or address:

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

National and/or regional ABS measures:

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

- Consider and/or address:

- How national and/or regional ABS measures could be considered inconsistent with, or duplicative of, the PABS Annex
- Time limitations and/or reporting requirements for Parties to share the outcomes of their review and any non-application of measures, taking

into account all elements of the PABS System coming into operation simultaneously

- Other arrangements for identification of contrary, inconsistent or duplicative measures

Applicable international, national and/or domestic law: The PABS System shall be "implement[ed] consistent with applicable international law and with applicable national and/or domestic law, regulations and standards related to risk assessment, biosafety, biosecurity and export control of pathogens, and data protection" [12.5(e)]

- Consider and/or address:

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

5. Governance and general provisions

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

- Consider and/or address:

- Provisions regarding the WHO Secretariat's responsibilities, terms of administration, and operational dimensions including how the PABS System will be situated within the WHO Secretariat, and resourcing considerations compatible with WHO's reprioritization efforts
- Provisions to ensure complementarity and non-duplication with the administration and coordination of the PIP Framework, the Cali Fund and other relevant ABS instruments
- Provisions regarding the development, review and amendment of terms of reference with laboratories and databases that are in line with the principles of the PABS System

- Provisions regarding the development, review and amendment of terms of reference between the WHO and relevant international organizations and relevant stakeholders, including forms for collaboration, and the relevant international organizations and relevant stakeholders that should be involved based on their respective mandates, interests and capacities

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

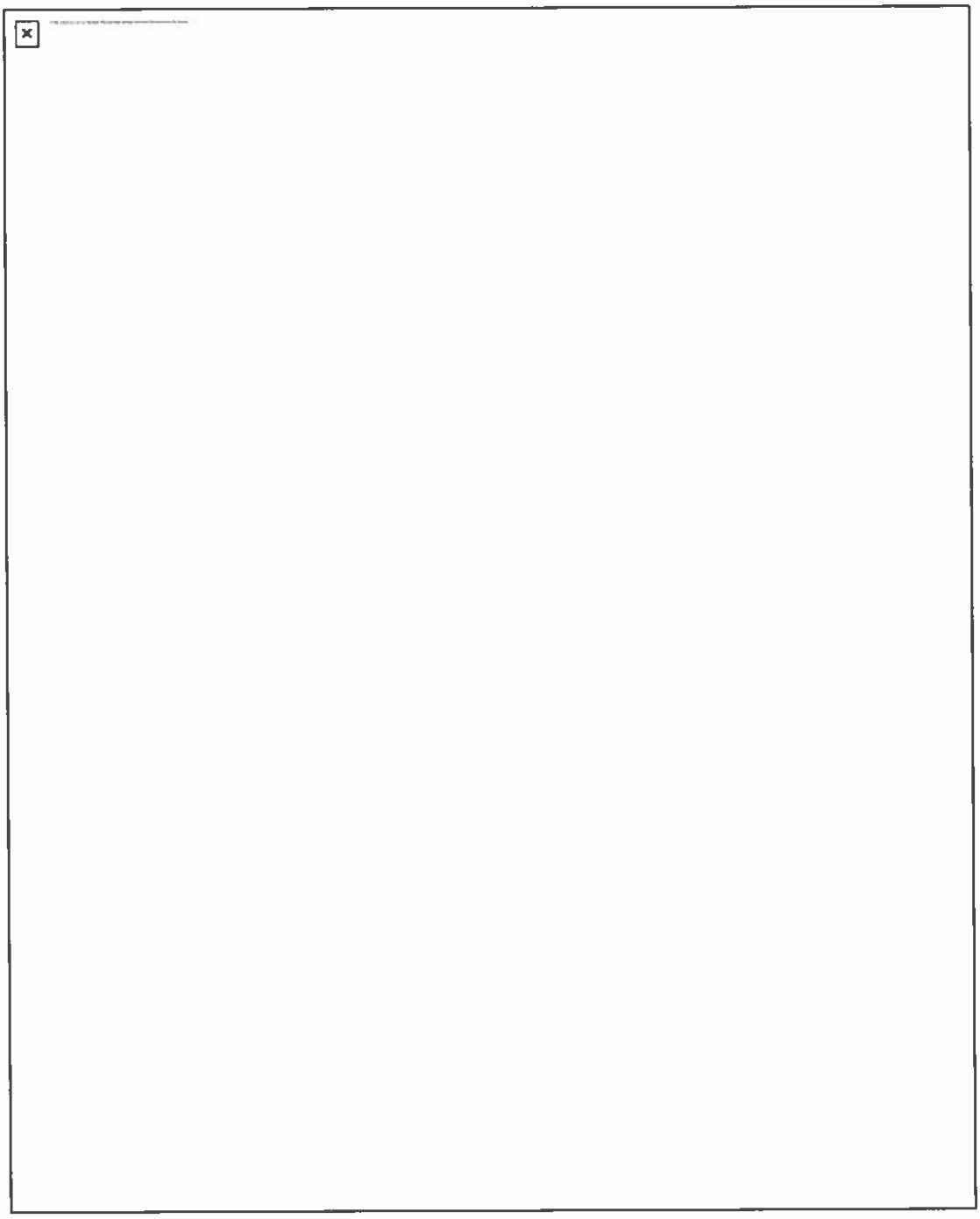
- Consider and/or address:

