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

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 ?

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?

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?

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?

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?

## 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?

In decision 15/9, the Conference of the Parties to the Convention on Biological Diversity recognized the different understandings of the concept and scope of digital sequence information on genetic resources, and the range of views regarding the need to define such concept and scope (preambular para. 18) and agreed on the continuing use of the term "digital sequence information" for further discussions (para. 1).

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?

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

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization establishes a system for monitoring the utilization of genetic resources (see, in particular, Art. 17 of the Protocol.) The system includes obligations on Parties to designate checkpoints who collect or receive information related to prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of genetic resources. A permit for access to genetic resources that is published online in the Access and Benefit-Sharing Clearing-House constitutes an internationally recognized certificate of compliance (IRCC). An IRCC can be provided to checkpoints as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established as required by the domestic measures of the Party providing prior informed consent.

Information collected or received by checkpoints is to be provided to relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-Sharing Clearing-House. Information from checkpoints published on the Access and Benefit-Sharing Clearing-House is shared with the country that provided access to the genetic resources in the form of a checkpoint communiqué.

In decision 15/9, the Conference of the Parties to the Convention on Biological Diversity recognized that tracking and tracing of all digital sequence information on genetic resources is not practical (para. 5).

## 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?

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

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?

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

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?

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

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"?

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?

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?

## 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?