Input by EU and its 27 Member States

on possible provisions of the PABS Annex based on elements deriving from Article 12 of the WHO Pandemic Agreement

Submitted to IGWG on 17 October 2025

This input is not intended to provide a complete set of provisions. The EU and its 27 MS reserve the right to put forward additional inputs and modify and revise the input below in light of discussions within the IGWG and engagement with experts and stakeholders.

USE OF TERMS

Elements deriving from art 12:	*Possible provisions:*
So called "definitions"	1. For the purpose of the Annex: (a) "Disease" means an illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans. (b) "Pathogen" means an infectious agent that causes, or can cause, a disease to its human host. (c) "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. (d) "Material" refers to the biological material (physical parts or components, including DNA, RNA, and proteins), including samples, specimens, and isolates. (e) "Sequence information" refers to the digital and printed representation of information on sequences of DNA, RNA and amino acids of a pathogen. (f) "PABS material" means material from a pathogen with pandemic potential, which has been transferred to the Laboratory Network. (g) "PABS sequence information" means sequence

Elements deriving from art 12:	*Possible provisions:*
	information from a pathogen with pandemic potential, which has been transferred to the Laboratory Network. (h) "Laboratory Network" refers to the laboratories or biorepositories participating in a network coordinated by the WHO in consultation with the PABS System Partners. (i) "Participating manufacturer" means any entity that manufactures vaccine, therapeutic or diagnostic products, which has willingly entered into and concluded a contract with WHO setting out mutually agreed terms pursuant to the provisions of this Annex. (j) "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. (k) "WHO Pathogen Access and Benefit-Sharing System", hereinafter the "PABS System", refers to the set of multilateral arrangements laid out in this Annex. (l) "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. …….

BENEFIT SHARING

Elements deriving from art 12:	*Possible provisions:*
Legally-binding contracts as the tool for benefit sharing	2. 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.
Specification of parameters for the making available of set aside quantities of VTDs to WHO	3. 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 7, 8 and 9, such provisions shall allow sufficient flexibilities for participating manufacturers to specify additional commitments according to their capacity, expertise and portfolio of products. 4. 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 5 and 12 to 16, shall apply.
Certainty that no additional benefit sharing claims will be made to participating manufacturers with respect to VTDs covered by the legally binding benefit sharing contracts	5. 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.
	6. 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.
Triggering event (declaration of pandemic emergency) Provisions on set aside quantities	7. 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.

Elements deriving from art 12:	*Possible provisions:*
	Manufacturers may choose to fulfill this provision through partnership with other manufacturers, which may include voluntary licenses.
Donation (adding a description of donation in use of term may be useful)	8. For the purpose of section 7 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.
Rapid access real time production	9. 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.
Flexibility & reservation at affordable prices	10. 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.
	11. 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 7–10 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.
Annual monetary contribution	12. 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.
Capacity-building and technical assistance;	13. A participating manufacturer **may** commit to engage in capacity-building and technical assistance and research and development cooperation willingly and on mutually

Elements deriving from art 12:	*Possible provisions:*
Research and development cooperation;	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.
Granting of non-exclusive licences to manufacturers in developing countries, for the effective production and delivery of vaccines, therapeutics and diagnostics;	14. 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.
Other forms of transfer of technology as mutually agreed, including transfer of relevant knowledge, skills and technical expertise.	15. A participating manufacturer **may** consider other forms of transfer of technology as mutually agreed[FN], including transfer of relevant knowledge, skills and technical expertise directly linked with the use of the VTDs covered by the contract. [FN] See footnote 8 of the WHO Pandemic Agreement that reads "For the purposes of the WHO Pandemic Agreement, "as mutually agreed" means willingly undertaken and on mutually agreed terms, without prejudice to the rights and obligations of the Parties under other international agreements."
Options for benefit sharing in the event of a PHEIC	16. 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 above.
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);	17. 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.
Facilitation of the manufacture and export of vaccines, therapeutics and	18. The Parties shall take all appropriate steps to facilitate the manufacture and export of VTDs, in accordance with applicable international law.

Elements deriving from art 12:	*Possible provisions:*
diagnostics for pathogens covered by the PABS Instrument.	
Definition of parameters and criteria for the distribution of vaccines, therapeutics, and diagnostics to be based on public health risk and need. (It may be useful to add a description of "Public health risk and need" in the Use of Terms section.)	19. 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.

ACCESS

Elements deriving from art 12:	*Possible provisions:*
Provisions to ensure "rapid and timely sharing" of PABS Materials Provisions to ensure "rapid and timely sharing" of Sequence Information	20. 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 Appendix to this Annex, to one or more laboratories within the Laboratory Network and by uploading them to one or more recognised database(s). 21. Section 20(i) and (ii) is without prejudice to any additional sharing of materials and data that a Party may

Elements deriving from art 12:	*Possible provisions:*
	decide, in accordance with applicable international law. 22. 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 20. 23. 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. 24. 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 20(i). 25. 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. 26. 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 23 and 25, 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. 27. The Laboratory Network and recognised databases

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	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. 28. 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.
Strengthening, facilitating and accelerating research and innovation Open access to data	29. 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.
Traceability (including purpose, scope, technical feasibility and cost).	30. 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.

GOVERNANCE ISSUES

Elements deriving from art 12:	*Possible provisions:*
Setting out the terms for the administration and coordination of the PABS System by the World Health Organization. Setting out the collaboration with relevant international organizations and relevant stakeholders.	31. The PABS System shall act under the oversight of the Conference of the Parties. 32. 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. 33. 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.
	34. 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.
Role of the Conference of the Parties, possible future reviews.	35. The COP shall review the functioning of the PABS System at least every four years.

Elements deriving from art 12:	*Possible provisions:*
	36. 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.

GENERAL AND FINAL PROVISIONS

Elements deriving from art 12:	*Possible provisions:*
Legal relation with national and/or regional ABS legislation so that provisions that are contrary to or inconsistent with or duplicative of the PABS System will not be applied.	37. 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.
Consistency 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.	38. The provisions of this Annex are without prejudice to applicable international law, as well as domestic and international rules and standards in the areas of biosafety and biosecurity, export control, risk assessment, and data protection.
Legal relation with the PIP Framework.	39. The provisions of this Annex are without prejudice to the operation of the PIP framework.
Legal relation with relevant international access and benefit sharing instruments (in particular the multilateral mechanism for DSI on genetic resources).	40. 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.
Entry into operation ("All elements of the PABS	41. This Annex shall enter into operation when the System is ready to do so, and when a sufficient number of

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System shall come into operation simultaneously in accordance with the terms of the PABS Instrument").	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.
Recognition that the PABS Instrument shall be consistent with, and not run counter to, the objectives of the Convention on Biological Diversity and the Nagoya Protocol.	*[Clause to be added at the end of the negotiations]* 42. The Parties agree and affirm that the PABS System, as set out in this Annex, subject to its entry into operation pursuant to section 41, 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.