Comments on Article 12: Pathogen Access and Benefit Sharing (PABS) of the "REVISED Draft of the negotiating text of the WHO Pandemic Agreement, 13th March 2024"

https://apps.who.int/gb/inb/pdf_files/inb9/A_inb9_3-en.pdf

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Introduction

The following comments are our reflections on the current draft text (doc: A/INB/9/3 dated 13 March 2024) of the Pandemic Agreement currently being negotiated at the World Health Organization (WHO). Our comments mostly focus on Article 12 of the draft text on pathogen access and benefit-sharing. Some of our reflections are in the form of questions, but this is not to suggest that there are easy answers (or any answers at all) to these questions. The pathogen access and benefit-sharing (PABS) system set out in the draft Article 12 is supposed to (1.) ensure rapid access to pathogen samples and associated genetic sequence data (GSD), and (2.) ensure fair and equitable distribution of vaccines, diagnostics and treatments in the event of a pandemic. We point readers to our previous publications where we analyse the various problems of using an access and benefit-sharing (ABS) mechanism in the public health space, and have advocated for the above public health issues to be addressed separately (e.g. Hampton, Eccleston-Turner, Rourke and Switzer, 2023, https://doi.org/10.1017/S0020589323000350). Linking these two public health issues using ABS creates more problems than it solves and we are concerned that it will not result in anything resembling fair or equitable for low- and middle-income countries (LMICs).

Commentary

Article 1 *"**PABS sequence databases** means publicly accessible databases that meet and agree to legally binding terms of reference that include arrangements to notify users of benefit-sharing provisions under the PABS system;"*

- The above definition directs that users of PABS genetic sequence data (GSD) are notified of relevant benefit-sharing provisions. The key phrase here is "notify", not monitor, or collect details, or verify….just notify. So, presumably this refers to a clickthrough user agreement. But then who is responsible for tracking usages? And how does that work with database access? And will there be any verification of users? While we wouldn't necessarily argue in favour of user verification, it is nevertheless necessary to consider the utility of a list of names and email addresses from a clickthrough user agreement. Would this be sufficient for the purposes of enforcing benefit sharing obligations?
- While the number of potential users undoubtedly depends upon the scope of the "object of regulation" (see Lawson, Humphries and Rourke, 2024 https://doi.org/10.1093/jiplp/jpad129), the scale of GSD users is potentially massive – there are 70,000 active registered users on GISAID (figure provided by GISAID, private correspondence), to give an example, and that system only manages influenza and COVID-19 data. The broader the object of regulation (that is, the broader the definition of GSD/biological materials that fall within the scope of the PABS system), the larger the number of potential users to verify and/or manage, and therefore the more resources this will require.
- It is worth considering whether the major existing databases will comply with the WHO's PABS requirements. Why would GISAID, for example, agree to the WHO's conditions? What is even in it for them? Will their funding be increased commensurate with the task at hand? And what happens if the established databases refuse? How will the WHO ensure that users are submitting information only on registered databases? Remember, also, that routing everything through official channels could produce perverse outcomes. Informal sharing through informal channels is extremely important during public health emergencies (see Halabi, Rourke and Katz, 2021 https://digitalcommons.law.umaryland.edu/jhclp/vol23/iss2/4/) and it is also how the world found out about COVID-19. When the Chinese government blocked information sharing with WHO, researchers shared the data through international collaborators on virological.org (a website that will probably never qualify as a WHO-registered database) (https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(23)00133-7/fulltext).

Article 1 Biological Materials - *"biological materials" means clinical samples, specimens, isolates and cultures, either original or processed, of a pathogen;*

