Written Submission for INB Interactive Dialogue on "Article 12 (Pathogen Access and Benefit-Sharing System)", 3 September 2024

Dr. Stephanie Switzer, University of Strathclyde

Dr. Michelle Rourke, Griffith University

Dr. Mark Eccleston-Turner, King's College, London

Dr. Abbie-Rose Hampton, King's College, London

Disclaimer: this work is the result of a joint submission by the above authors. The work is limited on two fronts. Firstly, due to the manner in which the questions were formulated it has not always been possible to understand the precise intent of the question. Secondly, the limited timeframe from the questions being released and the submission closing date has meant that it has not been possible to give a full account of the issues raised by the PABS system.

Discussion questions proposed by the Bureau for resource persons:

1. PABS and Nagoya Protocol related matters

If Member States reach consensus on the PABS instrument during the negotiation, including that its design is consistent with, and does not run counter to the objectives of the Convention on Biological Diversity and the Nagoya Protocol, and the INB decides that PABS can be recognized as a specialized international access and benefit-sharing instrument (SII):

1.1. Can PABS, as SII, be universally applied to all Parties to the Pandemic Agreement, i.e. both Parties and non-Parties to the Nagoya Protocol?

The competence to determine what is (and is not) a SII lies solely with the Parties to the Nagoya Protocol (NP).[1] With this in mind, there are several issues for the status of the Pandemic Agreement as a SII:

1. Decision 15/9 of the CBD COP began the process of creating a new multilateral mechanism specifically focused on DSI. There are also practical issues associated with

[1] Agreement on the relevant criteria has not yet been secured though possible indicative criteria have been discussed by the Nagoya Protocol's Meeting of the Parties (MOP).

the application of two (and potentially more) benefit-sharing mechanisms to pathogen sequences, which we discuss more fully below at 2.1

2. We should also consider the likely criteria applicable to whether an international instrument will constitute a SII. We discuss these further below (see 1.6) but would underscore that the ability of PABS to deliver 'fairness/equity in the context of the sharing of benefits' will very likely be a formal requirement for its identification as a SII. The legally binding PABS contracts will be a central element of the ability of the system to secure fairness and equity and we suggest that negotiators be granted permission to review the PIP Framework contract 'term sheets' which contain 'commercial in confidence' provisions negotiated under SMTA2.[2] The purpose of this would be to allow negotiators to assess for themselves the extent to which these agreements are capable of achieving fairness and equity, given that PABS is modelled on the PIP Framework.

3. Traditional Knowledge of Indigenous Peoples and local communities is a key component of the international ABS regime created by the CBD and Nagoya Protocol. To our knowledge, this has not been explored during the negotiations of the PABS instrument thus far.[3] For PABS to be a SII, it cannot ignore a key component of the Protocol - which requires PIC and MAT for Traditional Knowledge associated with pathogenic genetic resources.

1.2. What criteria and/or mechanism(s) are to be used for the recognition of PABS as a SII?

- **For Parties to CBD and the Nagoya Protocol who are Parties to the Pandemic Agreement?**

As noted above, competence to determine what is and is not a SII lies solely with the Meeting of the Parties to the Nagoya Protocol (NP), as the NP created the category of SII in the first place. If the Meeting of the Parties to the NP do decide that the PABS System component of the Pandemic Agreement constitutes a SII, then parties to the

[2] That is, the full details of the agreement signed between the WHO and recipients of PIP Biological Materials outside of the WHO GISRS. The benefit sharing provisions are outlined in the SMTA2 proper (which, for pharmaceutical companies, are made available on the WHO's website). But the definitions of the terms used in SMTA2 are kept commercial-in-confidence. We think these are vital for understanding how any new multilateral PABS System based on private law contracts is to work.

[3] Traditional knowledge related to pandemic pathogens could encompass traditional burial practices (which were important during Ebola in West Africa 2014) and traditional pig and poultry farming practices (influenza). It could include knowledge about livestock management, vector distribution and the identification of sick individuals, for example.

Nagoya Protocol will likely need to adopt something to that effect in their national ABS laws. Parties to just the CBD will have no such obligation.

It is, however, the case that treating something as a SII in domestic law does not necessarily mean that the entire class of genetic resources (e.g., pathogens with human pandemic potential) need to be shared using the SII. i.e., it does not automatically result in the disapplication of the CBD or NP (or the domestic laws implementing these instruments). Countries will still be able to decide which samples to contribute to the PABS System under the terms of the SII.

