EU drafting suggestions to the draft PABS Annex text of 24 October 2025 prepared by the Intergovernmental Working Group (IGWG) Bureau and circulated to IGWG ahead of its third meeting

Submitted to IGWG on 7 November 2025

Overall EU comments:

The Draft PABS Annex text is still in need of further clarifications and elaboration. While drafting suggestions have been introduced in blue characters in some parts of the text, the EU and its MS reserve their position on the entire text.

In light of further internal reflections, discussions with partners and development in the negotiations, the EU and its MS also reserves the right to modify or withdraw the proposals below and to put forward additional proposals.

Kindly note that inserting our proposals into the existing Bureau's text has proven complex, and the cross-referencing of the provisions difficult. We have made all efforts to ensure accuracy, but some further checks may be necessary.

ANNEX I: 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 the rapid, timely, fair and equitable benefit-sharing arising from the sharing and/or utilization of PABS Materials and Sequence Information;

(c) [**The provisions of this Annex are without prejudice to**] [~~is consistent with~~] applicable international law[**, as well as**] [~~and with applicable national and/or~~] domestic [**and international rules**] [~~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 the rapid, timely, fair and equitable benefit-sharing and distribution of benefits;

(f) [**The Parties shall take all appropriate steps to**] facilitate[~~s~~] the manufacture and export of vaccines, therapeutics and diagnostics for pathogens covered by the PABS System **[in accordance with applicable international law**];

(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; EU DEL; see new section IV.2 inserted at the end of the document]

(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 EU DEL, see new sections I.A.3 and 4 inserted below]

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

EU text proposals (sections 39 and 40 of EU text proposals of 17 October)

New 3. The provisions of this Annex are without prejudice to the operation of the PIP framework.

New 4. The Parties agree that as of the date of entry into operation of the PABS System relevant international access and benefit sharing provisions shall not apply to a participating manufacturer in respect to any VTD that is covered by a contract concluded by such a manufacturer and the WHO or any related PABS material

and PABS sequence information.

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. EU DEL]

EU text proposals (section 1 of EU text proposals of 17 October):

Alt (a). “Pathogen with pandemic potential” refers to a pathogen that has the capacity to cause a pandemic emergency due to high virulence, morbidity and/or mortality in humans, high transmissibility with the potential for wide geographic spread in human populations, and lack of existing effective and available countermeasures. A pathogen listed in the non-exhaustive Appendix to this Annex shall be deemed to be pathogens with pandemic potential.

(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”) EU DEL].

EU text proposals (section 1 of EU text proposals of 17 October) as alternatives to (b):

- “Material” refers to the biological material (physical parts or components, including DNA, RNA, and proteins), including samples, specimens, and isolates.
- “Sequence information” refers to the digital and printed representation of information on sequences of DNA, RNA and amino acids of a pathogen.
- “PABS material” means material from a pathogen with pandemic potential, which has been transferred to the Laboratory Network.
- “PABS sequence information” means sequence information from a pathogen with pandemic potential, which has been transferred to the Laboratory Network.

(c) “Participating Manufacturer” means [~~a public or private~~] **[any]** entity[~~, for profit or not-for-profit,~~] that manufactures vaccines, therapeutics and/or diagnostics [**products**] (VTDs), **[which has willingly entered into and concluded a]** [~~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~~] [**setting out mutually agreed terms pursuant to the provisions of this Annex**] (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.

EU text suggestions for additional definitions (section 1 of EU text proposals of 17 October):

- "Disease" means an illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans.
- "Pathogen" means an infectious agent that causes, or can cause, a disease to its human host.
- "Laboratory Network" refers to the laboratories or biorepositories participating in a network coordinated by the WHO in consultation with the PABS System Partners.
- "Vaccines, therapeutics and diagnostics", hereinafter "VTDs", means those vaccine, therapeutic and diagnostic products, as set out in legally binding contracts that have been granted (emergency use) designation or authorization by a stringent regulatory authority (WHO-listed authority) to prevent, treat or diagnose the disease which has given rise to a Pandemic Emergency, or have been Prequalified by WHO or have received WHO Emergency Use Listing for that same purpose.
- "WHO Pathogen Access and Benefit-Sharing System", hereinafter the "PABS System", refers to the set of multilateral arrangements laid out in this Annex.
- "PABS System Partners" means international and regional organisations which are competent to support and collaborate in the implementation of the Annex and the operation of the PABS System, including but not limited to GAVI, UNICEF and WOAH, as well as relevant stakeholders, including civil society and the private sector, as appropriate, with whom the WHO will collaborate in the operation of the PABS System.

