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

Input of EU and its 27 Member States of 25 July 2025

Introductory remarks

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

The elements can usefully be grouped into five main themes or areas: 1. Use of terms, 2. Benefit sharing, 3. Access, 4. Governance issues and 5. General and final provisions. To facilitate and advance work on the Annex in the best possible way, the EU and its MS consider that an enhanced common understanding of the overall purpose of the PABS, as well as of the eventual content of these five key areas will be beneficial. In this respect, the EU and its Member States look forward to constructive substantive discussions to this end at the second meeting of the IGWG in September.

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

1. USE OF TERMS

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

2. BENEFIT SHARING

- **Benefit Sharing parameters:**
  - Contracts with participating manufacturers (which are both legally-binding and voluntarily concluded) as the instrument for benefit sharing
  - Specification of parameters (model clauses can be set out in an Appendix to the Annex if considered useful) for the making available of set aside quantities of VTDs to WHO, including:
    - ✓ scope of VTDs

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

- o Definition and parameters for quantification of annual monetary contribution
- o The distribution and use of annual monetary contributions
- o Options for benefit sharing in the event of a PHEIC

- **Definition of additional benefit sharing options (including in times of neither PHEIC nor PE):**
  - o capacity-building and technical assistance;
  - o research and development cooperation;
  - o 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);
  - o granting of non-exclusive licences to manufacturers in developing countries, for the effective production and delivery of vaccines, therapeutics and diagnostics;
  - o other forms of transfer of technology as mutually agreed, including transfer of relevant knowledge, skills and technical expertise.

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

3. ACCESS

- **Provisions to ensure "rapid and timely sharing" of PABS Materials** (obligations for Parties)
  - o Modalities and requirements for sharing (including laboratory requirements for handling materials, mechanisms for rapid shipment of materials, etc)
- **Provisions to strengthen, facilitate and accelerate research and innovation**

- **Provisions to ensure "rapid and timely sharing" of PABS Sequence Information** (obligations for Parties)
  - o Modalities and requirements for sharing (including mechanisms to enhance analysis of SI, etc)

- **Provisions to strengthen, facilitate and accelerate research and innovation**

4. GOVERNANCE ISSUES

- **Terms for the administration and coordination of the PABS System by the World Health Organization**

- **Collaboration with relevant international organizations and relevant stakeholders**
  - Modalities for collaboration
  - Possible dedicated consultative body

- **Role of the Conference of the Parties and possible future periodic reviews of the PABS System.**

5. GENERAL AND FINAL PROVISIONS

- **Relationship / consistency of PABS System with other international instruments or with applicable domestic law**
  - Requirements to ensure that the PABS Annex shall be consistent with, and not run counter to, the objectives of the Convention on Biological Diversity and the Nagoya Protocol
  - Requirements to ensure that national and/or regional ABS measures that are contrary to or inconsistent with or duplicative of the PABS System will not be applied
  - 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
  - Legal relation with the PIP Framework
  - Legal relation with other relevant international access and benefit sharing instruments (in particular the multilateral mechanism for DSI on genetic resources)

- **Provisions aimed at facilitating and accelerating research and innovation**
  - Open access to data
  - Traceability (including purpose, scope, technical feasibility and cost)

- **Entry into operation** ("All elements of the PABS System shall come into operation simultaneously in accordance with the terms of the PABS Instrument")
  - Criteria for the entry into operation