This means that ABS for the entire class of genetic resources will still default to bilateral ABS arrangements. This is the case for the PIP Framework. There are many samples of influenza virus with human pandemic potential in the possession of countries that have not been contributed to the GISRS under the terms of the PIP Framework. The PIP Framework only applies to the samples countries ***choose*** *to contribute under the PIP Framework, not all existing influenza viruses with human pandemic potential as a subset of all the world's genetic resources. The same will be true of the PABS System —only those pathogens with human pandemic potential that countries* ***choose*** *to contribute under the terms of the PABS System will fall under its scope.*

- **For non-Parties to CBD and the Nagoya Protocol who are Parties to the Pandemic Agreement?**

Countries that are party to the Pandemic Agreement but are not party to the CBD and/or the Nagoya Protocol would be under no obligation to regard the PABS System created by the Pandemic Agreement as a SII. This is the case even if the Meeting of the Parties to the NP decide that it is a Specialised International ABS Instrument. Such a decision has no legal bearing on the actions of non-parties to the NP. They may, however, ***voluntarily*** *decide that they will treat the PABS System as though it is a SII (i.e., determine that they will use the PABS System preferentially over any bilateral ABS arrangements they have in place) if it suits their interests and intent. This will, however, be a particularly hard sell for non-parties to the NP that are federations as it will be very difficult to justify treating the PABS System as a SII when the country has not even adopted the NP.*

- **What domestic legal arrangements are needed, such as amendment of national ABS laws, to recognize PABS and ensure that PABS materials are not subject to additional or different PIC and MAT ?**

Legal certainty and the associated concept of a 'license to operate' would best be achieved if PABS materials were not subject to additional or different PIC/MAT. But

pathogen samples are still the sovereign genetic resources of the states in which they originate, so Parties can do what they want with them. That is, they can choose to contribute certain samples to the PABS System, while still applying their domestic (bilateral) ABS rules to other samples, even if they are deemed to have human pandemic potential.

More generally, the scope of any PABS System must be precisely defined to be workable for scientists. This is particularly notable in respect of what counts as a "pathogen with human pandemic potential" as the present language ("potentially highly transmissible and/or highly virulent, with the potential to cause a public health emergency of international concern") is highly subjective and does not give sufficiently clear guidance to national labs about what constitutes a "pathogen with human pandemic potential" for the purposes of PABS. Of course, this is assuming that (like the PIP Framework) the authority to determine what samples have or do not have pandemic potential rests with the country of origin (or National Influenza Center). It becomes a judgement call of the scientists whether or not to contribute samples to the PABS System.

1.3. During the INB negotiations, what are the considerations that should guide the INB so as to maintain coherence between the future PABS and the Nagoya Protocol?

AND

1.4 Are there any specific issues in the PABS under ongoing INB negotiations that may prejudge the ongoing discussions on the handling of DSI within the CBD and the Nagoya Protocol?

While the central elements of the PABS System are still to be defined, it is clear that the system intends to include pathogen DSI within its scope. This is concerning as it means the PABS System negotiations are already attempting to carve out special exceptions to the CBD's DSI multilateral mechanism instrument before it even exists. More generally, the lack of genuine engagement with the CBD's negotiations for the DSI multilateral mechanism is of considerable concern, as it has the potential to create conflicting obligations for the sharing of pathogen GSD to arise under different legal regimes. After all, pathogen DSI will fall within the scope of both PABS and the CBD's DSI mechanism, unless there are discussions to exclude PABS GSD/DSI from the scope of the DSI mechanism. Active efforts are needed to deconflict the scopes so as to not fragment the legal landscape here, with such fragmentation likely to cause particular difficulties for scientists (including the potential risk of having to pay for the same DSI twice. The DSI

*multilateral mechanism might, for example, require publication in an **open access** sequence database, while the PABS System might require publication in a WHO-recognised **public access** database only (with terms and conditions attached). We are concerned that carve outs from the scope of the DSI multilateral mechanism risks its future adoption and effective operation.*

In 2018, the CBD commissioned study on specialised international instruments that explicitly addressed the need for the negotiations of any potential SII to be mutually supportive.[4] International law is replete with tools and techniques to manage regime 'overlap' and the interplay between different strands of a 'regime complex.' There are 'a variety of ways in which the existence of regime overlaps can be carefully managed, to provide for synergistic outcomes, even when membership is not congruent between the relevant regimes.' Present negotiations should take note, and ensure the mutual supportiveness of PABS with other relevant international law processes.

1.5. In principle a non-Party to PABS who is a Party to the Nagoya Protocol could view that PABS is not 'consistent with and not run counter to the objectives of the CBD and the NP'. In this case, is the non-Party to PABS that is affected by the conclusion of a SII entitled to dispute settlement under Article 27 of the CBD?