[In the context of defining parameters and criteria for the distribution of VTDs, it may also be useful to add a description of "**Public health risk and need**" in the Use of Terms section.]

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; (See sections 20 to 23 and 26 of EU text proposals of 17 October, reproduced below under Section II.B.)

   (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 EU DEL]

EU text proposals (section 2 of EU text proposals of 17 October)

Alt 1. The Parties shall, individually and jointly, encourage manufacturers of VTDs to willingly conclude legally binding benefit sharing contracts with the WHO (hereinafter "contracts") as early as possible to ensure the entry into operation of this Annex and additional contracts thereafter.

   (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. EU DEL]

EU text proposals (sections 4 and 6 of EU text proposals of 17 October)

New 1 bis. In case where an entity that is not a manufacturer of VTDs decides to conclude a contract, agreement or arrangement with WHO the relevant provisions of this Annex, in particular sections II.C.2 bis, II.C.2 octies, and II.C.3 Alt, 3 bis, 3 quarter and 3 quinquies shall apply.

New 1 ter. Entities which are not-for-profit, including academic or research institutions, shall not be expected to conclude contracts with the WHO, but are encouraged to make voluntary contributions to support the implementation of the PABS System, including through scientific collaborations, training and capacity building activities.

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). EU DEL]

EU text proposals (section 37 of EU text proposals of 17 October)

Alt 3. The Parties agree that as of the date of entry into operation of the PABS System domestic and regional access and benefit sharing provisions of any Party shall align with the provisions of this Annex, so that such domestic and regional provisions shall not apply to a participating manufacturer in respect to any VTD that is covered by a contract concluded by such a manufacturer and the WHO or any related PABS material and PABS sequence information.

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. EU DEL]

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

EU text proposals (sections 20 to 24, as well as 26 of EU text proposals of 17 October):

Alt 1. Each Party shall, in a safe, secure, rapid and systematic manner:

(i) Transfer, on a priority but not exclusive basis, material and related, available public health information, including clinical and epidemiological metadata, of any pathogen within its control which it assesses in line with the elements described in section 1(c). to have pandemic potential, or which is included in the Appendix to this Annex, to one or more laboratories within the Laboratory Network, and

(ii) Transfer, on a priority but not exclusive basis, sequence information and related, available public health information, of any pathogen within its control which it assesses in line with the elements described in section 1(c) to have pandemic potential, or which is included in the in the Appendix to this Annex, to one or more laboratories within the Laboratory Network and by uploading them to one or more recognised database(s).

New 1 bis. Section II.B.Alt 1(i) and (ii) is without prejudice to any additional sharing of materials and data that a Party may decide, in accordance with applicable international law.

New 1 ter. In case a notification to the WHO is required pursuant to articles 6 and 7 of the IHR (2005) the notifying Party shall also transfer the relevant material and sequence information in accordance with section II.B.Alt 1.

New 1 quarter. For purposes hereof:

(a) "recognised database" means a database which is publicly accessible, capable of receiving and transferring sequence data in a timely and secure manner and so recognised by a Party and/or the WHO;

(b) "rapid" transfer of materials shall mean provision no later than [48] hours from the time of its acquisition and assessment by a Party;

(c) "rapid" transfer of sequence information shall mean provision no later than [48] hours from the time the relevant sequence information has become available to a Party.

New 1 quinquies. Where necessary, a Party shall seek the cooperation and support of the Laboratory Network in order to ensure the rapid identification and characterization of pathogens. Where necessary a Party may also request assistance from the WHO and/or PABS System Partners to cover handling and shipping costs related to transferring materials as provided for in section II.B.Alt 1(i).

New 1 sexies. In case any entity requests the Laboratory Network to obtain PABS material or PABS sequence information, the Network shall transfer such PABS material or PABS sequence information, subject to sections II.B.1 ter and II.B.Alt 2, expeditiously and without discrimination. For purposes hereof, "expeditiously" shall mean transfer no later than 48 hours from the time of the request or availability of the material.

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 WHO recognized sequence database. EU DEL]

EU text proposals (section 25 of EU text proposals of 17 October):

Alt 2. In transferring material and/or sequence information to the Laboratory Network, a Party grants consent to the further transfer and use of any such PABS material and PABS sequence information, subject to applicable safety, security, export control and data protection rules and standards, as well as the provisions of this Annex.

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;

(f) agree not to claim intellectual property rights over PABS Materials and Sequence Information, *and parts thereof. EU DEL]*

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

EU text proposals (sections 30 and 28 of EU text proposals of 17 October):

Alt 3. The Laboratory Network will ensure by means of an electronic system that materials transferred by the Parties to the Network, transferred between laboratories of the Network, and out of the Network are registered in accordance with applicable international biosafety and biosecurity rules and standards and for the purpose of reporting on aggregate volumes of transferred PABS materials and on PABS activities.