- Note that "biological materials" does not just cover the pathogen itself. A human clinical sample will include human genetic materials/information. Are third-party recipients allowed to access/use/characterise the human genetic materials/information?
- The definition of biological materials set out here is also substantially different from that under the WHO Pandemic Influenza Preparedness (PIP) Framework (on which the PABS System is seemingly based). The definition of biological materials set out in the PIP Framework includes, *inter alia,* "modified viruses … and/or other … viruses with human pandemic potential developed by WHO GISRS laboratories, these being candidate vaccine viruses generated by reverse genetics and/or high growth re-assortment" with the assertion of intellectual property (IP) rights prohibited over any PIP biological materials. It is unclear why a different – and narrower – approach to defining biological materials is being taken under PABS which defines PABS biological materials as "clinical samples, specimens, isolates and cultures, either original or processed, of a pathogen".
- Furthermore, it must be remembered that any material/GSD which falls outside of the scope of the PABS system automatically falls within the scope of the current United Nations Convention on Biological Diversity (CBD) and the Nagoya Protocol bilateral regime on ABS and/or the proposed multilateral instrument on digital sequence information (DSI, see https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-09-en.pdf). We therefore need to ensure that benefit-sharing arrangements under PABS are coherent and consistent across the other ABS regimes (Amber Scholz, Michael Halewood et al 2024, forthcoming article on DSI harmonization).

Article 3, Principles *- "the sovereign right of States to adopt, legislate and implement legislation, within their jurisdiction, in accordance with the Charter of the United Nations and*

the general principles of international law, ***and their sovereign rights over their biological resources*** *(emphasis added);"*

- The above, combined with Article 12(12) regarding PABS as a specialised international ABS instrument (SII) (see discussion below), leaves considerable uncertainty surrounding whether bilateral transfers of pathogens are allowed under the proposed system. If States retain "sovereign rights over their biological resources" and the Pandemic Agreement is not recognised as an SII (merely treated as such) does that mean that States can also engage in bilateral transfers as long as they have satisfied their multilateral obligations by contributing the sample to PABS? If so, then there is a significant free-rider problem built into PABS, whereby pharmaceutical companies (for instance) can obtain samples from elsewhere on a bilateral basis, without having to agree to benefit-sharing obligations under PABS. This is especially true as States do not have to contribute samples to PABS in order to qualify for benefits because benefits must be distributed according to public health risk and need and not based on whether they have contributed to PABS.

Article 12 (3) (a) *"When a Party has access to a pathogen with pandemic potential, it shall, using applicable biosafety, biosecurity and data protection standards: (a) share with WHO any pathogen sequence information as soon as it is available to the Party"*

- Some clarity around the timescale of this would be helpful. Putting a time on it would provide greater certainty, e.g., 24 hours.
- We note that this paragraph does not refer to the country of origin of a pathogen sample, but to a "Party [that] has access to a pathogen". Remembering that Article 3 recognises the sovereign rights of States over their biological resources, if a Party has access to a pathogen sample that did not originate in their territory, it must be obtained in accordance with ABS laws, where applicable (i.e., with the prior informed consent of the originating country, in accordance with the Convention on Biological Diversity/Nagoya Protocol).

How does sharing another State's sovereign genetic resources without their prior informed consent affect any other possible legal claims over that resource?

Article 12 (3) (b) *"as soon as biological materials are available to the Party, provide the materials to one or more laboratories and/or biorepositories"*

- How is the international transfer of dangerous biomaterials going to be paid for? There is nothing in the text regarding shipping costs, but, depending on how broad the interpretation is of "pathogen with human pandemic potential," this could include a great many samples, largely coming from LMICs. It is not clear who is going to bear the cost of shipping? Will a shipping fund be created to facilitate such transfers? Will this be separate to any benefit-sharing fund(s)?

Article 12(3)(b) *"All users of biological materials shall have legal obligations under PABS regarding benefit sharing"*

- While we recognise that the number of potential users very much depends on the legal object of regulation – that is, the definition of GSD/biological materials included within the PABS system – we would advocate a scoping review be performed based on different scenarios to determine just how many users there might be, and if the WHO has sufficient capacity to form legal relations with them all, monitor compliance and usage, as well as enforce contractual obligations.
- A scoping review would also allow for assessment of the likely effectiveness of the proposed PABS system as well as the costs and benefits of its operation. Obviously we do not want an ineffective, unwieldy system that cannot actually be operationalised, or can only be operationalised at a very high cost. Benefits must outweigh the costs in order for PABS to work. In addition, it should be remembered that the effectiveness of the system is likely to be a criterion for assessment as to whether PABS constitutes an SII (see SBI recommendation). We would therefore recommend an econometric analysis of whether

the benefits of any eventual PABS system actually outweighs the cost of implementation. The example of the International Treaty on Plant Genetic Resources for Food and Agriculture (Plant Treaty) is instructive here: it is highly reliant on voluntary contributions (as opposed to benefit-sharing through its SMTAs, operating for 20 years now).