*The wording of the question is very confusing. It is not clear to us why a non-Party to the PABS System would even care whether or not it constitutes a SII as it clearly has no intention to use the PABS System (it is a **non**–Party after all). As such, the premise of the question is unclear.*

*The CBD is largely about bilateral ABS. While nothing in the CBD rules out multilateral ABS, the dispute resolution mechanism under Article 27 of the CBD is about disputes **between** Contracting Parties. While the current text of Article 12 of the Pandemic Agreement is sparse on details, with little relevant content in yellow or green, negotiations on the PABS System to date have not seen an intention to create direct legal relations between the providers and users as relevant parties to a private contract. Instead, what has been envisaged in negotiations so far is the creation of legal relations between Member States (as providers of genetic resources) and the WHO, with the separate creation of legal relations between the WHO and user parties (e.g., pharmaceutical manufacturers). This is similar to the PIP Framework where the WHO is the intermediary between provider parties and user parties. At no point in the process*

[4] Meaning "*managed from the start in a mutually supportive manner by, for example, setting a negotiating mandate that seeks coherence with an existing instrument, keeping the governing body of an existing instrument informed of progress in negotiations, and/or drafting the provisions of a new instrument that will specifically cater to mutually supportiveness.*"

are WHO Member States entering into an agreement with manufacturers. Article 27 was not adopted for the purpose of mediating between disputes that already had a mediator (as in multilateral ABS agreements). In the case of the PABS System, the WHO is the mediator of relations between providers and users. It is further worth noting that the WHO would therefore be party to the proposed PABS contacts and so should ***not*** *be considered a suitable arbiter for any PABS-related disputes, as is the case under the PIP Framework. The fact that the PIP Framework has the WHO as both a party to the SMTAs and the resolver of any disputes that may arise from those same SMTAs raises questions about natural justice and the enforceability of these contracts - raising doubts regarding its status as a SII on grounds of 'legal certainty' and whether it 'operates in good faith'*

1.6. What are elements or designs of PABS that would be inconsistent with and run counter to the objectives of the CBD and the Nagoya Protocol?

The Meeting of the Parties to the Nagoya Protocol have not yet determined what criteria should be used to determine if an instrument constitutes a Specialised International ABS Instrument (SII) within the meaning of Article 4(4) of the Nagoya Protocol. However, in 2018 the Subsidiary Body on Implementation (SBI) under the CBD did commission a "Study into Criteria to Identify a Specialized International Access and Benefit-Sharing Instrument, and a Possible Process for its Recognition". This listed nine criteria under the categories of "specialization"and "supportiveness".[5]

Rourke and Eccleston-Turner published an analysis of the PIP Framework and its SMTAs to determine whether its ABS provisions met the nine criteria and might therefore be considered a SII. While the PIP Framework was found to meet the specialisation criteria, it failed to meet the supportiveness criteria outlined in the SBI report, and therefore would not meet the definition of a SII. Specifically, "the PIP Framework has major shortcomings when it comes to meeting three of the five criteria on supportiveness: fairness and equity in benefit-sharing, creating legal certainty for ABS and the general legal principles of effectiveness and legitimate expectations". Given that the PABS System is still very similar to the PIP Framework (where the WHO is the intermediary and establishes ABS terms through private law contracts), it is highly

[5] Specialization: intergovernmentally agreed, binding or non-binding, specific to a subset of genetic resources and requiring a specialised approach. Supportiveness: consistent with biodiversity and sustainable use objectives, fair and equitable sharing of benefits, provides legal certainty, contributes to sustainable development, and operates effectively and in good faith.

likely that it will also fail to meet the supportiveness criteria laid out in the CBD's SBI report.

2. Issues related to access to PABS materials and sequence information

2.1. What are the current most up-to-date progresses in CBD on definition and scope of digital sequence data (DSI)? Will the current negotiated text using "sequence information" contradict/hamper the ongoing negotiation of the CBD?

At this stage it looks as though the negotiations for the new multilateral DSI instrument under the CBD may not even define "DSI". This may be an intentional approach (strategic vagueness) to ensure that "DSI" under the new multilateral instrument means whatever parties want it to mean (and are therefore more likely to adopt the instrument). However expansive any potential definition of DSI may be, it will certainly cover nucleotide sequence data. So the term "sequence information" related to pathogens with human pandemic potential under PABS definitely encroaches on the scope of the new DSI multilateral mechanism.