New 3 bis. The Parties shall promote the adherence by all entities receiving PABS materials and PABS sequence information to the best practices in the use of such Material and Sequence Information, such as making publicly and easily accessible data analysis and publications, acknowledging data providers and engaging them in research projects, as appropriate.

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;

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

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

EU text proposals (section 29 of EU text proposals of 17 October):

Alt 4. Activities under the PABS System shall be consistent with, and mutually supportive of, relevant international rules and guidelines, notably those for collection of patient specimens, material and data, and shall promote effective, standardized, global and regional databases that make findable, accessible, interoperable and reusable data available to all Parties and other recipients. The WHO in collaboration with the PABS System Partners shall provide support.

EU text proposals (section 27 of EU text proposals of 17 October):

New 5. The Laboratory Network and recognised databases shall be requested to inform entities which receive

PABS material or PABS sequence information of the expectations of benefit-sharing under the PABS System, as well as of the expectation that such entities acknowledge the providers of such material or information, where known, in relevant communication and publications and contribute as appropriate to public dissemination and transparency of research results.

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: (See sections 4, 6, 27 and 28 of EU text proposals of 17 October)

   (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. EU DEL, entire section 1 needs reformulation]

   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.

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: EU DEL]

EU text proposals (sections 3 and 5 of EU text proposals of 17 October):

Alt 2. The provisions contained in this Annex form the basis of the benefit sharing commitments of participating manufacturers expected to be set out in the contracts. Without prejudice to sections II.C.2 ter, 2 quarter and 2 quinquies, such provisions shall allow sufficient flexibilities for participating manufacturers to specify additional commitments according to their capacity, expertise and portfolio of products.

New 2 bis. No benefit sharing measures, additional to those set out in contracts, shall be applied by any Party, including by national ABS authorities, towards a participating manufacturer with respect to products that are covered by such contracts.

a. to use the PABS Materials and Sequence Information for public health purposes; (See section 19 of EU text proposals of 17 October)

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

EU text proposals (sections 7 to 11 of EU text proposals of 17 October):

New 2 ter. In the case where a pandemic emergency is declared pursuant to art. 12 of the IHR (2005), a participating manufacturer shall make available as set out in a contract to the WHO for equitable distribution on the basis of public health risk and need a target amount of 20% of its real-time production of VTDs it may produce, while the declaration of pandemic emergency remains in effect. Manufacturers may choose to fulfil this provision through partnership with other manufacturers, which may include voluntary licenses.

New 2 quater. For the purpose of section II.C.2 ter a participating manufacturer shall make available as a donation to the WHO a minimum amount of 10% percent of its real-time production of safe and effective VTDs that it may produce.

New 2 quinquies. Donated products shall be made available ex- factory upon request of the WHO as early as possible in accordance with the provisions set out in the contract.

New 2 sexies. Participating manufacturer shall also make available to WHO options to buy at affordable price* an amount of VTDs it may produce of up to the difference between the overall amount targeting 20 % of its production and the minimum amount of 10% of its production it commits as a donation in accordance with the provisions set out in the contract. Such amount shall take into account the nature and capacity of each individual manufacturer.

* This includes consideration of equity tiered pricing.

New 2 septies. In case a VTD is a repurposed product, having already received market authorization for a disease different from the one for which a pandemic emergency is declared, and to safeguard the care of patients who need the product for the purpose of preventing, treating or diagnosing such other disease, the percentages set out in sections II.C.2 ter – 2 sexies shall be calculated on the basis of the production that is additional to the production prior to the granting of (emergency use) designation or authorization by a stringent regulatory authority (WHO-listed authority) or the Prequalification or Emergency Use Listing by WHO, for the repurposed use.

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.

EU text proposals (section 12 of EU text proposals of 17 October):

New 2 octies. An annual monetary contribution may be agreed between a participating manufacturer and the WHO as part of a contract, on mutually agreed terms. Such contributions shall be devoted to specific uses determined in the contract, clearly delimited and proportionate thereto and shall take into consideration the nature, size and capacity of each participant.

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 Article 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; EU DEL]

EU text proposals (section 16 of EU text proposals of 17 October):

Alt 3. In case a public health emergency of international concern is declared pursuant to article 12 of the IHR, participating manufacturers may willingly choose to undertake benefit sharing commitments in contracts, such as those set out in the Annex.

