Analysis of the European Union Proposal on the Pandemic Agreement Annex dated 17 October 2025

This note is prepared to provide South Centre Member States and other developing country delegations with analytical comments on the proposal of the European Union (EU) on the Annex to the Pandemic Agreement, implementing the Pathogen Access and Benefit Sharing (PABS) System as established in Article 12. The note begins with general commentary on the proposal, followed by detailed analysis of the EU proposal text, which is marked in red below the transcribed text.

Introduction

The current European Union (EU) proposal for the implementation of the Pathogen Access and Benefit Sharing (PABS) System presents structural gaps that would compromise both the integrity and the practical functioning of Article 12 of the Pandemic Agreement. While the text outlines mechanisms for access to materials and sequence information, it fails to deliver parallel and enforceable benefit sharing. This imbalance affects legality, feasibility and the confidence of Parties that their sovereign rights and contributions will be respected within a fair multilateral PABS system.

The core shortcoming in the proposal is the deep asymmetry between proposed obligations on access and obligations on benefit sharing. The proposal imposes tight, mandatory and time-bound requirements on Parties to transfer pathogen materials and digital sequence information (DSI). At the same time, benefit sharing is limited to manufacturers, based on their voluntary engagement, without clear duties or enforceable mechanisms. This diverges from the foundational principle in Article 12 that access and benefit sharing must stand on equal footing. Moreover, the proposal does not include the minimum elements required for the system to be elaborated in such a way as to become a specialized access and benefit sharing (ABS) instrument consistent with the Nagoya Protocol.

A second structural gap in the EU proposal is that it limits binding obligations only to manufacturers who voluntarily sign individual agreements, with ample scope for the manufacturer to negotiate the terms of the agreements, rather than establishing standard agreements (contracts) that would apply to all manufacturers as well as to other users of PABS materials and DSI. This creates uncertainty, weakens compliance, and allows commercial entities to use PABS materials and sequence information (SI) from the PABS system without committing to any benefit sharing. It also departs from the Pandemic Agreement text, which envisions an operational system upheld by Parties, not by the goodwill of private actors. Without a standard contract, Parties have no guarantee that utilization of the materials they provide will generate fair returns to support public health goals. The proposal for Parties to continue to provide access to PABS materials and SI through other means, in addition to the PABS system, would further undermine the ability to secure benefit sharing from users, including manufacturers.

The treatment of DSI represents another major shortcoming. The proposal contains extensive

obligations for Parties to upload sequence data rapidly, but it does not define a network of DSI databases nor provide benefit sharing terms for entities accessing that information. It shifts the burden to the Laboratory Network to merely "inform" users about expected benefit sharing rather than requiring prior informed consent and acceptance of standardized conditions. This reverses the basic principles of the Convention on Biological Diversity (CBD) and its Nagoya Protocol and exposes the system to legal uncertainty, inequitable use, and fragmented compliance.

The proposal also contains unresolved issues around definitions. Several terms required for legal clarity are missing or misaligned with Article 12. For example, "pathogen with pandemic potential" contains qualifiers that would make it burdensome for Parties to determine applicability, while other core elements such as "affordable prices" are not defined at all. These omissions weaken the Annex's enforceability and create opportunities for inconsistent interpretation. A coherent PABS system must rely on a shared and stable understanding of its scope, yet the current proposal leaves essential parameters open or delegated to manufacturers' negotiation.

In addition, the EU text introduces the new concept of "PABS System Partners," which adds unnecessary institutional complexity and does not reflect the structure negotiated under Article 12. This approach risks shifting influence over the operation of the system from Parties to external organizations, even before the Global Supply and Logistics Network under Article 12 has been designed. Instead of strengthening governance, this addition fragments accountability and complicates the coordination roles of the World Health Organization (WHO) and the Conference of the Parties.