The only way for the DSI multilateral mechanism to have any chance of working is to ensure that there are no exceptions to the scope. The system needs to be fully harmonised across all types of DSI. Indeed, what these discussions often fail to realise is that the way we categorise certain types of genetic resources or associated DSI are entirely arbitrary. All life on earth is related and there are often no clean lines of separation for what we call "species". For the multilateral DSI instrument to work, we cannot be treating some arbitrarily defined categories of DSI differently to other categories.

*Whether or not the new DSI multilateral mechanism defines DSI, it is clear that **any** definition of pathogen DSI would fall within its scope. It is disappointing that the WHO is already attempting to carve out a subset of genetic resources that they consider should be an exception to the rules of the DSI multilateral mechanism. It undermines the functioning of the DSI multilateral mechanism before it even has a chance to get started. It cannot create a holistic approach to DSI benefit-sharing if the WHO has already carved out some of its scope.*

2.2. What are the effective technical or operational measures to ensure all users (primary users and secondary users shared by primary users) of

materials and sequence information account to benefit sharing arise from the use of them?

The wording of this question is confusing, but we assume this question pertains to when user parties ("primary users") can share PABS materials and sequence information with a third party (what the question refers to as "secondary users"), and how to ensure that third parties, who may not have entered into a PABS Agreement, share benefits from the use of such materials and sequence information. This could be achieved by not allowing transfers to third-parties under the terms of the PABS Agreements.

We further assume that this question requires consideration of tracking and tracing, which we discuss more fully below. It should, however, be noted that it is possible to design a multilateral system where the benefits are not associated with specific samples, like the PIP Framework's Partnership Contribution component which raises funds (monetary benefit-sharing) equivalent to 50% the running costs of the GISRS system (as at 2011). Other potential mechanisms for monetary benefit-sharing/revenue generation have been discussed in relation to the CBD DSI multilateral mechanism, and these may prove useful and instructive for the ongoing discussions within the WHO.

In addition, and as we discuss more fully below at 3.3., the PABS System artificially connects two resource allocation problems together: (1) access to scientific samples, and (2) access to medicines. There is no reason, other than path dependency, for these two public health concerns to be tied together, and no reason why countries should have to trade their sovereign resources in return for vaccines, therapeutics and diagnostics (VTD), particularly given that access to essential medicines is a human right.

2.3. What are the effective "traceability" measures which ensure users of materials and sequence information account to benefit sharing obligations?

In respect of any effort to either track or trace, there are thousands of potential users of materials. Every single manufacturer of relevant VTD globally could be liable for benefit-sharing of some sort: the scale and cost of tracking, tracing, compliance and enforcement is significant and highly likely to outweigh the benefits generated if the PABS System is designed as a contract-mediated multilateral system.

Within the current draft, no information is provided on tracking/traceability or how this will be monitored and/or enforced. The PABS System is highly vulnerable to bilateral transfers outside of the system that will be invisible to the WHO and Member States.

Beyond intentional circumvention of the PABS System, it is worth considering the possibility of industry unknowingly using PABS materials and particularly DSI. Unless PABS DSI is exclusively hosted on PABS-only databases (which is undesirable and potentially damaging to the CBD's DSI multilateral mechanism negotiations) or PABS labels are used and extensively monitored (which would require significant changes to database functions) then industry users could unwittingly download and use PABS DSI. This will become a greater problem as the use of Artificial Intelligence (AI) and Machine Learning (ML) are increasingly employed in the pharmaceutical R&D process.

The scale of tracking and tracing should not be underestimated. As an example, there are 511 labs/users under the Influenza Virus Tracing Mechanism (IVTM). This mechanism only records transfers of physical samples of influenza with human pandemic potential under the scope of the PIP Framework, and it is likely that many transfers are not captured. For PABS, the costs of tracking such an extensive exchange of samples and data is significant and it is unclear whether doing so would even result in benefit-sharing (to such an extent that it would outweigh the significant costs).

3. Issues related to benefit sharing

3.1. What are the positive or negative consequences to manufacturers should a PABS System be established in which there are a legally binding benefit sharing requirements to allocate certain percentage of vaccines, therapeutics and diagnostics (VTD) on a free-of-charge basis and at not-for-profit prices, as well as annual monetary contribution?

A key issue for manufacturers in terms of their ability to both plan for, as well as adhere to, any benefit-sharing obligations set out under 'legally binding' PABS Agreements, is that of legal certainty. They will need to know when they will be required to share VTD, which leads to questions as to the scope of the PABS System, and in particular: when benefit sharing is triggered and its temporal scope.

For example, what should happen with VTD developed using samples or DSI which predate the establishment of the PABS System? What if a new outbreak of Ebola in Central Africa is declared a PHEIC, and ZEBOV and SEBOV vaccines are the recommended treatments; do the benefit sharing obligations of PABS apply in this scenario even when these countermeasures were developed pre-PABS?

