

## **SUBMISSION BY THE GROUP FOR EQUITY**

### **OUTLINE & KEY ELEMENTS FOR ANNEX ON WHO PATHOGEN ACCESS AND BENEFIT SHARING SYSTEM (PABS SYSTEM)**

This submission contains some elements to be addressed by the Annex, and is without prejudice to any further elements and textual proposals and suggestions put forward jointly or individually as the discussion progresses.

#### **A. OBJECTIVE**

This Annex is developed pursuant to Article 12 of the Pandemic Agreement and establishes the provisions governing the PABS System, in order to operationalize a fair, transparent, and accountable multilateral access and benefit-sharing system for PABS materials and sequence information.

#### **B. SCOPE**

1. The Annex applies to the rapid and timely sharing of “materials and sequence information on pathogens with pandemic potential” (hereinafter “PABS Materials and Sequence Information”) and, on an equal footing, the rapid, timely, fair and equitable sharing of benefits arising from the sharing and/or utilization of PABS Materials and Sequence Information.
2. For the purpose of the Annex “pathogen with pandemic potential” means [placeholder]
3. The PABS System shall operate complementarily to the PIP Framework.
4. All elements of the PABS System shall come into operation simultaneously.

#### **C. DEFINITIONS FOR THE PURPOSE OF THE ANNEX** (the list below is non-exhaustive and may be expanded)

1. PABS Materials: (i) isolated wild-type pathogens assessed to have pandemic potential, and parts thereof; (ii) any modified forms of such pathogens; and (iii) any other materials derived from, generated or prepared using the materials described in (i) and (ii).
2. PABS Sequence Information: any data or information generated from PABS Materials through the application of sequencing technologies
3. Authorized national laboratories: laboratories authorized and designated by a Party to provide PABS Materials and/or PABS Sequence Information to the PABS System and recognized as part of the WHO Coordinated Laboratory Network.
4. Clinical Specimens: materials taken from humans including specimens collected from the respiratory tract (for example, swabs and aspirated fluid), and also blood, serum, plasma, faeces, and tissues.

5. Originating laboratory: a national authorised laboratory that sent the initial clinical specimens and/or the isolated pathogen with pandemic potential
6. Participating Manufacturer: public and/or private entities that develop and/or manufacture vaccines, therapeutics and diagnostics for pathogens with pandemic potential including academic institutions, government owned or government subsidized entities, nonprofit organizations or commercial entities.
7. WHO Coordinated Laboratory Network an international network of authorized national laboratories coordinated by WHO and governed by the PABS System under the supervision of COP. To be a part of the WHO Coordinated Laboratory Network, an authorized national laboratory must meet the criteria for designation and agree to comply with terms and conditions as set out in the Standard Contract 1, the applicable Terms of Reference, and any other requirements of the PABS system.
8. [placeholder: affordable prices]

#### **D. FRAMEWORK OF THE PABS SYSTEM<sup>1</sup>**

##### **1. WHO Coordinated Laboratory Network (WCLN)**

- a. WCLN coordinated by WHO under the oversight of COP, shall be established. The network will link authorised national laboratories that meet the criteria for participating in the WCLN and agree to accept the Terms of Reference (ToR), the legally binding terms and conditions applicable to the sharing/utilization of PABS Materials and PABS Sequence Information, as well as other requirements of the PABS system.
- b. WHO shall be responsible for facilitating the funds required to cover the costs related to shipment of PABS Materials to and within the WHO Coordinated Laboratory Network, by developing country Parties.

##### **2. Standard Legally Binding Contracts Applicable to the Sharing of PABS Materials and PABS Sequence Information**

- a. All transfers of PABS Material by an authorised national laboratory to a laboratory that is part of WCLN and further transfers within WCLN are subject to Standard Contract 1.
- b. By providing PABS Materials to laboratories designated as part of the WHO Coordinated Laboratory Network, the provider Party provides their consent for the onward transfer to and use of PABS Materials by Recipient Entities outside the WCLN that have signed Standard Contract 2 with WHO. Recipients agree not to transfer or share PABS materials to entities outside WCLN that have not signed Standard Contract 2.
- c. Both Standard Contract 1 and 2 shall contain terms and conditions applicable to the storage, sharing, and use of sequence Information generated by recipients from PABS Materials.

