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

Discussion questions proposed by the Bureau for resource persons

Response from Cédric Mahé. President, Foundation for Influenza Epidemiology

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?

Non applicable

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

Non applicable

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?

Non applicable

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?

Non applicable

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-Partiy to PABS that is affected by the conclusion of a SII entitled to dispute settlement under Article 27 of the CBD?

Non applicable

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?

Non applicable

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?

Non applicable

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?

This will be very challenging for DSI (see below)

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

Traceability will be very difficult in particular for DSI. DSI can be altered easily. Attribution to a single primary source may be challenging and it remains to be defined how close enough should it be from the origin sequence to trigger benefit sharing.

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?

Such PABS mechanism will probably affect negatively potential investments in pandemic solution. Indeed, investment are usually huge (100s of millions of USD) with a low chance of success (<5% for vaccines). During the COVID pandemic more than 200 vaccine candidates have been documented. How many reached the finish line?
History has shown that past epidemics had very different patterns, magnitude, duration and expected revenue generation (Ebola, Zika, H1N1p, MERS), making the investment case already difficult compared to other "less volatile" infectious disease target. Investment in pandemic vaccine is often incentivized by risk sharing (R&D investment) and/or advanced market commitment from public sector.
A negative side effect of a PABS would be a lower competition in this high-risk pandemic area affecting negatively affordability and access.
Annual monetary contributions could be associated with facilitation of access to relevant pathogens but experience shows that money alone is not enough to strengthen surveillance. A

combination of expertise and in-kind contributions will also be most helpful (see response to 3.3).

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

Most probably. Speed and access are two critical success factors for countermeasure development. Because of the related administrative burden, non-Nagoya protocol signatory countries are often the preferred providers of virus strains at the risk of not choosing the best strain in favor of timely access to the strain.

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?

Pathogen access and benefit sharing need to be decoupled. For example, in vaccines, only a very small fraction of pathogens used to formulate candidate vaccines will lead to successful product registration despite a large upfront investment.

On the pathogens access side, manufacturers participation can be incentivized by the setup of public private partnership mechanisms to strengthen surveillance. Infectious disease surveillance is probably the area where public and private sector have the most shared interest. Besides pandemic preparedness, expanded surveillance data is critical to improving key elements of strengthening routine immunization including burden of disease, strain selection and formulation and timing of vaccination. The Pandemic Accord offers a window of opportunity to set up a catalytic private funding instrument under a true public-private partnerships governance (vs. a purely transactional system like PIP) allowing private organizations to contribute to surveillance system strengthening and access relevant data for their portfolio.

The Global Influenza Hospital Surveillance network (GIHSN – see www.gihsn.org) which is now covering all respiratory viruses is an excellent example of such a platform and it can be easily scaled up and expanded. It is coordinated by the Foundation for Influenza Epidemiology (FIE) and is already supported by several companies (currently Sanofi, Seqirus, Pfizer and Abbott diagnostic). A Memorandum of Understanding has been signed between FIE and WHO in 2023, allowing to develop a joint roadmap. It shows that, such an instrument can demonstrate strong governance, transparency, and audit processes together with measurable and impactful public health value. These elements are strong incentives for industry contribution.

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

Benefit sharing part should be triggered by a successful regulatory approval. The benefit sharing system should ensure it does not discourage manufacturers to invest in pandemic countermeasures for example by linking it to advanced market commitment levels.

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?

Non applicable

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

Non applicable

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?

Non applicable

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"?

Non applicable

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?

Non applicable

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?

Non applicable

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?

Non applicable