INB related interactive dialogues
Topic 1. Article 12 (Pathogen Access and Benefit-Sharing System)

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Discussion questions proposed by the Bureau for Resource Persons

1. **PABS and Nagoya Protocol related matters**

If Member States reach a 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?

An SII is essentially an option under Nagoya 4(4) so that Parties can agree that the Nagoya Protocol will not apply to a specific genetic resource (a pathogen, here) and instead the SII will be agreed by countries. There would be no limitation to its application to non-Parties to the Nagoya Protocol, assuming they are willing to accept this arrangement. As a result, yes, it could be universally applied.

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?

The PABS system will, of course, be developed with the intent of qualifying as an SII, but require a determination of the CBD COP, serving as meeting of the Parties to the Nagoya Protocol. As stated in a recommendation adopted by the Subsidiary Body on Implimentation: "Decides that the meeting of the Parties to the Nagoya Protocol shall act as the authority to assess, determine, review or terminate the status of instruments as specialized international access and benefit-sharing instruments in the context of Article 4, paragraph 4, of the Nagoya Protocol based on the criteria provided in the annex to the present draft decision and that the Parties to Nagoya Protocol can approach the meeting of the Parties for determination or termination of the status of instruments".[1] This recommendation will likely be discussed further in 2024. If it is indeed determined by the appropriate CBD process to be an SII, there is no reason it cannot be applied to all parties to the Pandemic Agreement.

[1] https://www.cbd.int/doc/recommendations/sbi-03/sbi-03-rec-16-en.pdf

It would be important to state the intent to have the PABS system qualify as an SII clearly in the Pandemic Agreement and any subsequent agreement outlining the PABS system and create a direct line of contact to the CBD COP, serving as meeting of the Parties to the Nagoya Protocol.

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

See 1.1.

• 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 ?

This will depend on the specific domestic legal circumstances and whether and how, for instance, infectious pathogens are specifically identified and treated. It would be important to include a provision in the Agreement that requires State Parties to review and amend domestic legislation, as appropriate.

1.2. 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?

The Subsidiary Body on Implementation has agreed on recommended text,[2] some still bracketed, which can guide negotiators. The criteria that can be considered mutually supportive under the "indicative criteria" are: consistency with biodiversity conservation and sustainable use objectives; fairness and equity in benefits sharing; legal certainty for access, including PIC and fair and equitable sharing; full and effective participation of communities concerned; contribution to sustainable development; and other general principles of law including good faith, effectiveness, and legitimate expectations. Key amongst these issues include "Fairness and equity in the sharing of benefits" and "Contribution to sustainable development…", both key areas of contention in the negotiations over the scope of benefits. Unresolved in the text is whether the SII can be non-binding as the text in the Subsidiary Body on Implementation recommendation remains bracketed.

1.3. 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?

[2] https://www.cbd.int/doc/recommendations/sbi-03/sbi-03-rec-16-en.pdf

The Kunming-Montreal Global Biodiversity Framework includes as Goal C and target 13 the introduction of a new 'multilateral system for benefits sharing form the use of digital sequencing information" (https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-04-en.pdf). Care should be taken to coordinate with the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources.

1.4. 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?

No, they are not a contracting party under the terms of Article 27.

1.5. 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?

Making manufacturers' participation in the PABS system voluntary or very weak benefit-sharing requirements could run counter to the Nagoya Protocol.

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?

To our knowledge, the negotiations and related terms continue to be complex and evolving. It will be important clarify whether "sequence information" is intended to cover the same scope as DSI or if it represents a narrower or different concept.

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?

While a tracking system of all contracts should be established with an associated database, focusing too much on very specific traceability should not be the focus. The main point is the benefits available through mechanisms that are broadly open-sourced such that, particularly in a pandemic/PHEIC, the benefits in terms of access to technology stemming from the sharing of PABS materials should be available to all comers.

If there is a tracking system, there will need to be dedicated staff that tracks the agreed benefits on a regular basis (e.g. monetary benefits) and in the case of a PHEIC or pandemic emergency. This task could be assigned to an organization such as the Medicines Patent Pool or potentially the GSCL established under Article 13.

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

This will depend on whether the Member States agree to traceability. If there is traceability, an organization such as the ones noted in 2.2 could be tasked with managing the tracing activities. Otherwise, there should be regular reporting and communications requirements in the contracts signed with manufacturers (and others as appropriate) that require reporting to ensure benefits-sharing obligations are met. Provisions should also include audit functions in case there are bad-faith actors. The work of the GSCL and other major purchasers can also be leveraged to understand the global distribution of VTD sales and double-check that obligations under the PABS system are being met.

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?

There is strong evidence from a range of diseases (e.g., HIV/AIDs, TB, COVID-19, and mPX) that donations and not-for-profit prices are ineffective in a pandemic due to the market dynamics + likelihood of competition and scarcity. Instead of not-for-profit prices, there should be technology licensing.

In COVID-19, for example, it was not the price that was the problem but the lack of production of vaccines in LMICs to serve LMIC markets. In another example from HIV, when tech has been shared the "not-for-profit" price has turned out to be 10-100 times higher than the price charged by licensed manufacturers in LMICs to make generic/biosimilar versions. Instead of lower prices from HIC-based producers, tech transfer is needed.