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<sup>1</sup> Colombia requires further internal consultation on section D, sub-sections 1, 2, 3, and 5.

### **3. PABS Sequence Information & Traceability Measures**

#### **3.1. WHO Coordinated Database Network (WCDN)**

- a. Sharing of any PABS sequence information shall be through a WHO PABS Sequence Database that is transparent and accountable to Parties and implements requirements set out in sub-paragraph (d) and COP decisions. WHO may host such a database or may, following a COP decision, organise an existing database to host the WHO PABS Sequence Database.
- b. Other databases may access and share PABS sequence information, subject to the database entering into a legally binding contract with WHO, agreeing to comply with terms and conditions set out in sub-paragraph (d) (hereinafter referred to as “Participating Databases”).
- c. WHO PABS sequence database, along with participating databases constitute WCDN.
- d. WHO PABS Sequence Database and other Participating Databases hosting PABS Sequence Information to comply with terms and conditions including:
  - (i) require registration and acceptance of Data Access Agreement (Standard Contract 3) from all users of database intending to access PABS Sequence Information;
  - (ii) provide access to PABS Sequence Information to all registered users, whose identity is verified, without any fee charged and without any form of discrimination.
  - (iii) attach persistent unique labels to sequence files or datasets in a manner identifying originating country of the PABS materials from which sequence information is generated
  - (iv) make available facilities for registered users to link their scientific or other publications, provide information of R&D progress and R&D outcomes that use/refer to PABS Sequence Information;
  - (v) provide information related to usage of databases, including a list of registered users as well as other particulars, to WHO periodically and/or upon request.
  - (vi) agree to comply with all requirements of PABS system and act in accordance with WHO/COP decisions in this regard.
  - (vii) In the event, the participating database is generating revenue from the sharing/utilization of PABS Sequence Information, the participating database agrees to contribute towards monetary benefit-sharing;

#### **3.2 Standard Legally Binding Contract Applicable to the Sharing of PABS Sequence Information**

- a. Parties to take measures to ensure that PABS sequence information is shared through the WHO PABS Sequence Database and consistently with its requirements.
- b. Laboratories within WCLN to share all PABS Sequence Information through the WHO PABS Sequence Database.
- c. Submission of PABS Sequence Information to be based on the format as decided by the COP, and such format shall include requiring the submitter to provide information on the country of the originating laboratory

#### **4. Fair and Equitable Benefit-Sharing from Recipients of PABS Materials and Sequence Information (to be reflected in Standard Contracts 2 and 3)**

##### **4.1 Annual Monetary Contributions** (applicable to all recipients accessing PABS Materials and/or PABS Sequence Information)

- When revenue is generated from the sharing/utilization of PABS Materials and/or PABS Sequence Information, to annually contribute x% of total annual revenue for each product or service developed and commercialised using the PABS System. Annual revenue includes all financial benefits such as income from sales and royalties.

##### **4.2 Non-monetary Benefit Sharing**

###### **a. Participating manufacturer:**

(i) in the event of a pandemic emergency, to make available make available to the WHO 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 WHO 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 WHO, in accordance with paragraph 6 of Article 12

(ii) to provide to WHO on request, at not-for-profit prices and on a priority basis, the vaccines, therapeutics and diagnostics, for stockpiling and/or to supply affected developing countries, to prevent, prepare for and respond to a PHEIC. The set-asides to be determined in IGWG

(iii) in the event of a PHEIC and/or a pandemic emergency, to grant WHO non-exclusive licenses that can be sublicensed to manufacturers in developing countries, especially to those that provided PABS Materials and PABS Sequence Information, for the development and/or production of pandemic-related products needed in developing countries, to expand supply rapidly, ensuring prompt equitable access in developing countries. Such a license to include provision of the full regulatory dossier, technical know-how, and any necessary materials (e.g. cell-lines etc.).