Traceability is another area where the proposal provides insufficient guarantees. While it calls for registration of materials transferred through the Laboratory Network, it does not require traceability for access to sequence information nor provide enforceable conditions for downstream users. Without binding terms attached to every transfer, the system cannot follow the movement, utilization or commercialization of PABS materials and DSI, undermining the ability to implement benefit sharing or prevent misuse.

Finally, the proposal does not articulate a relationship with the Nagoya Protocol or the Pandemic Influenza Preparedness (PIP) Framework that would ensure legal consistency and predictable operation. The text seeks to prevent domestic or regional ABS measures from applying to participating manufacturers, yet it does not first establish compatibility with international ABS law. This creates substantial legal risk for Parties and weakens confidence that national authorities will retain adequate oversight. A functional PABS must sit firmly within the broader ABS landscape, not outside of it.

Overall, the proposal does not provide what Article 12 requires: a balanced, enforceable and legally coherent system where facilitated access is matched by equitable benefit sharing, supported by clear definitions, standardized contracts, traceability, and governance aligned with the CBD and the Nagoya Protocol. Addressing these gaps is essential for building trust among Parties and ensuring that the PABS system can operate effectively in future public health emergencies.

ART. 12 ELEMENTS AND POSSIBLE PROVISIONS

Input by the EU and its 27 Member States

Note: Text in red below are South Centre comments. Emphasis has been added in **bold.**

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.** There should be no reference to "and lack of existing effective and available countermeasures" in the definition of "pathogen with pandemic potential." This is an unnecessary qualifier in the definition that should remain focused on identifying pathogen with pandemic potential. It would create a burden to identify a priory what Vaccines, therapeutics and diagnostics (VTDs) exist that could be effective against the pathogen with pandemic potential, which would also create legal uncertainty about the obligations. There is already a definition of 'pandemic emergency' in article 1 of the Pandemic Agreement (PA) which seems to be redrafted here with the reference to 'high virulence, morbidity and/or mortality in humans' thereby narrowing down the concept of Pathogen with pandemic potential. Final agreement on the definition of "pathogen with pandemic potential" (scope) for the purposes of PABS, should be reached once there is final agreement on extent of the access obligations and benefit sharing obligations. (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 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.

There is no mention of Laboratory Network in Article 12. The proposal does not specify who and how this network will be created.

No definition is included for network of DSI databases.

(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.

Limited to "entity that manufactures VTDs" who have willingly entered into contracts clearly departs from what has been agreed upon under article 12. There should be a standard contract for all the entities that make a commercial use of PABS material and DSI that sets out the mandatory contractual terms and conditions.

(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.

This definition is unnecessary. Article 12.5(a) refers to "production of safe, quality and effective VTDs." The regulatory aspects should be dealt with separately as part of the contracts between participating manufacturers and the WHO. All products require national regulatory authorization, and the granting of WHO Emergency Use Listing (EUL) would expedite the process. Manufacturers should be encouraged as part of the contracts to apply for WHO vaccine prequalification.

(k) "WHO Pathogen Access and Benefit-Sharing System," hereinafter the "PABS System," refers to the set of multilateral arrangements laid out in this Annex.

This definition is unnecessary as the PABS will be the title of the Annex. If definition is included, it should be added: "in accordance with Article 12".

