Third meeting of the open-ended Intergovernmental Working Group on the WHO Pandemic Agreement (resolution WHA78.1)

Provisional agenda item 2

A/IGWG/3/3

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Draft PABS Annex text

Background and approach

1. This draft text was prepared by the Bureau of the open-ended Intergovernmental Working Group on the WHO Pandemic Agreement (IGWG) with support from the WHO Secretariat, for consideration by the IGWG at its third meeting (taking into account all elements, building on the draft outline of elements, and taking into consideration written submissions by IGWG members, inputs received during the second meeting of the IGWG and informal discussions) (see A/IGWG/2/5).

2. The Bureau has included explanatory notes in italics in the text to highlight areas that may require further discussion among the IGWG, and possibly with input from relevant resource persons.

Annex

WHO Pathogen Access and Benefit-Sharing System ("PABS System")

I. Scope and objectives, and use of terms

A. Scope and objectives

1. This Annex sets out the provisions governing the multilateral system established in Article 12 of the WHO Pandemic Agreement for the rapid and timely sharing of PABS Materials and Sequence Information (as defined herein) 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 PABS System").

2. The PABS System shall be implemented in a manner that:

(a) recognizes the sovereign right of States over their biological resources and the importance of collective action to mitigate public health risks;

(b) recognizes the equal footing between the rapid and timely sharing of PABS Materials and Sequence Information and rapid, timely, fair and equitable benefit-sharing arising from the sharing and/or utilization of PABS Materials and Sequence Information;

(c) is 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;

(d) provides legal certainty for all participants in the PABS System;

(e) strengthens, facilitates and accelerates research and innovation, as well as rapid, timely, fair and equitable benefit-sharing and distribution of benefits;

(f) facilitates the manufacture and export of vaccines, therapeutics and diagnostics for pathogens covered by the PABS System;

(g) is consistent with, and does not run counter to, the objectives of the Convention on Biological Diversity and its Nagoya Protocol, in accordance with Article 12.4;

(h) is complementary to, and not duplicative of, 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

(i) respects traditional knowledge of Indigenous Peoples as well as local communities with regard to PABS Materials and Sequence Information and the PABS System.

Note: The Bureau notes that paragraph 2 above is a non-exhaustive list of parameters for implementation to meet the objectives of the Annex, and that additional provisions in section II may be needed to operationalise some of the listed parameters.

B. Use of terms

For the purposes of this Annex:

(a) "Pathogen with pandemic potential" means a known pathogen that is determined to have caused a public health emergency of international concern, or a novel pathogen or a variant of a known pathogen infecting humans, and to which humans have limited or no immunity, with the risk of high transmissibility, virulence, severity, wide geographical spread, and which may cause a public health emergency of international concern that may develop into a pandemic emergency.

(b) "PABS Materials and Sequence Information" means: (i) the biological material (physical parts or components, including DNA, RNA, and proteins) from pathogens with pandemic potential, including samples, specimens, isolated wild-type pathogens, modified pathogens, and derivatives of a pathogen, and includes clinical or epidemiological data, metadata or information derived from such biological materials ("PABS Materials"); and (ii) the order of nucleotides, generated through the application of sequencing technology, found in a molecule of DNA or RNA of a pathogen with pandemic potential, as well as sufficiently detailed public health information generated from or available on that pathogen, and includes data, metadata or information derived from the biological or genetic materials, ("PABS Sequence Information").

(c) "Participating Manufacturer" means a public or private entity, for profit or not-for-profit, that manufactures vaccines, therapeutics and/or diagnostics, including by means of licensing agreements, and that has signed a legally binding contract with WHO regarding that entity's participation in the PABS System (hereinafter the "WHO PABS Contract").

Note: The Bureau notes that the terms listed above are those which the IGWG is specifically mandated to include in the Annex under Article 12; other terms may be added if considered necessary by the IGWG.

II. Provisions for implementation of the PABS System

A. Operation of the PABS System

1. Safe, transparent and accountable access and benefit-sharing through the PABS System is on an equal footing, requiring:

   (a) rapid and timely sharing by providers of PABS Materials and Sequence Information;

   (b) manufacturers of vaccines, therapeutics and diagnostics seeking to access PABS Material and Sequence Information through the PABS System to sign a WHO PABS Contract with WHO, setting out their commitments for rapid, timely, fair and equitable benefit-sharing; and

   (c) other participants who are not covered by paragraph 1(b) to make possible legally binding commitments for rapid, timely, fair and equitable benefit-sharing, based on their nature, capacity and use of PABS Materials and Sequence Information.