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

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

- Consider and/or address:

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



BRAZIL

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

MISSION PERMANENTE DU BRESIL AUPRES DE L'OFFICE DES NATIONS UNIES ETDES AUTRES ORGANISATIONS INTERNATIONALES A GENEVE

Chemin Camille-Vidart 15, 1202 Genève

N° 3802025

The Permanent Mission of Brazil to the United Nations Office and other International Organizations in Geneva presents its compliments to the World Health Organization and has the honour to submit, as an attachment, Brazil's text proposals, with elements to be addressed by the Annex of the WHO Pandemic Agreement.

The Permanent Mission of Brazil avails itself of this opportunity to renew to the World Health Organization the assurances of its highest consideration.

CÃODOBRA URDEN PROO GENEBR

Geneva, August 14, 2025

To

World Health Organization Geneva

hqgoverningbodies@who.int

GENERAL PROPOSAL AND OUTLINE SUBMITTED BY BRAZIL TO THE PABS ANNEX PURSUANT TO ARTICLE 12 OF THE PANDEMIC AGREEMENT, AS APPROVED BY RESOLUTION WHA78.1

Pathogen Access and Benefit-Sharing System (PABS) Annex

Recalling Resolution WHA78.1, which adopted, pursuant to Article 19 of the Constitution of the World Health Organization, the WHO Pandemic Agreement and decided to establish an openended Intergovernmental Working Group (IGWG);

Emphasizing the role of the International Health Regulations (2005), adopted through resolution WHA58.3 (2005), and subsequently amended through resolutions WHA67.13 (2014), WHA75.12 (2022), and WHA77.17 (2024), in pandemic prevention, preparedness and response, and the need for coherence and complementarity in the implementation of the International Health Regulations (2005) and the WHO Pandemic Agreement;

Recognizing the continuing threat of pathogens with pandemic potential which calls for enhancing pandemic prevention, preparedness and response and for refraining from taking measures that adversely affect it;

Reaffirming that States have sovereign rights over their own biological resources, as well as the sovereign right to legislate and implement laws, including national access and benefit-sharing legislation;

Recalling the importance of ensuring access to human pathogens for public health preparedness and response purposes,

Considering Article 4.4 of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their utilization to the Convention on Biological Diversity, which states that where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument,

Bearing in mind the parameters established by Article 12 and other applicable provisions of the Pandemic Agreement, Have agreed as follows:

ARTICLE 1: OBJECTIVE

This Annex is developed pursuant to Article 12 of the Pandemic Agreement and establishes the modalities for the implementation of the multilateral system for access and benefit sharing of pathogen materials and sequence information ("PABS System"), in order to render functional a fair, transparent, and accountable multilateral system for the sharing of pathogens and sequence

information. The system aims to facilitate rapid access, equitable sharing, and benefit sharing related to pandemic pathogens.