Clearly, for benefit-sharing to occur in the scenarios outlined above, the PABS System would need to apply retrospectively, and there is no guarantee that Member States, or

indeed manufacturers would agree to this.[6] *Furthermore, setting out retroactive scope in individual benefit-sharing contracts would also result in a piecemeal and fragmented application of the PABS System, and thereby threaten to undermine its effectiveness and predictability, risking its status as a SII (see discussion above in question 1).*

While the Nagoya Protocol is silent on the issue of temporal scope, in part due to the difficulties of securing agreement on this issue,[7] *it is clear that for PABS, leaving the issue of temporal scope silent will undermine the legal certainty of the system, as well as result in uncertainty as to when benefit-sharing will be required. All of this will have* ***negative consequences*** *for benefit-sharing, as well as for manufacturers since, if the CBD's DSI multilateral mechanism negotiations can act as a guide, manufacturers will be seeking a 'licence to operate', and so key issues such as scope cannot remain unresolved.*

3.2. Would the manufacturers and commercial users of materials and sequence information consider not using the PABS system because of this required contribution?

The PABS System is highly vulnerable to bilateral transfers outside the system. There is nothing within the text, which indeed notes the 'sovereign right of States over their biological resources', that can prevent this. Second, the likelihood of some WHO Member States not endorsing the Pandemic Agreement/the PABS System (see discussion below at 4.1) raises the possibility of avoidance and forum and jurisdiction shopping.[8] *In this regard, it is worth remembering that the USA is not a party to the CBD or Nagoya Protocol and has bilateral health security agreements with at least 50 countries which more than likely cover arrangements for sample and data sharing.*

[6] Noting that *non-retroactivity is considered a principle of international law.* See discussion in Chua, Adrian, and Rohan Hardcastle. 1997. "Retroactive Application of Treaties Revisited: Bosnia-Herzegovina v. Yugoslavia." *Netherlands International Law Review* 44(3): 414–20

[7] However, it should be noted that the BBNJ agreement sets out in Article 10 (1) a presumption in favour of the retrospective temporal application for marine genetic resources and DSI, albeit one that, a 'Party (can) make(s) an exception in writing under article 70 when signing, ratifying, approving, accepting or acceding to this Agreement.'

[8] On jurisdiction/forum shopping, see generally SPDA Report from the ABS Capacity Development Initiative, 2021; European Commission, Joint Research Centre, Weissgold, L., Switzer, S., Eccleston-Turner, M. and Scholz, A.H., A technical and legal analysis of triggers for monetary benefit-sharing from digital sequence information on genetic resources, Publications Office of the European Union, Luxembourg, 2024, https://data.europa.eu/doi/10.2760/936096, JRC138679

*The extent to which PABS avoidance is either possible or attractive will depend on a number of factors, such as how benefit-sharing contracts, if even signed[9], will be enforced, as well as the point at which an obligation to share benefits is triggered. If the obligation arises from the **use** of specific samples shared via the PABS System, then opportunities for benefit sharing will likely be limited If benefit sharing is designed as some sort of monetary contribution (like the PIP Framework's Partnership Contribution) then benefit sharing may be more likely. Furthermore, the INB should carefully consider the range of unintended consequences that could arise from the new incentives and disincentives brought about by the operationalisation of the PABS System, including changes to the types and methods of R&D conducted by the pharmaceutical industry (e.g., the further neglect of already neglected diseases).*

3.3. If not a PABS system, are there other options which could facilitate rapid and timely sharing of materials and sequence information, and on an equal footing, sharing of monetary and non-monetary benefits arising from the use of materials and sequence information, and incentivize greater manufacturer participation? Would any of these options be preferable to a PABS system?

We have written in the past that the PABS System artificially connects two resource allocation problems: (1) access to scientific samples, and (2) access to medicines. There is no need to treat these two resource allocation problems as an ABS issue. It is possible to set up incentives to encourage LMICs to share pathogens and associated genetic sequence data in the knowledge that their scientists and other researchers will get the credit and respect they deserve when those resources are used by scientists in HICs. Scientific resources can be (and have been) effectively treated as managed common goods.