- Linked to the above, the WHO Secretariat should invite someone from the Plant Treaty's Multilateral System to present to negotiators on, among other things, the quantum of benefits generated from SMTAs and the fact that the costs of running the system far exceed the benefits. The Plant Treaty was agreed in 2001.
- In what jurisdiction does this "legal obligation" actually originate? How are legal relations to be formed? Who is responsible for enforcement? Does the relationship align with notions of natural justice found in contract law? It should be noted that the Standard Material Transfer Agreements (contracts) under the PIP Framework are not enforceable under Swiss law; they are just to be interpreted with reference to Swiss law. So they appear to be without jurisdiction for the purposes of enforcement. This rather begs the question: if the contract cannot be enforced, is it even a contract, and what is its utility here?

Article 12(4) *"The Parties consent to the further transfer and use of biological materials and GSD provided to the CLNs and SDBs, with an electronic label of "PABS biological material" or "PABS GSD", in accordance with the provisions of this Article including on benefit sharing,"*

- There are thousands of potential users of materials. Every single manufacturer of relevant diagnostics, vaccines and other countermeasures, and personal protective equipment (PPE), all around the world. All of whom apparently have a "legal obligation" to share benefits – see above for comments on how this will be formed, monitored, and enforced. We should not underestimate the potential scale of this.
- The requirement of an electronic label is a new addition to the text. We are unsure how this would work in practice when applied to biological *materials*, and there does not seem to be any tracking mechanism akin to the PIP Framework's Influenza Virus Tracing

Mechanism (IVTM, not that we would necessarily advocate for this, particularly given the state that the IVTM is in) attached to it. We understand that inspiration may have been drawn here from the UN's Biodiversity of Areas Beyond National Jurisdiction (High Seas) Treaty (BBNJ), which makes provision for batch identifiers. But the system of registration under the BBNJ is based upon the premise of a limited number of sampling expeditions occurring in one legally-defined area (the high seas) and the BBNJ's Clearing House Mechanism (CHM) provides a unique identifier to the expedition which attaches to the samples they collect. However, for PABS, there are thousands of laboratories from hundreds of national jurisdictions (not to mention thousands of subnational jurisdictions) sampling what could turn out to be PABS materials every single day. These are clearly very different situations and it seems difficult to see how to transpose a CHM/electronic label inspired by the BBNJ onto PABS.

- Furthermore, attaching an electronic label to an electronic resource (like genetic sequence data/DSI) is very different to attaching an electronic label to a tangible/material resource like a virus sample or even genetic material isolated from that sample. It is not clear how this will work, especially once samples start to be manipulated in the lab, which is a very routine practice.
- Related to the above, the electronic label presents issues with regards to the tracking of GSD. The actual conduct of research and development – which uses a very large variety of inputs – means that it is fundamentally impossible to create a tracking mechanism that can determine the relative contribution of different inputs. By extension, the increased use of artificial intelligence (AI) may present further difficulties with regards to tracking if the use of AI leads to the design of a protein or a DNA molecule that does not actually exist in nature, but has instead been developed *de novo* (albeit inspired by wild-type pathogens).

Article 12(4) ***"****The Parties consent to the further transfer and use of biological materials and GSD provided to the CLNs and SDBs, with an electronic label of "PABS biological material" or "PABS GSD", in accordance with the provisions of this Article including on benefit sharing, as*

well as applicable biosafety, biosecurity and data protection standards. Parties agree that intellectual property rights may not be sought on such materials and GSD."