ARTICLE 2: SCOPE

Paragraph 1: This annex applies to the timely and equitable sharing of "Materials and Sequence Information on Pathogens with Pandemic Potential" (hereinafter referred to as "PABS Materials and Sequence Information"). It also covers the sharing of benefits derived from the use or sharing of such materials and information.

Paragraph 2: For purposes of this annex, "pathogen with pandemic potential" shall be defined as any pathogen that has been identified to infect a human and that is: novel (not yet characterized) or known (including a variant of a known pathogen), potentially highly transmissible and/or highly virulent with the potential to cause a public health emergency of international concern that may develop into a pandemic emergency; in addition to the high potential for transmissibility and severity, it can also be taken into consideration the capacity for severe socioeconomic impact, overloading health systems, and disproportionately affecting vulnerable populations. The WHO Secretariat will make available non-exhaustive list of pathogens with pandemic potential based on its global pathogen prioritization process, which can serve as an initial indication.

Paragraph 3: The PABS System shall operate in complementarity with the Pandemic Influenza Preparedness (PIP) Framework, and shall not, hence, regulate the sharing of influenza virus material or sequence information.

Paragraph 4: All elements of the PABS System shall enter into force simultaneously.

ARTICLE 3: DEFINITIONS

Paragraph 1: PABS Materials and Sequence Information: includes data, metadata or information derived from biological or genetic materials. This definition is operational and may be revised by the Conference of the Parties of this instrument, taking into account changing circumstances.

[OR SEPARATE MATERIALS FROM SEQUENCE INFORMATION]

PABS Materials: isolated wild-type pathogens with pandemic potential, and parts thereof, modified pathogens, and any other materials derived from, generated or prepared using the PABS Materials.

PABS Sequence Information: any data or information generated from PABS Materials through the application of sequencing technologies

Paragraph 3: "Authorized National Laboratories" are laboratories authorized and designated by a Party, recognized within the WHO Coordinated Laboratory Network, to provide PABS Materials and Sequence Information.

Paragraph 4: "Clinical Specimens" include samples obtained from humans, such as respiratory specimens (e.g., swabs, aspirates), blood, serum, plasma, feces, and tissues.

Paragraph 5: "Originating Laboratory" is the authorized national laboratory that first sent the clinical specimen or the isolated pathogen with pandemic potential.

Paragraph 6: "Participating Manufacturer" refers to public or private entities, including academic institutions, government-owned [or government subsidized entities], or nonprofit organizations, involved in developing or manufacturing vaccines, therapeutics, and diagnostics for pathogens with pandemic potential.

Paragraph 7: WHO Coordinated Laboratory Network is an international network of authorized laboratories managed by WHO, governed by the PABS System under the supervision of the Conference of the Parties (COP). Membership requires meeting designated criteria and compliance with contractual terms.

Paragraph 8: "Pandemic related health products" means those relevant health products that may be needed for prevention, preparedness and response to pandemic emergencies (from HIR)

ARTICLE 4: SYSTEM STRUCTURE

Section 4.1: WHO Coordinated Laboratory Network (WCLN)

Paragraph 1: The WCLN will be established under WHO coordination, linking authorized national laboratories that meet the criteria and agree to abide by the Terms of Reference (ToR), which are legally binding.

Paragraph 2: WHO shall facilitate the funding required for transportation of PABS Materials among laboratories within the network, supported by developing country Parties.

Section 4.2: Legally Binding Contracts

Paragraph 1: All transfers of PABS Materials within the network are subject to Standard Contract 1, which establishes the terms and conditions for sharing.

Paragraph 2: By providing Materials, Parties consent to onward sharing under Standard Contract 2, restricting transfers outside the network unless formal agreements are in place.

