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

Discussion questions proposed by the Bureau for resource persons

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*Due to the limited timeframe to answer the questions, the responses below are my tentative view.

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 instrument. 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 Convention on Biological Diversity and the Nagoya Protocol, and the INB decides that PABS can be recognized as a specialized PABS instrument during 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): see

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?

If PABS is recognized as a Specialized International Instrument (SII) under the Nagoya Protocol (NP) in the WHO Pandemic Agreement (PA), PABS would be exempted from application of NP ABS for Parties to NP and PA (All NP provisions, including its ABS system, do not apply to non-NP Parties.).

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

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

The issue of recommending SII criteria[5] for NP was discussed in 2022[6], but Parties could not reach an agreement due to difference in their opinions. The same issue will be discussed at the next MOP5[7]. In order to avoid any contradiction and inconsistencies with the discussion in CBD, the parties to CBD and MS of INB should be mutually aware of the general direction of the discussions in each other's meeting.

For this purpose, efforts should be made to promote coordination and collaboration between the CBD Secretariat and the WHO Secretariat (e.g., mutual participation as observers in meetings, consultations, etc.). In fact, there have been efforts for such collaboration in the past, for example, in 2017 a delegation from the WHO Secretariat

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[5] CBD/SBI/REC/3/16
https://www.cbd.int/doc/recommendations/sbi-03/sbi-03-rec-16-en.pdf

[6] CBD/NP/MOP/DEC/4/11https://www.cbd.int/doc/decisions/np-mop-04/np-mop-04-dec-11-en.pdf

[7] CBD/NP/MOP/5/1
https://www.cbd.int/doc/c/b501/9eb3/d1c92fedc35b4f519692cbd7/np-mop-05-01-en.pdf

visited the Secretariat of the CBD. Two sides agreed upon future collaboration and identified the key linkages between the Nagoya Protocol and pathogen sharing ABS at WHO. In 2018 a workshops to facilitate on ABS of pathogens for public health was held.[8]

- For non-Parties to the 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 ? additional or different PIC and MAT ?

Adoption of “the principle of avoidance of duplicative ABS rights and obligations”: It is necessary to ensure that there are no duplication of ABS rights and obligations in the domestic implementation of ABS under the CBD (and other related ABS agreements). To this end, it is essential for all Parties to the Pandemic Agreement (PA) to have materials and GSDs subject to PABS exempted from national ABS rules in each country, taking into account the need to ensure the effectiveness of SII within NP countries and the possibilities that even non-NP parties may have national laws, etc. with their own ABS functions. (However, it is desirable to leave the details of the operation to the discretion of each state). Japan, for instance, exempts both seasonal influenza and PIPF from the ABS guidelines, and similar measures should be taken for PABS.

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? 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 ? 1.4.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

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[8] EXECUTIVE BOARD EB146/19 146th session 16 December 2019 Provisional agenda item 15.4 The public health implications of implementation of the Nagoya Protocol Interim report by the Director-General. https://apps.who.int/gb/ebwha/pdf_files/EB146/B146_19-en.pdf

A delegation from the WHO Secretariat visited the Secretariat of the Convention on Biological Diversity in March 2017 and exchanged information and discussed coordination of activities. The two sides agreed on mutual areas of work and future collaboration and identified key linkages between the The two sides agreed on mutual areas of work and future collaboration and identified key linkages between the Nagoya Protocol and WHO's work on access and benefit-sharing for human pathogens, including (a) implementation of the Nagoya Protocol in the context of health emergencies, not (a) implementation of the Nagoya Protocol in the context of health emergencies, notably under Article 8(b) of the Nagoya Protocol; (b) reference to specialized international access and benefit- (b) reference to specialized international access and benefit-sharing instruments under Article 4(4) of the Nagoya Protocol; (c) digital sequence information and access and benefit-sharing under the Convention on Biological Diversity/Nagoya Protocol and the Pandemic Influenza Preparedness Framework; and (d) linkages with other provisions of the Nagoya Protocol, such as Articles 19 and 20. Protocol, such as Articles 19 and 20, especially as they may apply to the sharing of pathogens.

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 the NP is not 'consistent with and not run counter to 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?

1.6. What are the 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 the definition and scope of digital sequence data (DSI)? Will the current negotiated text using "sequence information" contradict/hamper the ongoing negotiation of the CBD?