- It is not entirely clear whether this paragraph prevents the patenting of modified PABS samples, however, it does clearly still allow for IP rights to be sought over any resulting products that make use of PABS materials or GSD. We know from COVID-19 that such patents over products was a major barrier to scaling up manufacturing, especially in LMICs. This therefore poses a potential barrier to accessing medicines and equity during the next pandemic.
- The definition of "biological materials means clinical samples, specimens, isolates and cultures, either original or processed, of a pathogen" (Article 1). The "processed specimen" is included in the definition of biological material. It appears that this is intended to mean that if an end user receives an already modified sample (modified by a WHO-affiliated laboratory, for example), end users cannot patent it in its modified form. But does that mean if a user receives an unmodified sample which they then modify to generate a higher yield in the vaccine manufacturing process, for example, that they can patent *that* modified sample? We read it as if end users **can** patent modified PABS biological materials, provided they are the ones to do the modifications, but the fact there is a question mark and uncertainty here is alarming and clarification is needed. Such modification is done as a matter of course in drug and vaccine development, and we would strongly argue against intellectual property being sought over modified PABS biological materials.
- The mention of "biosecurity" also raises a further point: The US Government has suppressed the publication of influenza GSD in the past on the basis of biosecurity concerns. Does this mean States can just decide that biosecurity concerns override the obligations to share? What is the evidentiary burden for demonstrating that such concerns are legitimate? Or will this be a self-judging provision, akin to a "national security" exemption seen in other international legal regimes (including the USA's understanding to the International Health Regulations 2005)? Or perhaps, countries wishing to take such measures will want to provide themselves with legal certainty here and make a reservation on this point?

Article 12(6) *WHO shall conclude legally binding standard PABS contracts with manufacturers to provide the following, taking into account the size, nature and capacities of the manufacturer:*

- Does "taking account of the size" imply they will not pursue benefits from a small(er) manufacturer? What about non-commercial users such as research institutes and universities which are expected to sign SMTA2s under the PIP Framework?
- In what jurisdiction does this obligation actually originate in? How are legal relations formed, and in what jurisdiction? Who is responsible for enforcement? Does the relationship align with notions of natural justice found in contract law? This is not even clear for the PIP Framework SMTA2s. While the WHO claims that the PIP SMTA2s are "enforceable", it is unclear under what jurisdiction enforcement will occur, if this is even possible.
- And what of multinationals? How is such a provision going to be enforced in respect of corporate entities that have a parent-subsidiary relationship or are in joint ventures across different jurisdictions? The legal form that pharmaceutical companies typically take needs to be accounted for, together with clarity on how enforcement will take effect in respect of transnational groups of companies. We need to consider how these contracts will work for subsidiaries established in different Parties; in essence, the business form of the type of entity likely to be covered by the benefit-sharing arrangements set out under Article 12 needs to be considered when designing PABS contracts
- Has the WHO done an analysis to identify just how many users we are talking about, and if it has the capacity to form such legal relations, monitor compliance, and seek enforcement if necessary? Even pandemic influenza vaccine manufacturers have received PIP biological materials without having an SMTA2 in place because it has taken so long to negotiate contractual terms, and that is a very, very small potential pool of end users. PIP biological materials were even provided to Theranos Inc., without an SMTA2 in place.
- What is a "standard PABS contract" and how standard is it? Have examples been shared with negotiators, including any proposed term sheets? Why a "PABS contract" and not an

SMTA, as is usual practice within CBD/ABS systems? Note that the SMTA2 under the PIP Framework is supposed to be enforceable as a contract but this is probably not the case (see discussion above); so how is the PABS contract different?

Article 12(6)(a) *"annual monetary contributions to support the PABS System and relevant capacities in countries"*

- What is the estimated running cost for the PABS System on a yearly basis? And what does this estimate actually include? We don't even know what the PABS System actually entails because there has been no detail on this throughout the negotiations (e.g., will it use existing infrastructure or make new laboratories and databases?).
- The Partnership Contribution under the PIP Framework (which the PABS System has been modeled on) largely funds the PIP Secretariat, and does not engage with a number of considerable costs which are incurred under the PIP Framework. These costs include: transport/shipping costs, insurance costs, liability and indemnification costs for the vaccine rollout in-country. This has not been finalised in the PIP Framework's SMTA2s and has been noted as a major barrier preventing manufacturers from signing SMTAs under PIP. Each of the above presented major barriers to the distribution of vaccine from the COVAX initiative during COVID-19, does "support of the PABS system" include these sorts of costs? If not, has provision for such costs been made elsewhere?