2. All elements of the PABS System shall come into operation simultaneously.

3. Each Party shall review and, as it deems appropriate, align its national and/or regional access and benefit-sharing measures in accordance with Article 12.5(d)(ii).

B. Access to PABS Materials and Sequence Information

1. PABS Materials and Sequence Information that are detected shall be shared in a rapid and timely manner, 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, as follows:

    (a) PABS Materials shall be shared, through a laboratory or laboratories authorized under relevant national or domestic procedures, with a laboratory or laboratories in a WHO Coordinated Laboratory Network;

    (b) PABS Sequence Information shall be shared to a WHO recognized sequence database or databases;

    (c) laboratories in a WHO Coordinated Laboratory Network and WHO recognized sequence databases shall comply with the respective WHO terms of reference, as well as applicable terms and conditions;

    (d) all PABS Material and Sequence Information shared with the PABS System shall be assigned a unique persistent identifier; and

    (e) all PABS Materials and Sequence Information shared through the PABS System shall include accurate and sufficiently detailed public health information, clinical and epidemiological information, and metadata needed for risk assessment.

Note: The Bureau notes that further discussion is required, with input from relevant resource persons with regard to unique persistent identifiers.

2. PABS Materials or Sequence Information may be shared outside of the PABS System, provided that they are shared on a priority basis with a laboratory in a WHO Coordinated Laboratory Network and/or a WHO recognized sequence database.

3. Laboratories in a WHO Coordinated Laboratory Network, receiving PABS Materials and Sequence Information, shall comply with the following terms and conditions:

    (a) implementation of biosecurity and biosafety standards, as well as other standards, applicable within WHO Coordinated Laboratory Networks;

    (b) sharing all results and analyses in a timely manner with the provider of the PABS Materials;

    (c) use of the PABS Materials and Sequence Information for public health purposes;

    (d) engagement of scientists from originating laboratories, especially those from developing countries, in scientific projects associated with research on PABS Materials and Sequence Information, and in preparation of manuscripts for presentation and publication;

    (e) acknowledgement in presentations and publications of the contributions of collaborators, including laboratories/countries providing PABS Materials and Sequence Information; and

    (f) agreement not to claim intellectual property rights over PABS Materials and Sequence Information, and parts thereof.

Note: The Bureau notes that further discussion is required on paragraph 3(f), with input from relevant resource persons.

4. WHO recognized sequence databases receiving PABS Sequence Information shall comply with the following terms and conditions:

   (a) apply relevant information security policies and practices, and quality standards (sequence data and information curation), with relevant interoperability requirements;

   (b) inform users of its database of the WHO Pandemic Agreement and the PABS System, including notification of possible legally binding benefit-sharing commitments under Section C below;

   (c) acknowledge in presentations and publications the contributions of collaborators, including laboratories/countries providing PABS Materials and Sequence Information; and

   (d) agree not to claim intellectual property rights over PABS Materials and Sequence Information.

Note: The Bureau notes that further discussion is required on paragraph 4, with input from relevant resource persons, including on the modalities for informing database users and identification of users.

C. PABS System benefit-sharing

1. All participants in the PABS System shall receive notice of possible legally binding benefit-sharing commitments to be undertaken based on their nature, capacity and use of PABS Material and Sequence Information, which may include, inter alia:

   (a) providing access to pandemic-related health products;

   (b) capacity-building and technical assistance;

   (c) research and development cooperation;

   (d) granting non-exclusive licenses to manufacturers in developing countries for the manufacture of pandemic-related health products;

   (e) other forms of transfer of technology as mutually agreed;[1]

   (f) engaging scientists from originating laboratories especially those from developing countries in scientific projects associated with research on PABS Material and Sequence Information and in preparation of manuscripts for presentation and publication;

   (g) appropriately acknowledging in their presentations and publications, the contributions of collaborators, including laboratories/countries providing PABS Material and Sequence Information; and

   (h) monetary contributions.