(l) "PABS System Partners" means international and regional organizations 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. This should not be included as a definition in the Annex, and there should not be mentions of "PABS systems Partners" throughout the Annex, as it is suggested in the proposal. Article 12.2 already establishes that the PABS instrument will be administered and coordinated by the WHO, and for the purposes of the coordination and operation of the PABS system, the WHO shall collaborate with relevant international organizations and relevant stakeholders. There is no inclusion of the term "Partners". It will be sufficient for relevant stakeholders to be allowed to observe the COP concerning PABS system matters. Any discussion on "partners" for the implementation of the Annex should be conducted by the Conference of the Parties (COP), considering what would be their functions. Furthermore, as the Global Supply and Logistics Network (GSLN) has not yet been established nor its partners defined, it would be more suitable for the COP to first define the operation of the GSLN and then turn to the question of collaboration for implementation of the PABS, as provided for in Article 13.3(i). The proposal does not suggest a definition for "rapid access" as referred to in Article 12.5(a) for each participating manufacturer to make available to WHO pursuant to legally binding contracts signed with WHO rapid access targeting 20% of their real time production of VTDs The proposal also does not suggest a standard for determining "affordable prices" as referred to in Article 12.6(a) for the rapid access for the remaining percentage of VTDs other than a minimum threshold of 10% of real time production of VTDs. It will be important that the standard contract for participating manufacturers includes a formula for determining affordable pricing, not merely leaving it open for the negotiation of the participating manufacturer with the WHO.

BENEFIT SHARING

Elements deriving from art 12:	*Possible provisions:*
Legally-binding contracts as the tool for benefit sharing for VTDs under Article 12.6	The proposal restricts benefit sharing only to implementation of Article 12.6 of the Pandemic Agreement, with no proposal to implement broader elements of Article 12.5, 12.7 and 12.8. The proposal does not meet the requirement for access and benefit sharing on equal footing, Art. 21.1. 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. This provision is not aligned with article 12 as it does not require any concrete action on Parties. Any mention to the contracts should refer to a single "standard" contract with the WHO. There must also be **obligations on Parties to take action to**

	compel users of PABS materials to enter into contracts. For example, by having provisions in the PABS that establish that 1) Parties shall only procure from manufacturers that are participating manufacturers in PABS (having signed contracts with WHO) with exceptions for manufacturers in developing countries in case of urgency; 2) Parties will request in their procurement contracts with manufacturers that they should set aside VTDs, as applicable, in compliance with PABS and enter into contracts with WHO for this purpose; 3) Parties will establish check points to ensure manufacturers have entered into contracts under PABS, such as by requiring evidence at the point of seeking patent protection (similar to the disclosure obligation of the source-origin or a genetic resource or associated traditional knowledge) and marketing authorizations. The EU in fact in its own legislation for implementation of the CBD Nagoya Protocol establishes a Due Diligence requirement for users with check points for monitoring user compliance, at the time of research funding or for products at the time when market approval or authorization is sought. An obligation can also be included that Parties shall encourage and support participating manufacturers of VTDs to seek and obtain emergency use designation or authorization by a stringent regulatory authority (WHO-listed authority) or Prequalification by WHO or WHO Emergency Use Listing.

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. The language in this provision requires flexibilities for participating manufacturers in determining their benefit sharing obligations beyond Article 12.6 thereby diluting the benefit sharing obligations. There should be provisions for implementing Article 12.6 separate from provisions for implementing Article 12.7, in addition to other benefit sharing provisions that apply not only to participating manufacturers but other beneficiaries of the PABS system, i.e., Article 12.5 and Article 12.8. The benefit sharing obligations are established in this Annex and will be enforced through contracts. The language should refer to standard contracts that are legally binding. Their enforcement should be supported by measures taken by Parties. 4. In the 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. This provision would mean that there is no obligation on benefit sharing under PABS on any entity other than a participating manufacturer. Only if "an entity" would want to voluntarily and unilaterally conclude a "contract, agreement or arrangement" with WHO, would there be any benefit sharing, that would be in the form of choice of the entity. If this were accepted, Parties will have no incentive to provide unhindered access to pathogen material and DSI through PBAS and will maintain their right to require on a bilateral basis clearing of Prior Informed Consent subject to mutually agreed terms for benefit sharing. There must be benefit sharing that is established through standard contracts for users that make revenue from the sharing/utilization of PABS materials and DSI.
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. The language of this provision is worded very broadly which would create legal uncertainty for the Parties and could be misinterpreted. It would need to be narrowed to specify that it refers to benefit sharing measures arising from PABS and clarify that any procurement for products outside of PABS would not be considered a benefit sharing measure. Outside of PABS, Parties must be able to negotiate purchase agreements with manufacturers for additional VTDs (i.e. beyond the target 20% that can be the same VTDs covered in the contracts with WHO) directly or through any procurement mechanism (i.e. regional, GSLN) with conditions that should not be interpreted by a manufacturer as "benefit sharing" for example when negotiating for affordable prices.
	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. As part of facilitating access to PABS materials and DSI, all users must agree to benefit sharing. The trigger for monetary benefit sharing should not be the type of entity (not-for-profit, including academic and research institutions that would be exempt), but should be based on whether any entity makes any commercial use