Article 12(6)(b) *"real-time contributions of relevant diagnostics, therapeutics or vaccines produced by the manufacturer, 10% free of charge and 10% at not-for-profit prices during public health emergencies of international concern or pandemics, to be made available through the Network established under Article 13 for use on the basis of public health risks, needs and demand;"*

- How will "public health risks, needs and demand" be determined? What constitutes greater need and/or demand? How will such a decision be made and by whom, and will the decision-making protocol/matrix be made public? Will demand be judged on whether the recipient country will indemnify the manufacturer or the WHO for any adverse events

related to the products ("benefits") provided? By the time countermeasures become available (if the PABS System functions as intended, though this is not guaranteed) there will be significant "public health risk, need and demand" in numerous States all around the world – particularly amongst LMICs. Further clarity is required regarding who decides if the first shipment goes to country A or country B and how this is to be decided, and by whom.

- What happens if an end user says "we are not agreeing to 10%, we will do 2.5%" as has been the case with many of the SMTA2 contracts under the PIP Framework? The WHO had to negotiate a handful of contracts under the PIP Framework (because there are a limited number of manufacturers who can make pandemic influenza vaccines around the world), and even then they did not get close to the proposed % of benefits.
- Will the terms agreed to by end users under PABS be made public for scrutiny by Member States and interested parties (NGOs and academia)? Full transparency will be needed to ensure that these PABS contracts will work during a public health emergency. We understand that there are some terms that will be considered "commercial-in-confidence" and will not be made available to the public. However, these commercial arrangements should be made fully transparent to anyone conducting a periodic review of the PABS system to ensure its ability to deliver on benefit-sharing.

Article 12 (7) *"Each Party, in respect of such a user operating within its jurisdiction, shall take all appropriate steps, in accordance with its relevant laws and circumstances, to encourage such a user to provide benefits in accordance with subparagraphs (a) and (b) above."*

- "Encourage" and "relevant laws and circumstances" leaves the door wide open to ridiculous force majeure provisions, vaccine nationalism and export controls, where high-income countries (HICs) can frustrate the intended functioning of PABS, and the delivery of benefits to the WHO.
- This is also much weaker language than was promised on this very point. It renders the benefit sharing obligations (if agreed to) meaningless, because national governments can still reserve the right to seize and use the vaccine that was promised to WHO for the PABS system.

Article 12(8) - "*The Parties shall cooperate and take appropriate measures, such as conditions in public procurements or on public financing of research and development, prepurchase agreements, or regulatory procedures, to encourage and facilitate as many manufacturers as possible to enter into standard PABS contracts as early as possible."*

- Sharing samples is required, but it would seem that getting pharmaceutical companies (and other users) to sign these PABS contracts is totally optional. This is the same problem as the PIP Framework. Weak, meaningless language which enables a considerable degree of flexibility to HICs and pharmaceutical companies.
- What does this clause obligate HICs to actually do? How do they demonstrate that they have "encouraged and facilitated"? It is a vague provision, and ultimately meaningless. What measures are considered appropriate, and by whom? How should this be achieved? The text remains highly deferential to pharmaceutical companies who do not appear to have any genuine incentives to actually sign these contracts because they can still engage in bilateral ABS to obtain samples outside of the PABS system.
- We would further recommend that the measures taken by Parties are subject to monitoring and potentially to peer review. Indeed, one would expect the monitoring of such measures to be part of a wider review of the effectiveness of the system. The vague provisions on the review of the effectiveness of the PABS system need to be bolstered to ensure that lessons learned throughout are actually taken on board.

Article 12(9) *"During a pandemic, each Party in a position to do so shall, within available resources and subject to applicable laws and in line with Article 13, set aside a portion of its total procurement of relevant diagnostics, therapeutics or vaccines in a timely manner for use in countries facing challenges in meeting public health needs and demand for relevant diagnostics, therapeutics or vaccines"*

- All this is doing is asking HICs to consider sharing the vaccine they have hoarded during the next pandemic. This type of provision simply entrenches the status quo of charity and dependency, and gives HICs a loophole to not even bother doing that if their national circumstances do not seem favourable enough. Attaching the phrase "in a position to do

so" renders any obligation essentially a best endeavour provision. We recommend that such hortatory language is removed and replaced with substantive obligations.