Paragraph 3: Both contracts include terms on storage, sharing, and use of Sequence Information generated from Materials.

Section 4.3: Sequence Information & Traceability

Paragraph 1: Sharing of Sequence Information occurs via a WHO-managed database, which may host or coordinate with existing databases, ensuring transparency and accountability.

Paragraph 2: Access to the Sequence Database and Participating Databases requires registration, adherence to data access agreements, and verification of user identity.

Paragraph 3: Sequence data must be labeled with identifiers linking the information to the originating country.

Paragraph 4: Users must report their analyses and publications to WHO, and agree to terms ensuring compliance and benefit-sharing, including contributions from revenue.

ARTICLE 5: BENEFIT SHARING

Paragraph 1: Access to PABS Materials and Sequence Information is contingent upon agreement to share benefits. Those benefits will be listed in the legally binding contracts as alternatives for different categories of users, and will include:

a) Annual financial contributions by commercial users based on revenues generated from pandemic-related health products developed using PABS Materials or Sequence Information;

b) Capacity-building and technical assistance;

c) Research and development cooperation;

d) Open and timely access to research data and results. Includes scientific findings, analyses, and outcomes derived from PABS use.

e) The granting of non-exclusive licenses to manufacturers in developing countries, for the effective production and delivery of vaccines, therapeutics and diagnostics; and

f) Other forms of transfer of technology as mutually agreed, including transfer of relevant knowledge, skills and technical expertise.

Paragraph 2: When revenue arises from commercialization of products which were developed thanks to the sharing or utilization of Materials or Sequence Information, participating manufacturers shall contribute a percentage of the income to benefit-sharing;

Paragraph 3: In the event of a pandemic emergency, each participating manufacturer shall make available to the World Health Organization, pursuant to legally binding contracts signed with the World Health Organization, rapid access targeting 20% of their real time production of safe, quality and effective vaccines, therapeutics, and diagnostics for the pathogen causing the pandemic emergency, provided that a minimum threshold of 10% of their real time production is made available to the World Health Organization as a donation, and the remaining percentage, with flexibility based on the nature and capacity

of each participating manufacturer, is reserved at affordable prices to the World Health Organization.

ARTICLE 6: TRANSPARENCY, TRACEABILITY AND REPORTING

Paragraph 1: Access to PABS Materials and Sequence Information shall be subject to prior informed consent of the providing Party, and mutually agreed terms between providers and users.

Paragraph 2: WHO shall establish a PABS tracking mechanism to record all transfers of Materials and Sequence Information within the system.

Paragraph 3: WHO shall publicly disclose:

a) the list of registered recipients of Sequence Information;

b) the list of laboratories within the WHO Coordinated Laboratory Network (WCLN);

c) monetary contributions received from each recipient and their utilization;

d) the contracts (Standard Contracts 2 and 3) concluded with each recipient.

ARTICLE 7: GOVERNANCE OF THE SYSTEM

Paragraph 1: The PABS System shall be coordinated and administered by WHO, under the authority of the Conference of Parties (COP), ensuring fair, transparent, and effective implementation.

Paragraph 2: An independent, conflict-of-interest-free oversight "PABS Advisory Group" shall be established to monitor the system's functioning and provide guidance. The Group shall submit annual evaluations to the COP.

Paragraph 3: The Director-General, in consultation with Member States, shall ensure that the Advisory Group has balanced regional representation, including experts and stakeholders from developing countries.

Paragraph 4: In cases of breaches-by laboratories, databases, or recipients-the DirectorGeneral shall review and, if necessary, suspend or revoke recognition or designation.

Paragraph 5: Parties shall facilitate the rapid manufacture and export of vaccines, therapeutics, and diagnostics, and ensure compliance with benefit-sharing obligations.