###### **b. Recipients accessing PABS Materials and/or PABS Sequence Information for strictly for Non-Commercial uses (not intended to generate revenue)**

To make available all outcomes from the non-commercial use of PABS Materials and PABS Sequence Information freely available and accessible in the public domain, and the same shall be reported through the WHO PABS Sequence Database such that it shall be linked to the sequence information accessed. In the event revenue is generated, monetary benefit sharing will be required.

###### **c. Other Recipients**

[placeholder to add further non-monetary benefit sharing as discussion progresses]

## **5. Transparency, Traceability & Reporting Mechanism**

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

5.2 WHO to establish a PABS tracking Mechanism to record all transfers of PABS Materials

5.3 WHO to make publicly available:

- a. the list of registered recipients of PABS Sequence Information;
- b. the list of WCLN labs
- c. monetary contributions received from each recipient and their utilization;
- d. standard contracts 2 & 3 concluded with each recipient.

## **6. Governance of the PABS System**

6.1. PABS system to be coordinated and administered by the WHO, under authority of the COP. WHO to take all measures necessary to ensure a fair, transparent, equitable, effective, efficient and accountable implementation of the PABS System.

6.2. An independent, free of conflict of interests, oversight “PABS Advisory Group” to be established to monitor and to provide guidance to WHO on the functioning of the PABS system in accordance with the terms of reference for the Advisory Group. The PABS Advisory Group to present an annual report to the COP on its evaluation of the implementation of the PABS system, with its recommendations for COP’s approval.

6.3. The Director-General, in consultation with Member States, to ensure that the PABS Advisory Group is based on fair and equitable representation of the WHO regions, taking into account the importance of representation from developing countries. The PABS Advisory Group will comprise xx members drawn from each WHO Region, with a skill mix of internationally recognized policy makers, public health experts and technical experts.

6.5. In the event of any alleged breaches of the terms of reference or the Standard Contract by a WCLN laboratory, the Director-General will review the circumstances and discuss with the PABS Advisory Group any appropriate action in response to those breaches. Where there has been a serious breach, the Director-General may consider suspending or revoking the WHO designation of the relevant laboratory.

6.6 In the event of any alleged breaches of the terms of reference or the Standard Contract by WHO PABS Sequence Database or participating databases, the Director-General will review the circumstances and discuss with the PABS Advisory Group any appropriate action in response to those breaches. Where there has been a serious breach, the Director-General may consider suspending or revoking the WHO designation of the relevant database.

6.7. In the event of any alleged breaches of the Standard Contract by receiving entities (outside the WCLN laboratory, WHO PABS Sequence Database, and participating database), the Director-General will review the circumstances and discuss with the PABS Advisory Group any

appropriate action in response to those breaches. Where there has been a serious breach, the Director-General may consider suspending or revoking the access of such receiving entities.

**6.8. Responsibilities of Parties:**

- a. to take all steps to facilitate the rapid and timely manufacture and export of vaccines, therapeutics and diagnostics, and to operationalise other benefit-sharing obligations that recipients have committed to provide to prevent, prepare for and to respond to a PHEIC and/or a pandemic emergency for pathogens covered by the PABS system.
- b. to ensure compliance of non-state actors with all components of the PABS System

**E. STANDARD LEGALLY BINDING CONTRACTS**

**STANDARD CONTRACT 1:**

**TERMS AND CONDITIONS APPLICABLE TO NATIONAL AUTHORISED LABORATORIES AND WCLN LABORATORIES**

Legally binding contract between the Provider (national authorised laboratory sending PABS Materials and Sequence Information) and Recipient (WCLN laboratory receiving PABS Materials and Sequence Information), to be concluded when becoming a member of WCLN. Terms and conditions to be included in the standard contract include:

1. The recipient agrees to comply with its ToR and to use the PABS Material and clinical specimen solely for public health purposes as set out in the Terms of Reference, for the prevention, preparedness and response to a pandemic, and not-for-profit.
2. All transfers of PABS Materials to be recorded in the PABS Materials Tracking Mechanism.
3. Onward transfer and use of the PABS Materials to all WCLN laboratories to be on the same terms and conditions applicable to WCLN; and to entities outside the WCLN subject to the Entity concluding Standard Contract 2 with the WHO.
4. Recipient to actively seek participation of scientists from originating laboratories, especially those from developing countries, in scientific or R&D projects associated with research on PABS Material and Sequence Information from their countries, as well as actively engage them in preparation of manuscripts for presentation, publication or any other outcomes;
5. Recipient to appropriately acknowledge in presentations and publications the contributions of collaborators, including originating laboratories/countries providing the PABS Material and Sequence Information.
6. Intellectual property shall not be sought or asserted over any PABS Materials and Sequence Information, or parts thereof, in any form, including any modified form or for any use.
7. The recipient to regularly and/or on request, share all analyses and outcomes from the sharing/utilization of PABS Materials and PABS Sequence Information with the Provider.
8. Sharing of PABS sequence information to be through the WHO PABS Sequence Database and agree to comply with the terms and conditions as applicable to the users of PABS Sequence Information.
9. Agrees to comply with COP decisions with respect to the PABS system
10. Criteria for an authorized national laboratory to ensure biosafety and biosecurity.

**STANDARD CONTRACT 2:**

**TERMS AND CONDITIONS APPLICABLE BETWEEN WHO AND ENTITIES OUTSIDE OF WCLN**

Legally binding contract between: WHO and the Recipient Entity (outside of the WCLN laboratory receiving PABS Materials and PABS Sequence Information). The recipient entity can access PABS Materials and PABS Sequence Information from WCLN, subject to the conclusion of a legally binding contract with WHO. Terms and conditions of the standard contract include:

1. using the PABS Materials and PABS Sequence Information solely and strictly for research and development in connection with pathogens with pandemic potential within the scope of the PABS system for the prevention, preparedness and response to a pandemic.
2. to keep WHO informed of all uses of PABS Materials and PABS Sequence Information, as well as any changes to their intended use. Any use of PABS Materials and Sequence Information outside the scope of the PABS System must obtain prior informed consent from the originating country.
3. transferring the PABS Materials only if the prospective recipient has concluded the required contract with WHO. Any such transfer shall be reported to the WHO through the PABS Tracking Mechanism.
4. sequence information generated by the Recipient from the PABS Materials, sharing/transfer through WHO PABS Sequence Database and recipient to comply with terms of data access agreement (standard contract 3)
5. not to seek or assert intellectual property over any PABS Materials and PABS Sequence Information, or parts thereof, in any form, including any modified form or for any use.
6. to comply with monetary and non-monetary benefit-sharing obligations
7. Agrees to comply with COP decisions with respect to the PABS system

**STANDARD CONTRACT 3: DATA ACCESS AGREEMENT** (may potentially be in a form of a click-wrap agreement)

**TERMS AND CONDITIONS APPLICABLE TO ANY PERSON/ENTITY ACCESSING PABS SEQUENCE INFORMATION FROM WHO PABS SEQUENCE DATABASE/PARTICIPATING DATABASES**

Legally binding contract for parties - the Database, WHO and person/entity seeking access to PABS Sequence Information. Access to PABS Sequence Information is subject to registration and acceptance of data access agreement with terms that include:

1. use solely and strictly for research and development in connection with pathogens with pandemic potential within the scope of the PABS system for the prevention, preparedness and response to a pandemic;
2. not be used in any activity that may lead to the development, or production of biological agents, toxins, weapons, equipment, or means of delivery specified in Biological Weapons Convention;
3. transfer or share sequence information only if the prospective recipient is also a registered user either of the WHO PABS Sequence Database or a Participating Database;
4. acknowledge the contributions of the persons and institutions who submitted the sequence information as well as the originating laboratories that first collected the clinical specimen and isolated the pathogen with pandemic potential;
5. actively seek the participation of scientists from originating laboratories/countries of PABS Materials and clinical specimens from which the PABS Sequence Information was generated, especially those from developing countries, in scientific or R&D projects associated with the

PABS Sequence Information, and to actively engage them in the development and implementation of the projects;

6. not seek or assert intellectual property over PABS Sequence Information or parts thereof, in any form, including any modified forms or for any use;
7. Agrees to comply with the monetary and non-monetary benefit-sharing obligations.
8. Agrees to comply with COP decisions with respect to the PABS system