	(revenue generating). If they engage in commercial activity, for example through licensing of technology and intellectual property and get royalties from it, they must contribute to PABS.
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. Manufacturers may choose to fulfill this provision through partnership with other manufacturers, which may include voluntary licenses, The contract should be a standard agreement with the same conditions for all manufacturers with respect to the 20% target VTDs. Note that the 20% target amount is only with respect to fulfilling the PABS Annex obligation. It is independent of additional amounts that a Party may negotiate/purchase from manufacturers through purchase agreements either on bilateral, or regional basis or through the GSNL (article 13). The manufacturer can choose to fulfill the provision through partnership with other manufacturers, which may include voluntary licenses, provided that that they provide all the means necessary (transfer of technology, know how, intellectual property, as may be relevant) to the other manufacturers for the speedy production and delivery of the VTDs to the WHO. The partnerships should not frustrate or delay the fulfillment of the obligation.
Donation	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. The wording "that it may produce" weakens the obligation. It should refer to 10% of real-time production.

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.

	Reference is not made to the standard contract, only to "contract." The reference to "as early as possible" is not specific enough. In contrast, the "access" provisions in the proposal does define the timeline very strictly, requiring a "rapid transfer of materials no later than 48 hours".
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. The language proposed does not include the element of "rapid access" in Article 12.6(a) that should be retained. A more precise definition of affordable pricing has to be established in the PABS Annex. The definition of affordable pricing should contain elements other than "consideration of equity tiered pricing", such as: 1- price shall be below the offered private market price, 2- not higher than that offered for procurement under bilateral agreements with High Income Countries (HICs) and with the GSNL (to be established, Article 13), 3- considering public funding for the R&D for the product development, 4- the cost of production, adding a predetermined percentage of profit margin, 5- considering the purchasing power of the country(ies) in need (following the definition to be established later on "public health risk and need, with particular attention to the needs of developing countries" (Article 12.6(b)),. Unless there is a pre-established threshold for determining "affordable pricing," it could be stipulated that the WHO shall not be obliged to purchase the reserved VTDs from the participating manufacturer.
	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. This situation is an example of the need for additional benefit sharing (Art. 12.8) in the form of facilitating rapid access to VTDs licenses, including the granting of non-exclusive licenses to manufacturers in developing countries and other forms of transfer of technology, for the PABS system to function as envisaged.

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. The annual contribution is voluntary and not standard.
Capacity-building and technical assistance; Research and development cooperation;	13. 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. Such collaboration should not be optional for negotiation, but rather follow the terms established in the standard contract that is to be agreed as part of the PABS Annex. There should be no reference to PABS System Partners. Until the GSLN is established by the COP, the relationship of the GSNL partners to the PABS Annex will not be defined; therefore, the negotiation of the PABS Annex should not preempt the negotiations on the GSNL operation, which have been set to be conducted after the PABS Annex is agreed.
Granting of non-exclusive licenses 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. This provision does not create any obligation on the participating manufacturer. It should be part of the benefit sharing obligations of the participating manufacturer to provide non-exclusive licenses for production and transfer of technology during a PHEIC including a pandemic emergency.

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." This provision does not create any concrete obligation on the participating manufacturer regarding technology transfer.