Separately, a more fair and equitable response to pandemic preparedness and response could be achieved using mechanisms other than ABS. It is immoral to tie access to life-saving medicines to the provision of a country's sovereign samples, particularly when we have 30 years of experience with the CBD to show that ABS has

[9] To the best of our knowledge, and based on publicly available information on the WHO website, Pfizer still hasn't signed an SMTA2 under PIP Framework, and yet appears to remain very active in the influenza space. PIP biological materials were even provided to Theranos Inc., without an SMTA2 in place.

not worked to deliver fair and equitable outcomes in the environmental law space.[10] *Rather, it further entrenches the inequalities already experienced by LMICs.*

It is abundantly clear that in a health emergency, HICs will do whatever it takes to protect their own populations first. We know things will not be any different next time and the negotiations about the quantum of benefits that should be available under PABS are a distraction from the real, more consequential options available for ensuring genuine equity during an emergency. This would include enhancing primary healthcare in LMICs, building capacity and engaging in meaningful technology transfer to break the neo-colonial charity-based model that ensures the Global South remains dependent on the Global North for drug development and production. HICs should engage in the sharing of benefits of scientific progress without connecting it to access to the sovereign genetic resources of LMICs. Access to essential medicines is a human right; not something that should be bargained for with sovereign genetic resources.

3.4. What would be appropriate and sufficient triggers for such benefit sharing under a PABS system?

We discuss potential triggers below (see 3.8). However, no matter where the triggers fall, or how they are designed, in the absence of securing benefits upfront, the PABS System is unlikely to meet its intended goals. Tinkering with the technical elements of the system is a distraction from the fact that ABS is fundamentally flawed as a concept and was never designed to be the main mechanism for addressing global equity in scientific R&D. Negotiators should remember that the ABS mechanism was designed to address a very specific market failure in international environmental law - not to tackle resource allocation problems in global health. Furthermore, they should dedicate some time to a close study of the Plant Treaty's Multilateral System and whether participants in that scheme are satisfied with the quantity of benefits and their disbursement since the Plant Treaty's adoption in 2001.[11]

We are concerned that the vast majority of the benefit sharing under the PABS System is in the form of VTD products that are triggered by the declaration of a pandemic or PHEIC. As we outline below (in 3.10), there is no guarantee that VTD will be forthcoming or that it will reach populations with relevant public health risk and need,

[10] And noting that the PIP Framework has not been tested in an influenza pandemic, which is when its key benefit-sharing requirements are triggered and there are serious doubts as to whether it will be able to achieve its intended outcomes.

[11] We also wish to note that there was existing infrastructure to support the implementation of both the Plant Treaty's Multilateral System (CGIAR Centers) and the PIP Framework (GISN/GISRS), and that no such global infrastructure exists of the nature and scope required for implementation of the PABS System as it is currently written.

*with export restraints by states with manufacturing capacity a particular risk. We would prefer to see LMICs obtain **upfront benefits** over the sharing of benefits triggered by a particular public health event. Such upfront benefits include IP waivers, technology transfer and capacity building to ensure that manufacturers in the Global South can manufacture their own VTD and not be reliant on manufacturers in the Global North in their time of need, and at a time when such "benefits" are least likely to be delivered.*

3.5. Should benefit sharing of VTDs cover: a) PHEIC, b) pandemic emergency, c) pandemic? What would be the public health impact of each of these options?

*The present draft places a great deal of authority in the hands of the WHO Director-General, with certain aspects of the benefit-sharing arrangements potentially triggered by the declaration of a PHEIC/the declaration of a 'pandemic'/an assessment of an outbreak as being at risk of becoming a PHEIC. We have broader concerns that so much power is being placed in the hands of the DG: we already know that the declaration of a PHEIC is highly inconsistent, and heavily politicised, both by Member States, and by the DG and IHR Emergency Committee. Both groups often take into account how countries will respond to PHEICs, and there is a lack of transparency on how they do so. This leads to inconsistent outcomes, and PHEICs not being declared even when the criteria have very clearly been met. The current draft makes the PHEIC/Pandemic declaration even more contentious because it triggers all manner of benefit sharing proposals that have serious implications for the pharmaceutical industry, and HICs. As a result, there may be significant pressure on the EC/DG to **not** recommend a PHEIC/Pandemic in order to avoid triggering these clauses.*

3.6. How should the duration of the benefit sharing of VTDs be determined?

It is somewhat axiomatic that the duration of benefit-sharing of VTDs should be determined according to the same criterion on which benefit-sharing itself is likely to occur; that is, public health risk and need. We note, however, that the discussions seem to be going in the direction of requiring benefit sharing for the duration of the triggering event (i.e., PHEIC, pandemic or pandemic emergency). Negotiators must be clear on precisely what this means, for instance, whether benefit sharing obligations only apply to new products as they are being produced. Or whether, once a triggering event is declared, all relevant VTD products will be included in the benefit sharing requirements (e.g., pre-existing stockpiles of relevant vaccines in HICs). Furthermore, it is still not

*clear whether benefit sharing obligations only apply to products that specifically use PABS materials and/or DSI **and** are from manufacturers that have an active PABS Agreement (or SMTA) in place (remembering that the entity producing the VTD may not be the entity that originally accessed the PABS materials to conduct the R&D).*

3.7. Is it necessary to make a reference to the Biological and Toxin Weapons Convention and, if so, what would need to be considered for the development of a PABS system that is consistent with the objectives of this Convention, in particular its article 10?