ARTICLE 8: STANDARD LEGALLY BINDING CONTRACTS

Section 8.1: Contract 1 – Between the provider (national authorized laboratory) and WCLN recipient

a) The provider agrees to supply Materials and Information strictly for public health, non-profit purposes.

b) Transfers are recorded, and onward transfers only occur under Contract 2.

c) Recipients shall acknowledge origin and contributions, and agree not to claim intellectual property rights over Materials or Sequence Information.

d) All results and analyses must be reported back, and Sequence Information must be shared via the WHO database.

Section 8.2: Contract 2 - Between WHO and external entities outside WCLN

a) Use of Materials and Sequence Information is strictly for research related to pathogens with pandemic potential.

b) Use outside scope requires prior WHO approval.

c) Transfers must be reported and follow the agreed data formats.

d) No intellectual property claims; benefits from use must contribute to benefit-sharing obligations.

Section 8.3: Contract 3 - Data Access Agreement

a) Users agree to use Sequence Information solely for research in accordance with system rules.

b) Access is conditional on registration, signing the agreement, and compliance with confidentiality, rights acknowledgment, and benefit-sharing.

ARTICLE 9: DISPUTE RESOLUTIONS

Standard legally binding contracts in the PABS System shall contain dispute resolution clauses which determine that if a dispute cannot be resolved through negotiations or other non-binding means of the parties' choice, it shall be subject to binding arbitration on conditions that are mutually agreed by the parties.

CENTRAL AFRICAN REPUBLIC

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

The text below has been machine translated from the original French version.

Submission to the Intergovernmental Working Group (IGWG) for the Negotiations of the BSAP Annex Central African Republic

Submission from the Central African Republic

This submission is made in response to the IGWG's invitation to WHO Member States to submit initial text proposals, including elements to be included in the PABS Annex, to support the Bureau in developing a draft framework. We submit the following without prejudice to future text proposals.

Key Elements for the PABS Annex:

1. Benefit Sharing – VTD Stockpiles to Prevent PHEICs and Pandemics

A fundamental element of the PABS system is that benefit sharing must ensure equitable and guaranteed access to VTDs from the initial stages of outbreaks, to prevent their development into PHEICs, and during PHEICs to prevent pandemics. This guarantee should be materialized in the form of mandatory stockpiles for developing countries.

VTD manufacturers using PABS Materials and sequence information must commit to providing at least 15% of their production in real time (or from stockpiles in the absence of active production) to the WHO for these purposes, at least half of which will be free and the other half at cost.

This commitment should be applicable not only during emergency periods, but also during non-emergency periods, to build up WHO stockpiles and allow rapid access in the event of outbreaks with pandemic potential.

2. Benefit Sharing – During PHEICs and Pandemics

Article 12 currently sets a target of 20% VTD reserves for pandemic emergencies, with 10% guaranteed free of charge. As proposed in Element 1, extending these reserves to developing countries is essential to prevent PHEICs and pandemics.

Additionally, to ensure sufficient production during an emergency, manufacturers using PABS materials and sequences must grant manufacturing licenses to the WHO, which can then sublicense them to manufacturers in developing countries.

3. Benefit Sharing – Financial Contributions

Users of PABS Materials and revenue-generating sequences must make financial contributions.

These funds should be used to strengthen health systems in developing countries and develop geographically diverse VTD manufacturing and distribution capacities.

4. Legally Binding Contracts for Access to PABS Materials and Sequences

- Only individuals/entities accepting benefit-sharing commitments through legally binding contracts should have access to PABS Materials and Sequences.
- These contracts should specify that any access to the Materials and Sequences is subject to legal and specific conditions relating to the prevention, preparation and response to pandemics, with equitable sharing of the results obtained.

5. Scope of the PABS System

In accordance with Article 12, the scope of the PABS system must be limited to **"pathogens with pandemic potential."**

The use of materials and sequences must be for the sole purpose of preventing, preparing for, and responding to pandemics. Effective measures must prevent the reuse of resources for other purposes.