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. Similarly, this provision is ineffectual as it does not create any obligation on the participating manufacturer.
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. As the provisions above, this one does not create any obligation on the participating manufacturer. Note the previous comment on the need to define elements for determining "affordable price," which should be an element in the standard contract.
Facilitation of the manufacture and export of vaccines, therapeutics and diagnostics for pathogens covered by the PABS Instrument.	18. The Parties shall take all appropriate steps to facilitate the manufacture and export of VTDs, in accordance with applicable international law.
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	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. The PABS Annex does not need to define the parameters and criteria for the distribution of VTDs on public health risk and need. The focus should be on ensuring both facilitated access to PABS materials and DSI subject to benefit sharing, as defined in the Annex and with standard legally binding contracts as the means.

"Public health risk and need" in the Use of Terms	Not required to be defined in PABS Annex.

section.)	

ACCESS

Elements deriving from art 12:	The *access* framework outlined in the EU proposal is fundamentally flawed with disproportional "access" obligations imposed on Parties while, as noted above, the "benefit sharing" and traceability measures would be limited, voluntary and with no enforcement mechanism. The proposal seems to overlook that Parties have sovereign rights over their biological resources (Art.12), and it does not make access conditional, for purposes of PABS, to contracts being signed that define the terms and conditions and benefit sharing both for PABS materials and DSI. It is through standard contracts that the Parties would provide Prior Informed Consent and mutually agreed terms, thereby aligning the PABS system with the CBD/Nagoya Protocol. *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 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). Rather than fostering that the Parties share pathogens and DSI only through the PABS under mutually agreed terms for benefit sharing, it proposes that the sharing is not done on an exclusive basis, which also risks that the PABS material and DSI can be made accessible to entities that have not signed standard legally binding contracts for benefit sharing 21. Section 20(i) and (ii) are without prejudice to any additional sharing of materials and data that a Party may 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; requiring registration and subject to defined Terms of Use

	(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. Article 12 refers to "promoting the rapid and timely sharing of PABS material and DSI" on equal footing with "the timely, fair and equitable sharing of the benefits arising from the sharing and/or utilization" of PABS materials and DSI for public health purposes. The suggested definitions in the EU proposal for rapid transfer of materials and DSI are not proportionate with the proposed elements for establishing timely, fair and equitable sharing of benefits. The proposal poses very restrictive time limits for transfer, disregarding the different capabilities of countries and the applicable biosecurity requirements. 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). 24. 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. 25. 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. This provision allows for the use, including with a commercial purpose, of PABS material and DSI without subjecting the third party to any obligation regarding benefit sharing. This may radically undermine the operation of the PABS system. Such a transfer, if allowed, should

	require the third party to comply with the obligations as stipulated in the standard contract. 26. 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. The requirement to inform entities of "the expectations of benefit sharing under the PABS system" shifts the burden away from requiring mutual agreed terms as a condition for the grant of Prior Informed Consent from the Parties for access to PABS materials and SI. It is a reversal of the principle in the CBD/Nagoya Protocol. Such a provision would create significant legal uncertainty in the operation of the multilateral system. Prior Informed Consent for access to the PABS Materials and DSI should be made conditional to standard terms defined in contracts. Any user of PABS materials and DSI not having signed contracts would be in breach of the system. 27. 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. This provision does not create any obligation. The terms and conditions for use of the PABS material and DSI should be included in the standard contracts.

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. This provision is very broad and does not specify any obligation on any Party. There is no specification of what relevant international rules and guidelines are. No mention is made of the WHO guiding principles for pathogen genome data sharing - which are voluntary and have not yet been endorsed formally by WHO Member States. It does not promote legal certainty.
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. Registration is insufficient condition for traceability of materials, and this proposal does not include registration for access to DSI. There must be standard terms and conditions attached to the registration that creates obligations on the recipients/users. Moreover, the burden here is on the Laboratory Network. There is no provision requiring Parties to take any action towards ensuring compliance.