The Pandemic Agreement (and any subsequent protocols) should be read in a mutually supportive way with other relevant international law commitments. The current text directs that, "Development and implementation in a manner that is consistent with and does not run counter to the objectives of Article X of the Biological Toxin Weapons Convention." We would suggest changing this to: "Development and implementation in a manner that is consistent with and does not run counter to the objectives of ~~Article X of~~ the Biological Toxin Weapons Convention." There is no reason that this provision should be specific to Article 10 as development and implementation should be with all the provisions of the BTWC in mind.

3.8. What are the differences, in terms of legal obligations of those participating in a PABS system, between two terms: a) "benefits arising from the sharing (of material and sequence information)"; and b) "benefits covered by the PABS system"?

Central to this is the 'trigger' for benefit-sharing. Option a) implies a direct linkage between the benefit in question (i.e., a specific VTD) and access to a specific genetic resource/sequence information. In essence, under option a) it must be proven that the VTD in question was generated using a specific sample/sequence received from the PABS System. This requires a highly sophisticated legal architecture to demonstrate access to, and utilization of, samples in the R&D process for a specific product. It raises questions as to who is responsible for establishing this, and the level of evidence required to "prove" utilization (and to whose satisfaction). It also implies that only products developed from samples accessed after the PABS System becomes operational have benefit-sharing obligations attached to them.

Option b) could potentially result in a broader scope, depending on how benefits are defined. It implies (given that a PHEIC/pandemic declaration could act as the triggering

event) the potential retroactive application of benefit-sharing obligations, by removing the direct link between samples from the system and products to be shared. If the VTD is a relevant product during a triggering event (and the manufacturer has signed a PABS agreement/SMTA) then the benefit-sharing obligation may exist.[12]

However, the benefit-sharing obligations appear to relate only to real-time production, i.e., new production ***from*** *the trigger point (i.e., PHEIC/pandemic). This makes sense for the development of a novel vaccine which is made once a novel pathogen is discovered (as for pandemic influenza, or SARS-CoV-2). But this does not cover products already developed and stored by manufacturers before the trigger point, or the vast stockpiles of VTD held by HIC.*

For example, unless specifically provided for in the PABS System, it presumably would not cover the millions of doses of Mpox vaccine currently stockpiled by HIC, despite the ongoing PHEIC, and extraordinary access inequity for impacted African nations. It would only apply to a set percentage of new vaccines made by the manufacturer, if said manufacturer had an active PABS agreement/SMTA under PABS at the time of the trigger.

3.9. Are the expressions "benefits arising from the sharing", used in the PIP Framework, and "benefits arising from the utilization", used in the Nagoya Protocol synonymous? If not, what are the consequences of each for the PABS system?

'Benefits arising from the sharing' is only used once in the PIP Framework and not in any operative provisions, appearing only in the principles. It is clear that this term is not synonymous with utilization; under the PIP Framework, benefits arising from the sharing are taken in the aggregate and are fundamentally different to the benefits arising from utilization.

The present text lacks any specificity in regard to the relationship with the PIP Framework, merely stating that, implementation (shall be) in a manner, complementary to, and not duplicative of, the PIP Framework and other relevant access and benefit

[12] This is assuming that the PABS agreements/SMTAs have been competently drafted by the WHO. We should remember that in a multilateral agreement mediated by SMTAs, the SMTA used by provider parties to contribute specimens to the multilateral system is the only one that is actually *standardised.* User parties, on the other hand, are allowed to negotiate the terms and conditions (and even the definitions of legal terminology). Their standardised MTA is not standardised at all. Furthermore, while the SMTAs may have the *appearance* of a private law contract, it is not necessarily valid, binding or enforceable.

sharing instruments where applicable.' This implies that the PIP Framework will remain a separate instrument to the PABS System which is inherently problematic.

If negotiators have confidence in the PABS System it should subsume the PIP Framework, or else a bizarre situation will arise whereby physical samples of influenza with human pandemic potential obtained from human specimens will be regulated by PIP, the DSI will come under PABS (and potentially the CBD's DSI multilateral mechanism) and any influenza viruses with human pandemic potential isolated from animal specimens will come under the CBD and Nagoya Protocol.