Article 12(10) "*WHO shall make such contracts public, while respecting commercial confidentiality."*

- This is an oxymoron. How can the contracts be public while respecting commercial confidentiality? We assume that this means they intend to follow the PIP Framework SMTA2 contractual model, whereby the public SMTA2 just contains the names of the Parties, and all the meaningful details are held in the confidential Term Sheets. An analysis of the STMA2s (see "access by design, benefits if convenient") these agreements contain a number of very alarming clauses which indemnify companies from meeting their obligations **if there is a pandemic**. Any PABS contracts – and any associated documents that materially impact the obligations under the contracts – should be made available for public scrutiny.
- To support the negotiations, the PIP Secretariat should make the Term Sheets from the PIP Framework's SMTA2s available to the Pandemic Treaty negotiators to assess how legally-binding those contracts actually are. The negotiators should be given an opportunity to understand what sort of terms and conditions are included in those "commercial-in-confidence" documents (which are a crucial part of the SMTA2) so they know what to expect from "legally binding standard PABS contracts".

Article 12(11) *"Templates for the standard PABS contracts and for legally binding terms of reference agreements with CLNs and SDBs shall be developed by the Parties."*

- The entire success of this operation appears to rest on these PABS contracts, and yet they will not even be written before the Pandemic Agreement is ratified, never mind being made available for scrutiny during the negotiations?

- Remember that the fairness or otherwise of such contracts, as well as their ability to actually deliver benefits, will very likely be a criterion on which any assessment of whether PABS constitutes an SII will be made (see https://www.cbd.int/doc/c/9376/a644/1bed20a1837af8e3d1edc5f9/sbi-02-inf-17-en.pdf).
- We are placing a considerable degree of faith in the ability of WHO to draft legally sound PABS contracts, and get hundreds (maybe thousands) of end users to agree to those terms. As we have seen from how these agreements have been negotiated under the PIP Framework, such faith is highly misplaced. Furthermore, the SMTA2s under the PIP Framework suggest there is nothing "standard" about these Standard Material Transfer Agreements when the lawyers from huge multinational pharmaceutical companies are negotiating the terms.

Article 12 (12) "*The Parties who are Parties to the Convention on Biological Diversity and its Nagoya Protocol recognize that the PABS System, when fully operational, is consistent with and does not run counter to the objectives of the Nagoya Protocol;"*

- Competence to determine what is and is not a specialised international instrument (SII) lies solely with the Parties to the Nagoya Protocol (NP), as the NP created the category of SII in the first place, and this is therefore subject to *lex specialis Derogat legi generali*.
- We do not think the Conference of the Parties to the CBD serving as the Meeting of the Parties to the NP (COP/MOP) would allow for their own rules to disapplied by a decision taken in a separate international law forum – particularly when the process for determining and designating a SII has begun in the MOP already (see https://www.cbd.int/doc/c/9376/a644/1bed20a1837af8e3d1edc5f9/sbi-02-inf-17-en.pdf).
- There are several issues for the status of an instrument being an SII:

    1. Decision 15/9 of the CBD's COP began the process of creating a new multilateral system for sharing the benefits associated with the use of DSI (which will likely be recognised as an SII). Therefore, we believe there is a potential overlap/conflict with the fact that the proposed Pandemic Treaty also includes DSI within its scope (that is, GSD). The overlapping scope requires clarification.

2. More importantly, based on the current criteria for identifying an SII, the ability to deliver "fairness/equity in the context of the sharing of benefits" is a formal requirement. It is not clear that PABS will deliver fairness and equity to such an extent that it would meet this threshold. Whether the PABS System is fair and equitable would need to be determined based on its operation, not on the text of the Pandemic Agreement simply stating that it is fair and equitable. Given that the PABS system is modeled on the PIP Framework, and the many fundamental problems outlined in this document (and elsewhere) there are good reasons to believe such an instrument would not meet this criteria.

3. Traditional Knowledge (TK) of Indigenous Peoples and local communities is a key component of the international ABS regime created by the CBD and Nagoya Protocol. Why has TK never been mentioned in these discussions? Traditional Knowledge related to pandemic pathogens could encompass traditional burial practices (which were important during the Ebola outbreak in West Africa in 2014) and traditional pig and poultry farming practices (related to influenza). It could include knowledge about livestock management, vector distribution and the identification of sick individuals, for example. For the PABS System to be an SII, it cannot simply ignore a key component of the Nagoya Protocol (which requires PIC and MAT for Traditional Knowledge associated with genetic resources).