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 organizations to be included among the PABS System Partners. The introduction of the concept of "PABS System Partners" adds significant additional, unnecessary complexity to PABS negotiations. The focus should be on the Parties that are signatories to the Pandemic Agreement, and the role of the WHO. The Advisory Body for the PABS System can address the need for any additional expertise required. 33. For the purpose of giving effect to the provisions of this Annex, the WHO may enter into agreements, contracts or arrangements with public and private entities, organizations and institutions, and take other necessary actions, subject to approval of the COP. This would give WHO broad power to negotiate agreements, contracts and arrangements, without any specific prior guidance from the Parties, which would review the proposed agreements only when they come for approval to the COP. The role of WHO in PABS should focus on implementing the standard contracts that will define the terms for benefit sharing.

	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 organization 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. The individuals in the Advisory Group should be free from conflict of interests and should not include "relevant stakeholders." The COP will have "relevant stakeholders" observing which should be the mechanism for their engagement with PABS. It is unclear why participating manufacturers should participate in the Advisory Group, if standard contracts -for the grant of Prior Informed Consent) PIC for access to PABS materials and DSI subject to benefit sharing- are defined as part of 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. The specific term of review is to be negotiated.
	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. There should be no reference to PABS System Partners.

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. If the Parties agree multilaterally that they are granting PIC through the standard contracts - which set the mutually agreed terms for benefit sharing to PABS materials and DSI for the purposes defined in the contracts- there is no need to add a provision that requires Parties to align their domestic and regional ABS provisions to the Annex. The ABS provisions will not apply with respect to the sharing/utilization of the PABS material and DSI for the purposes defined in the standard contract that each participating manufacturer should have signed with WHO. If the participating manufacturer has not signed a standard contract, or if the participating manufacturer has signed a contract but the access to the PABS material and/or DSI is for purposes other than those defined in the contract, Parties have the right to enforce their regional/national ABS rules under the Nagoya Protocol to the CBD.
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. The Annex must establish some minimum common rules for operation in these areas. It is a very glaring omission that the proposal does not refer to consistency with the Nagoya Protocol to the CBD or the CBD.

Legal relation with the PIP Framework.	39. The provisions of this Annex are without prejudice to the operation of the PIP framework. This does not specify what the relationship is with the PIP Framework. If the Annex does not define it, it should at minimum ensure the alignment to 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. This is like para 37, but here aiming to ensure the non-application of the Nagoya Protocol of the CBD. The PABS system must be compatible with the Nagoya Protocol for Parties to define that their national regulations on ABS in accordance with the Nagoya Protocol will not be applied. Until the other provisions of the Annex ensure this, this provision cannot be accepted. A related provision could be added to state that bilateral PIC can be required as a condition for access to PABS materials and DSI from a participating manufacturer, or any user/entity of the PABS system, until the date of entry into operation of the PABS system.
Entry into operation ("All elements of the PABS System shall come into operation simultaneously in accordance with the terms of the PABS Instrument").	41. 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. The entry to operation of the system should revert to the formulation in Article 12. All elements shall come into operation simultaneously. This would mean that there is no multilateral rapid and facilitated access to PABS Materials and DSI if there is no certainty of the sharing of benefits from their utilization, including under signed contracts by participating manufacturers, but also by other users/entities that should sign standard contracts for access. Countries have the right to implement their national ABS with respect to pathogens with pandemic potential, if there are no standard contracts defining terms for sharing of benefits.

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 specialized 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. The proposal of the EU would not meet the necessary criteria to determine that it could potentially constitute a specialized access and benefit-sharing instrument under the Nagoya Protocol. Moreover, while the Parties to the PABS system can eventually signal the expectation that the system should be recognized as a specialized ABS instrument under the Nagoya Protocol, it will be up to the Nagoya Protocol COP to decide that for it to have legal effect.