6. Traceability and Reporting Mechanism

- For increased transparency and accountability, it is essential that all users of PABS Materials be identifiable and under a reporting obligation.
- All transfers of PABS Materials, including those to WHO-designated laboratories, must be recorded.
- Sequence databases must report to WHO and the Parties to the Agreement. No anonymous sharing.
- All contracts, as well as financial and non-financial benefits received, must be made public.

7. Governance of the PABS System

WHO shall coordinate and administer the PABS system, under the supervision of the Conference of the Parties, including all the key elements mentioned above.

CHINA

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

Unofficial Translation

Comments and Suggestions of the China Regarding Elements to be Addressed in the Annex of the WHO Pandemic Agreement

According to the negotiation vision for the main text of the World Health Organization Pandemic Agreement, the dedicated Annex formulated under Article 12 will provide specific implementation details on the provisions for Pathogen Access and Benefit-Sharing (PABS), clarifying the obligations and responsibilities of PABS participants under the WHO multilateral system. To this end, the following comments and recommendations are proposed:

I. Guiding Principles Suggestions:

While safeguarding national biosafety and reaffirming States' sovereign rights over their biological resources, every effort should be made to facilitate the sharing of pathogen-related information, maximise its public-health value, and promote equitable global access to vaccines, therapeutics and diagnostics arising from such sharing.

II. Participation in the PABS System Suggestions:

Define the scope of eligible participants and the modalities of their engagement, covering national governments, manufacturers of health products, research institutions, international organisations and philanthropic entities. For manufacturers participating in the PABS framework, specify qualification criteria, boundaries of liability, and both financial and technical benchmarks,

and make these contingent on whether their home State is a Party to the Pandemic Agreement.

III. Definition of Pathogens with Pandemic Potential Suggestions:

A pathogen should qualify only if it is both highly transmissible and highly virulent, lacks effective countermeasures, and shows clear potential for cross-regional spread that could evolve into a global emergency. The definition should draw on WHO's June 2024 publication "Pathogens Prioritisation – A Scientific Framework for Epidemic and Pandemic Research Preparedness" to establish a PABS pathogen list, while also taking into account the feasibility of manufacturing and access to related medical countermeasures so as to avoid an over-expansive list that would dilute focus.

IV. Governance of Genetic Sequence Data Suggestions:

Apply a tiered-management approach to GSD: sensitive data must be de-identified, access strictly controlled, and multiple technical safeguards deployed to prevent leakage or misuse, all in line with existing standards. Establish cross-platform sharing mechanisms, clarify rules on data use, keep basic data fully open, and allow high-risk information to be shared on a restricted basis after vetting. Build upon the three existing WHO databases (GISRS, FluNet and FluID) to extend platform coverage, strengthen the link between physical samples and digital data, and ensure full traceability.

V. Traceability of Pathogens Suggestions:

Institute a mechanism that tracks both the chain of custody of biological samples and the linkage to associated data, thereby creating a complete evidentiary trail. The Influenza Virus Traceability Mechanism (IVTM) can serve as a reference model.

VI. Data Openness:

Uphold the principles of controllable security, tiered and classified openness, and matching rights with responsibilities. High-risk data may be released only after review and only to accredited laboratories (endusers). Conditionally open data shall require certification or application; restricted data must be de-

identified or shared solely with authorised entities. Non-sensitive baseline data should be fully open. End-users must commit to lawful use, provide timely feedback on results, and offer the providing party opportunities to participate in related research.

VII. Pathogen Transport and Biosafety Suggestions:

Guided by the principles of respect for sovereignty, risk stratification and global equity, establish a safe, equitable and efficient cross-border transport regime that facilitates pathogen and sample sharing while maintaining full traceability of biological material transfers. The regime should cover import/export approvals, packaging, transport and emergency-response requirements, and must align with domestic legislation and internationally recognised technical standards. Explore a global logistics coordination framework comprising multimodal corridors, strategic stockpile hubs, regional nodes, unified technical standards, standardised protocols, priority-clearance mechanisms, digital platforms and blockchain-based traceability. Ensure that all pathogen samples are handled in accordance with the WHO Laboratory Biosafety Manual and other relevant guidelines to mitigate laboratory biosafety risks.