Article 12 (14) *"The Conference of the Parties shall regularly review the operation, monitor adherence and effectiveness of the PABS System and shall take the decisions necessary to promote and support its effective and sustainable implementation."*

- Will there be an independent review of the operation of the system? At present, the competence to review seems to rest with the COP but given the *sui generis* nature of the system, and the competing interests States will have around the system, we would strongly recommend an independent system of monitoring, evaluation and learning is established. And this independent system should get to see all the PABS contracts,

including any term sheets or other associated "commercial-in-confidence" documents There should also be provision made for refinement and amendment to the PABS system, depending upon the findings of the monitoring and evaluation body. In devising the PABS System, we would recommend that the use of monitoring and evaluation processes in other international fora be surveyed and considered.

Other Issues

1. ***Interaction with the PIP Framework***

The scope of the PABS System overlaps with the scope of the PIP Framework. Therefore, the failure within the draft text to specify the relationship between the PABS System and the PIP Framework is likely to cause significant confusion when a novel sample of influenza virus with human pandemic potential (the only category of pathogen included within the scope of PIP) is identified by a country. It is to be underlined that the PIP Framework does not cover GSD and the benefit sharing components in the PIP Framework are potentially very different (e.g. different % of benefits shared, different triggers for sharing). The PIP Framework also addresses access in a very different way to the present draft: sharing of samples is not formally required, merely encouraged, and PIP has not been recognised as a specialised international instrument under Article 4(4) of the Nagoya Protocol, meaning it does not supersede the bilateral, sovereignty based ABS system created by the CBD. If the PABS System is capable of meeting its commitments, it should supersede the PIP Framework. There is no reason to run a parallel system that treats pandemic influenza differently for the purposes of ABS.

2. ***Entry into force***

There is no mention of when the PABS system will enter into force. Will the "access" side proceed as normal while issues around benefit-sharing remain to be resolved via the to-be-negotiated PABS contracts? This would mean that pharmaceutical companies and other

users can still access PABS materials and GSD, in the way they presently do, but in advance of (and possibly without ever) committing to any meaningful benefit-sharing. It is still not clear why the pharmaceutical companies and other users would even sign up to this multilateral system if there remains a bilateral ABS system in place by default (in which many countries choose not to regulate their genetic resources using ABS at all!).

3. Dispute Settlement

There is no explicit provision made for dispute settlement in the draft text of Article 12. Will any PABS-specific dispute settlement system be decided subsequent to the entry into force of the Pandemic Agreement? The dispute settlement provisions outlined in Article 25 of the current draft text only seem to apply to the Parties to the Pandemic Agreement and are weak in any case.

Under the PIP Framework, all disputes are supposed to be settled by the WHO Director General, who, it must be remembered, represents one of the parties to all the SMTAs under the PIP Framework. Having the WHO as a party to the agreement and as the final arbiter to disputes regarding the agreement does not align with notions of justice found in many contractual legal systems around the world. We would therefore recommend that the approach of the PIP Framework is *not* followed under PABS.

Clearly, further provisions are required on dispute settlement under PABS. We would further recommend a separate system for complaints and grievances be established, since the PABS contracts will have private entities (not Member States) as contracting parties and the areas covered by the PABS system will extend beyond that which would come within the purview of a typical dispute settlement system. An independent individual redress mechanism, of the kind that exists in other international fora, would seem a sensible proposal here.

4. Temporal Scope

The temporal application of the PABS System is not specified. It is not clear if the present draft applies only to countermeasures developed using new samples identified and shared post the

development of the PABS System, or if it applies to countermeasures developed using older samples, but during a new disease event. e.g., if a new outbreak of Ebola in central Africa is declared a PHEIC, and ZEBOV and SEBOV is the recommended treatment regime, do the benefit sharing obligations apply in this scenario, because these countermeasures were developed pre-PABS? A useful point of comparison may be made with the PIP Framework, SMTA 1 (Article 6.2) which directs that "The Provider and the Recipient acknowledge that any IPRs on the Materials obtained before the date of adoption of the Framework by the World Health Assembly will not be affected by SMTA 1."