(b) [capacity-building and technical assistance;

(c) research and development cooperation; EU DEL]

EU text proposals (section 13 of EU text proposals of 17 October):

New 3 bis. A participating manufacturer may commit to engage in capacity-building and technical assistance and research and development cooperation willingly and on mutually agreed terms with scientists and researchers from developing countries, which are Parties to this Agreement. Such collaboration as set out in the contract shall be facilitated by the WHO in consultation with PABS System Partners, when appropriate.

(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); EU DEL]

EU text proposals (section 17 of EU text proposals of 17 October):

New 3 ter. In case of public health risks and events in the context of Article 13.3 of the International Health Regulations (2005), a participating manufacturer may choose to facilitate access to relevant health products that it produces and which are not VTDs within the meaning of section 1(j), including by making offers to sell such products at affordable price* to the WHO, for equitable distribution on the basis of public health risks and needs.

* This includes consideration of equity tiered pricing.

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

EU text proposals (section 14 of EU text proposals of 17 October):

New 3 quater. A participating manufacturer may consider, inter alia, collaborating with internationally recognised mechanisms that can facilitate non-exclusive voluntary licensing* to increase the availability of such VTD.

* E.g. the Medicines Patent Pool.

(f) [*New 3 quinquies:* **A participating manufacturer may consider**] other forms of transfer of technology as mutually agreed[l], including transfer of relevant knowledge, skills and technical expertise [**directly linked with the use of the VTDs covered by the contract**].

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.

[l] See footnote 8 of the WHO Pandemic Agreement

EU text proposals (sections 19 of EU text proposals of 17 October):

New 6. The WHO in consultation with the Advisory Group and the PABS System Partners shall oversee the distribution of the VTDs made available to the WHO as set out in the contracts on the basis of public health risks and needs. In this regard the WHO shall take into account elements such as age distribution and susceptibility of the affected population.

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. [section 1 can be supported]

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; and

(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.

(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).

EU text proposals (sections 32, 33 and 34 of EU text proposals of 17 October):

Alt 2. The PABS System shall be administered by the WHO with the collaboration of the PABS System Partners, where appropriate. For this purpose, the WHO shall agree with the PABS System Partners on the terms of their collaboration in the administration of the PABS System. They shall collaborate in a consensual manner and contribute their respective expertise for the effective functioning of the System. The Conference of the Parties may recommend additional organisations to be included among the PABS System Partners.

New 2 bis. For the purpose of giving effect to the provisions of this Annex, the WHO shall enter into agreements, contracts or arrangements with public and private entities, organizations and institutions, and take other necessary actions.

New 2 ter. The Director-General shall establish, as soon as possible after the entry into force of the Pandemic Agreement,* an Advisory Group to further the implementation of this Annex. The Group shall consist of […] members, which are independent experts with recognized competence in fields relevant to this Annex. Such experts shall be nominated by Parties and elected by the Conference of the Parties, with due consideration

to gender equality, multidisciplinary, including public health, legal, economic and industrial organisation expertise, and equitable geographical representation. Relevant stakeholders, as well as participating manufacturers, shall be invited to participate in the deliberation of the Group, as appropriate. The Group shall be responsible for the establishment and periodic review of the non-exhaustive Appendix to this Annex listing pathogens which shall be deemed to be pathogens with pandemic potential.

*This element will need to be included in the WHA resolution adopting the Annex.

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. EU DEL]

EU text proposals (section 36 of EU text proposals of 17 October):

New 3. The WHO in consultation with PABS System Partners shall report periodically to the Conference of the Parties on the operation of the PABS System, including the list of participating manufacturers, and on the use of the annual contributions provided for in section 12.

B. Review of the PABS System

The Conference of the Parties shall review the implementation, operation[s] 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. [this section can be broadly supported]

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New IV. Final provisions

EU text proposals (section 41 of EU text proposals of 17 October):

New 1: This Annex shall enter into operation when the System is ready to do so, and when a sufficient number of manufacturers have concluded contracts with the WHO. In this regard the Director General of the WHO shall consult with the Advisory Group and make recommendations to the Conference of the Parties, with respect to:

(a) the date of entry into operation of the Annex and the date of execution of contracts, with a view to keeping them on an equal footing, and

(b) an adequate notice period for Participating Manufacturers prior to the dates referred to in sub-section (a).

The Conference of the Parties shall decide on such recommendations by consensus.

EU text proposals (section 42 of EU text proposals of 17 October):

[Clause to be added at the end of the negotiations]

New 2: The Parties agree and affirm that the PABS System, as set out in this Annex, subject to its entry into operation pursuant to section IV. 1, constitutes a specialised access and benefit-sharing instrument within the meaning of Article 4.4 of the Nagoya Protocol, or any other international agreement, in respect to materials and sequence information covered by, and for the purpose of, the PABS System.