VIII. Benefit Sharing Suggestions:

i) Ensure that benefits flow to the providing party. Create a feedback mechanism inspired by the Nagoya Protocol, grant priority access to resulting health products, and require attribution of contributions or the offer of collaboration opportunities.

ii) Develop quantified allocation criteria, allocation principles and oversight mechanisms for PABS benefit sharing, including sample handling fees, distribution mechanisms and workflows.

iii) Elaborate detailed rules for sharing pandemic-related health products, covering the scope of products, the timeframe for achieving target sharing ratios, applicable quality standards and risk-management measures.

iv) Clarify the recipients, necessity and calculation rules for annual contributions, assess possible adverse impacts and adopt appropriate safeguards.)

IX. Relationship with Other Instruments Suggestions:

Ensure coherence with other international instruments. The annex should include relevant provisions confirming that Article 12 creates no obligations for non-Parties to the Convention on Biological Diversity or the Nagoya Protocol, and imposes no additional obligations on institutions participating in the Pandemic Influenza Preparedness (PIP) Framework when accessing or utilising influenza or avian influenza viruses.

COLOMBIA

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

Colombia – criteria:

Dispositions of the mechanism should not hinder information sharing, data openness, transparency and innovation and research efforts through the sharing of materials and sequence information of pathogens.

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)

Colombia - Text Proposal:

Pathogens that represent, or could represent, a public health emergency of international concern, in the terms defined by the International Health Regulations (2005), and after applying the criteria contained in the Decision Instrument for the Assessment and Notification of Events that May Constitute a Public Health Emergency of International Concern.

Rationale:

The definition must be coherent with the International Health Regulations (2005) definition of "public health emergency of international concern" and its notification procedure, considering criteria such as risk significance, seriousness of the impact, among others.

PABS Materials and Sequence Information; (Article 12.2)

Colombia – Text Proposal:

- PABS Materials: Pathogen with pandemic potential and or its physical parts and components, including DNA, RNA, proteins, among others.

- PABS Sequence Information: Information derived from the analysis of PABS materials.

Comment:

It is essential that both elements (materials and sequence information) are separately defined.

Participating manufacturer (Article 12.6(a))

Other technical terms

(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)

Colombia – criteria:

The management and administration of the PABS system must involve focal point of country Parties and must have oversight and accountability mechanisms to ensure the adequate use of resources.

(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))

Colombia – criteria:

Dispositions of the mechanism should not hinder information sharing, data openness, transparency and innovation and research efforts through the sharing of materials and sequence information of pathogens.

(7) Facilitation and acceleration of research and innovation (Article 12.5(c))

Colombia – criteria:

PABS mechanism should not hinder Parties' autonomy to share PABS materials and sequence information in efforts associated to innovation and research.

Emphasis should be made in developing countries needs and possible mechanisms of support such as technologies and knowledge transfer agreements.

(8) Complementarity with the PIP Framework and other relevant ABS instruments (Article 12.5(d)(i))

Colombia – criteria:

PABS mechanism should not exclude other ABS instruments that include PABS materials and sequence information.

(9) Review and alignment of national and/or regional ABS measures (Article 12.5(d)(ii))

(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))

Colombia – criteria:

Mechanisms of knowledge and technology transfer should be detailed, including import and export arrangements to facilitate access to relevant technologies during a pandemic.

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

Colombia – Text proposal:

Any traceability measure cannot go against the sharing of information, including public information or sequence information, and should maintain the active communication and collaboration and the sharing of information with public health significance

Rationale:

Measures taken cannot go against free access to information and data bases and must not favor the creation of private data bases. Free sharing of information must be ensured, respecting national legislation and each State's autonomy.