*Companies are potentially using **both** physical and digital resources in the development of their products. To give an illustrative example: if GSK developed an influenza vaccine using influenza samples with human pandemic potential and associated DSI, they would have a benefit-sharing obligation of 2.5% of production under PIP, and an obligation for up to 20% under PABS. If there were an influenza pandemic that was declared a pandemic under the IHR, it is not clear (under the current arrangements) which of these obligations would be enforced, and how? There are clearly overlapping obligations if the PIP Framework continues to apply in conjunction with the PABS System.*

*A further question here is the notion of what the trigger point for benefit-sharing actually is. If a user downloads PABS DSI as part of a large data package, is it necessary to demonstrate that they **used** this data in the development of a VTD relevant to a PHEIC/pandemic? Or, is the act of accessing the data sufficient to be liable for benefit-sharing obligations even if not used in the final product?*

3.10. What are the WTO rules that should be taken into consideration, if any, in the design of a PABS system? Can Member States limit the export of VTDs that are identified as benefits arising from the PABS system, in light not only of the obligations agreed upon by parties to this system, but also of the public health goals emanating from it?

In terms of applicable WTO law, a relevant provision is Article XI of the General Agreement on Tariffs and Trade (GATT) which contains a general prohibition on the imposition of quantitative restrictions and export bans. However, there are a number of built-in exceptions to this, including where; "Export prohibitions or restrictions (are) temporarily applied to prevent or relieve critical shortages of foodstuffs or other products essential to the exporting contracting party."[13] Export restrictions during times of critical

[13] As set out in GATT Article XX (2) (a).

shortages of pandemic VTD would very much be covered by this provision, regardless of the wider public health concerns attached to their imposition. Similarly, assuming that particular public health events may be conceptualized as a security threat, GATT Article XXI allows WTO Members to take measures that would otherwise breach the GATT, though it is difficult to see how an export restriction taken in times of scarcity of the availability of medical countermeasures would be a breach, as noted above. To the extent that GATT Article XXI is relied upon by a WTO member to impose such export restrictions, it provides legal cover if the Member 'considers (such measures) necessary for the protection of its essential security interests.' There is also a public health exception set out in the general exceptions clause of the GATT (Article XX (b)). All of this points in the direction of WTO Members having the competence to impose export restrictions on VTD in a WTO compliant way. While, of course, WTO Members could voluntarily agree not to impose such restrictions and could implement domestic legislation to remove their power to introduce restrictions on PABS VTD, we find it difficult to imagine that any country would bind themselves in this way, particularly given the rampant vaccine nationalism apparent during COVID-19, and indeed, in the current Mpox PHEIC.

4. Legal issues related to the adoption of PABS system

4.1. What are the implications of adopting a PABS system under articles 19 (e.g. as a Protocol), 21 or 23 of the WHO Constitution?

As argued elsewhere, changing the form of PABS from Article 19 to Article 21 will not alter the significant differences states have regarding its purpose, content and functioning. The legal form of Article 21 ***cannot*** *ensure universal adoption of PABS. This is important for two reasons;*

1. *Fragmentation of the international system during the next pandemic will cause uncertainty regarding legal obligations. During the next health emergency any one of (or a combination of) the Pandemic Agreement, IHR, PIP Framework, PABS System or CBD/Nagoya Protocol (plus the CBD's DSI multilateral mechanism) could apply with respect to sharing information, data, and physical samples.*
2. *Carving PABS out of the Pandemic Agreement could further weaken any notion that the Pandemic Agreement is concerned with "equity".*

A solution may be to have clear language in both instruments (the Pandemic Agreement and any potential PABS Protocol) that Member States can only be a party to the Pandemic Agreement if they are also a party to PABS. However, crafting such language

would be challenging, and it seems politically impossible to guarantee such linkage between instruments. It is unrealistic for these two instruments to be linked in such a way that Article 21 PABS serves as a Protocol to the main Agreement. This would lead to bizarre situations whereby some countries are only party to an Article 21 PABS and not to the main Agreement, and others who are party to the Agreement and not the Article 21 PABS System.

There is no legal mechanism to force countries to become party to PABS, and it is clear that there are widely different expectations about PABS from HICs and LMICs, and very little hope for compromise on the substantive content. Either HICs or LMICs (or maybe both)[14] will be unhappy with the substantive content of the Article 21 PABS and will send reservations or opt-out of the instrument entirely. Universal application is a fallacy.

[14] We note that any stalemate on PABS is unlikely due to irreconcilable positions about how the system should operate, rather it is owing to the fact that access and benefit-sharing is ill-suited to the task at hand and is simply incapable of delivering the desired outcomes.