Also, while manufacturers are a key part of the ecosystem in developing and distributing VTDs during PHEICs and pandemic emergencies, tremendous amounts of public funding and research support goes into these same products, which often amounts to a significant proportion of the total financing for these products. In some cases, public sector financing almost fully covers the R&D costs for pandemic-related medical countermeasures (not including also other public contributions in the form of support from of public researchers, advance market commitments and privileged tax status)

The pharmaceutical sector is consistently one of the most profitable of all economic sectors; A 2020 analysis by the West Health Policy Center and Johns Hopkins Bloomberg School of Public Health found that even if the pharmaceutical industry were to lose $1 trillion in revenues, it would still be the most profitable industry.[3] The pricing model for these global public goods needs a radical shift (e.g., akin to the way that public utilities and other sectors are regulated with regard to pricing and other matters to support the public good).

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 final provisions of the Pandemic Agreement and the PABS system would determine from a legal perspective whether participation is voluntary. It should not be.

If it is voluntary and commercial users opt not to participate fully, there could be limitations on where they can legally source materials and sequence information from it.

As profit-maximizing entities, one can imagine they could consider ways to avoid participation, which is why it would be incumbent on member states to encourage and incentivize their participation while emphasizing the tremendous financial benefits the manufacturers receive from their development of pandemic-related VTDs.

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?

The system for financing VTDs for pandemic- and epidemic-prone diseases is effectively publicly funded at present. If this system were to be standardized and legally require the equitable sharing of products developed by this system in the early stages, followed by systematic and supportive transfer of technology and hands-on know-how, and fairly designed sharing of intellectual property, to enable rapid scale-up globally, the need for a stringent PABS system would be reduced. It would likely be preferable to a system based on an explicit quid pro quo. However, given the outcomes to-date in the text in Articles 9, 10, and 11, this is not the system in place and therefore a quid pro quo is necessary to leverage benefit sharing.

[3] https://westhealth.org/news/new-analysis-finds-large-drug-makers-could-lose-1-trillion-in-sales-and-still-be-the-most-profitable-industry/#:~:text=Adjusting%20the%20analysis%20to%20apply,profitable%20than%20any%20other%20industry.

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

The triggers will need to be appropriately suited to the type of benefit. Some formulations would see annual monetary benefits, which should be paid at regular intervals once the system comes online, even in the absence of a PHEIC or pandemic emergency. For other benefits, they should be shared coincident with the declaration of a PHEIC or pandemic emergency, as further discussed in 3.5 and 3.6.

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?

Benefit sharing for VTDs (and other benefits that may be agreed upon by Member States) should apply to both PHEICs and pandemic emergencies. Consideration should also be given to regional emergency declarations to prevent outbreaks from becoming PHEICs. The greened text in Article 2 of the draft Pandemic Agreement notes the objective of preventing pandemics.

Early sharing of VTDs (and other benefits that may be agreed upon by Member States) is key to this goal, as it prevents health emergencies from developing into pandemic emergencies. As an illustration, and while the reasons for lack of vaccine access in the case of Mpox are multifaceted, lack of access to vaccine has resulted in not only a great deal of human suffering where the virus is endemic but also has led to the unchecked spread of the virus to many Member States around the world, resulting in the declaration of a regional emergency and a PHEIC. Rapid access can now prevent further escalation of health emergencies and should be a clear example of why benefit sharing should cover PHEICs.

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

Benefit sharing related to VTDs should be linked to the declaration of a Pandemic Emergency under IHR and be continual throughout. This linkage provides clear markers for the beginning and ending of benefit sharing under the PABS system. Similarly, should Member States agree to benefit sharing during PHEICs, this should similarly be linked to the declaration of a PHEIC, which can then be linked to the declaration of a Pandemic Emergency should the situation escalate.

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?

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"?

For the reasons noted in answer to 3.9, Member States may wish to use “benefits arising from the utilization [of material and sequence information]”.

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?

One can understand “benefits arising from the sharing” and “benefits arising from the utilization” to have distinct, though complementary meanings. The use of “sharing” could be seen as a way to avoid the need to track specimens and GSD, and relatedly, that actual use of materials does not need to be demonstrated to receive benefits. This could be seen as a way to simplify the PABS system.

On the other hand, the use of the term could be seen as a step away from the stringency of the Nagoya Protocol, as the use of “sharing” as opposed to “utilization” has generally been paired with proposals that arguably do not meet the high standard set by Nagoya for access and benefit sharing. Consequently, “sharing” can be seen as part of a larger movement that would effectively weaken Nagoya standards.

“Utilization” could be used as the chosen term with or without tracking. As it is Member States who decide on the meaning of terms, they could decide that there is implied utilization when materials are shared, even if every specimen is not specifically tracked.

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?

While adoption under Articles 19 and 21 both imply firm, binding legal standing, adoption under 19 is the preferred option. As explained in the Lancet, there is evidence that even non-ratifiers tend to follow the rules of multilateral treaties. Article 19 also gives a strong basis for using compliance efforts under a COP with the potential for external reporting. While there is no bar to create a soft compliance mechanism under 21, for PABS, compliance is particularly important as it will require enforcement by national governments of their respective pharma companies.

Under Article 21, as a regulation, there is the benefit of potential greater universality (recognizing that countries the opt-out provision). However, in this case, the PABS must remain integrally linked to the governance of the Pandemic Agreement vs. falling solely within the remit of the WHA, which has been ineffective for IHR compliance.

Adoption under Article 23 as a recommendation would only serve to give an illusion of progress. The world has shown that when push comes to shove, vaccine nationalism can and likely will reign supreme, and barriers will be erected in the midst of a crisis, which will impact timely sharing and have long-lasting public health consequences.