Section D – Consistency with Nagoya Protocol (Article 12.4)

Colombia – criteria:

PABS must be compatible with article 15, paragraph 1 of CBD, and with article 3 of Nagoya.

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 12.5(b))

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

Colombia – criteria:

Section must remain consistent with article 12 of the International Health Regulations (2005). The risk assessment of the event at the international level and the effectiveness of control measures should be considered. Measures to prevent and avoid national spread should be included.

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

Colombia – criteria:

This section should address considerations for the effective implementation of mutually agreed forms of technology transfer, including the transfer of relevant knowledge, skills, and technical expertise, in accordance with the provisions of Article 12.8(e).

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

EUROPEAN UNION

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

EU input, 25 July 2025

OUTLINE OF ELEMENTS TO BE ADDRESSED BY THE ANNEX TO THE WHO PANDEMIC AGREEMENT DESCRIBED IN ARTICLE 12 OF THE WHO PANDEMIC AGREEMENT (THE "PABS ANNEX")

Introductory remarks

In response to the invitation by the Bureau of the IGWG to submit initial text proposals, in particular the elements to be addressed by the Annex of the WHO Pandemic Agreement, the EU and its Member States submit the below input for the purpose of supporting the work of the Bureau to develop a draft outline of elements to be addressed by the PABS Annex. The elements set out below derive from Article 12 of the Pandemic Agreement and are essential to develop a well-functioning PABS System.

The elements can usefully be grouped into five main themes or areas:

1. Use of terms
2. Benefit sharing
3. Access
4. Governance issues and
5. General and final provisions.

To facilitate and advance work on the Annex in the best possible way, the EU and its MS consider that an enhanced common understanding of the overall purpose of the PABS, as well as of the eventual content of these five key areas will be beneficial. In this respect, the EU and its Member States look forward to constructive substantive discussions to this end at the second meeting of the IGWG in September.

We underline that the below input is initial and entirely without prejudice to further input and proposals, including proposals for legal text, that the EU and its Member States may decide to submit subsequently during the process to develop the PABS Annex.

1. USE OF TERMS

- "Pathogens with pandemic potential"
- "PABS Materials"
- "PABS Sequence Information"
- "WHO PABS System" (understanding of what "System" means and what is its legal nature)
- Some of the parameters listed under Benefit Sharing and Access in particular may become defined "terms"

2. BENEFIT SHARING

Benefit Sharing parameters:

Contracts with participating manufacturers (which are both legally-binding and voluntarily concluded) as the instrument for benefit sharing

Specification of parameters (model clauses can be set out in an Appendix to the Annex if considered useful) for the making available of set aside quantities of VTDs to WHO, including:

- scope of VTDs [Vaccines, Therapeutics and Diagnostics]

- set aside quantities
- triggering event (declaration of pandemic emergency)
- rapid access
- real time production
- participating manufacturer
- flexibility based on the nature and capacity/ size of each participating manufacturer ✓ donation ✓ reservation at affordable prices, etc.

Definition and parameters for quantification of annual monetary contribution o The distribution and use of annual monetary contributions

Options for benefit sharing in the event of a PHEIC

Definition of additional benefit sharing options (including in times of neither PHEIC nor PE):

- capacity-building and technical assistance; o research and development cooperation;
- facilitating rapid access to available vaccines, therapeutics and diagnostics with a view to responding to public health risks and events in the context of Article 13.3 of the International Health Regulations (2005);
- granting of non-exclusive licences to manufacturers in developing countries, for the effective production and delivery of vaccines, therapeutics and diagnostics;
- other forms of transfer of technology as mutually agreed, including transfer of relevant knowledge, skills and technical expertise.

Distribution of VTDs:

- Definition of parameters and criteria for the equitable distribution of vaccines, therapeutics, and diagnostics based on public health risk and need;
- Facilitation of the manufacture and export of vaccines, therapeutics and diagnostics for pathogens covered by the PABS Annex

3. ACCESS

Provisions to ensure "rapid and timely sharing" of PABS Materials (obligations for Parties)