With regard to the CBD, divergent views exist on DSI and definitions have not yet been agreed upon (CBD COP15 Decision 15/9 Preamble para 9). Efforts should be made to ensure consistencies on the use of terms between the CBD and the WHO to avoid any contradictions. Having said this, it should be respected that each forum has their own mandates and the history of the use of terminology.
The WHO documents have long used "Genetic Sequence Data (GSD)" (even before the Pandemic Agreement negotiations were initiated), and the past draft proposals of the Pandemic Agreement initially did use GSD. However, the latest draft uses the term "genetic information". In this regard, “data” (sequence data: the order of nucleotides) is preferable than “information” as the latter is generally broader in scope with the possibility to include various factors.

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

A mechanism to ensure traceability from the use of materials and GSD to the generation of benefits is important.

As for the ABS mechanism for materials, it may be useful to study the ITPGRFA’s “Multilateral System of Access and Benefit-sharing (MLS)”, which ensures access to a common pool and provision of benefits by setting standardized SMTAs in advance for each registered crop (unlike PIPF, it does not require individual SMTA contracts for each participating company) and by ensuring traceability through a method whereby the user provides the SMTAs to secondary and tertiary users (approximately 0.7% of those sales are returned to the Fund when the product is commercialized). It may be worthwhile to consider whether similar measures are possible in the operation of PABS.

As for data sequencing, in the case of the BBNJ, it is said that data is traced by batch identifiers. This may work in a forum like the BBNJ where the number of target genetic data is relatively limited, however, in the case of PABS, the number of target GSDs is huge and there are many databases other than GISAID and INSDC, so it is difficult to ensure that all databases are traced by putting batches. Therefore, it may be

practical and feasible for users to report the use of GSDs when profits are generated (manufacturers who use them are required to keep such records).

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

Same as above for materials

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 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 a 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? prices, as well as annual monetary contribution?

There is a view that PABS can have a positive consequence if the ABS can be properly accommodated within the legal framework. This requires the consistency with the CBD and more importantly, avoidance of duplicative rights and obligations under ABS, as discussed in section 1.2. Once those are secured, establishment of a system to issue certificates of compliance with ABS that serves as evidence of avoidance of additional benefit sharing obligations may increase the incentives for companies to participate (such a mechanism is currently being proposed and discussed in the DSI's ABS Multilateral Mechanism in the CBD[11]).

In order for PABS to have positive consequences, a wide range of actors, from start-ups to large companies, must be involved, and it is important that the obligation burden be agile and flexible, proportionate to their capabilities and the size of their operations, rather than applying a uniform approach. It is essential that not only Member States and IOs but also a broad range of stakeholders with relevant expertise in PABS (industry, CSOs, etc.) be involved in negotiating its design. The success of the PIPF, a precedent for ABS mechanisms at WHO, is attributed to the WHO's effort to involve various stakeholders. The same approach should be attempted for PABS.

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

It is difficult to answer whether commercial users use the PABS without clarifying what the required contribution means, however, it is important to design a PABS system in which the size of obligation is imposed with flexibility according to the capability of manufacturer (knowledge of viruses/pathogens, (emerging/conventional) technological capabilities, manufacturing experience, etc.) and the scale of its business.
It is also important to consider some kind of reward/acknowledgement/incentive for contribution (since the contribution appears to be obliged at a stage where it is not clear if the company will be able to produce a pandemic product).

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[11] Para 15 of CBD/WGDSI/2/L.2

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 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 Would any of these options be preferable to a PABS system?

It is hard to imagine any entity other than WHO being able to do this.

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

Since the spirit of ABS is to share the benefits arising from the use of access, the trigger is considered to be at the stage when the product benefits are generated. However, during a pandemic, as the urgent provision of VTDs is required, the trigger should be ideally at the stage when the product is on the verge of commercialization or has been commercialized.

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?

A mechanism is needed to consider how to allocate benefits to which targets, at what level of health impact, and at what level of benefit (decision-making procedures, and if an advisory board or subsidiary body is to be established, the composition and selection of its members should also be considered). This mechanism requires the involvement of all stakeholders, including representatives of industry and CSOs etc, in order to create a mechanism that can actually function.

In past drafts, Bureau's Text (INB 5/6) proposed the establishment of a Benefit-Sharing Expert Committee (Article 25), and Negotiating Text (INB 7) proposed the WHO PABS System Expert Advisory Group (Article 21), etc. Since the PIPF has a PIP Advisory board, it is recommended to consider this issue based on past experiences and lessons learned.

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 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?

What are the differences, in terms of legal obligations of those participating in a PABS system, between two terms: a) "benefits arising from the 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"?

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

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? 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?