Note: The Bureau notes that further discussion is required on paragraph 1 above, with input from relevant resource persons, including on the modalities for notice to participants and arrangements for benefit-sharing.

[1] See footnote 8 of the WHO Pandemic Agreement.

2. To be recognized as a Participating Manufacturer, a manufacturer of vaccines, therapeutics and diagnostics must conclude a PABS Contract with WHO which shall cover all access to PABS Materials and Sequence Information for the duration of such Contract, and shall contain the following obligations by the Participating Manufacturer:

   (a) to use the PABS Materials and Sequence Information for public health purposes;

   (b) in the event of a pandemic emergency, to make available to WHO rapid access to their real time production of safe, quality, and effective vaccines, therapeutics, and diagnostics for the pathogen causing the pandemic emergency, in accordance with Article 12.6(a), for distribution in accordance with Article 12.6(b); and

   (c) provision to WHO of annual monetary contributions referred to in Article 12.5(a), with flexibility based on the Participating Manufacturer's nature and capacity.

3. In addition to the foregoing, each WHO PABS Contract shall also require the Participating Manufacturer to provide additional benefits, with flexibility based on the nature and capacity of the Participating Manufacturer, as referenced in Articles 12.7 and 12.8, including options for:

   (a) providing access to vaccines, therapeutics, and diagnostics for pathogens causing public health emergencies of international concern, in accordance with Article 12.7;

   (b) capacity-building and technical assistance;

   (c) research and development cooperation;

   (d) 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);

   (e) granting 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,[2] including transfer of relevant knowledge, skills and technical expertise.

4. The Conference of the Parties shall, at its first session agree on the model terms and conditions for the aforementioned WHO PABS Contracts and the notice, as well as the relevant modalities with respect to the annual monetary contributions.

5. The commitments undertaken by each Participating Manufacturer in its WHO PABS Contract shall be made publicly available by WHO.

III. Governance and review of the PABS System

A. Governance

1. The Conference of the Parties shall oversee implementation of the PABS System, as part of the WHO Pandemic Agreement.

[2] See footnote 8 of the WHO Pandemic Agreement.

2. The Secretariat of the World Health Organization, as Secretariat of the WHO Pandemic Agreement pursuant to Article 22 thereof, shall:

   (a) administer and coordinate the PABS System, in accordance with the terms of the WHO Pandemic Agreement, and, in so doing, collaborate with relevant international organizations and relevant stakeholders;

   (b) ensure that policies and practices applicable to the administration and coordination of the PABS System promote the fair, equitable and transparent sharing of pandemic-related health products, notably vaccines, therapeutics and diagnostics, during public health emergencies of international concern, including pandemic emergencies, based on public health risk and need;

   (c) develop terms of reference for, and coordination of, laboratories in WHO Coordinated Laboratory Networks, as well as WHO recognized sequence databases, so that they are available when the PABS System operations commence;

   (d) establish a PABS Advisory Group, in a manner consistent with WHO Regulations for Expert Advisory Panels and Committees, to provide evidence-based reporting and recommendations on implementation of the PABS System, including advice on fair and equitable sharing of benefits based on public health risk and need, and capacity strengthening; and

   (e) support Parties with alignment of national and regional access and benefit-sharing measures, applicable to PABS Material and Sequence Information within the scope of PABS instrument, in accordance with Article 12.5.d(ii).

3. Any Party may address any allegation(s) of non-compliance with the terms of the PABS System as follows:

   (a) any allegation(s) of non-compliance by an institution or laboratory in a WHO Coordinated Laboratory Network and WHO recognized sequence databases with its terms of reference may be brought to the attention of the WHO Director-General, who will review the circumstances and may discuss the matter with the PABS Advisory Group to determine appropriate action(s) to be taken; and

   (b) any allegation(s) of non-compliance or breach of WHO PABS Contracts will be brought to the attention of the WHO Director-General, who will review the circumstances and take the necessary action in consultation with the Advisory Group, and report thereon, as appropriate, to the Conference of the Parties.

B. Review of the PABS System

The Conference of the Parties shall review the implementation, operations and functioning of the PABS System five years after its entry into operation and thereafter every five years, with a view to ensuring its effective implementation, and may also convene extra-ordinary reviews of the PABS System, as it deems appropriate, following the occurrence of a pandemic emergency.
