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

Responses by Sangeeta Shashikant to 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):

Response: Article 12 draft text as presented in A77/10 merely contains an outline of a PABS system that will be developed. Hence it would be premature to consider such text as a SII. However if agreement is reached on a detailed complete PABS instrument including all its parts, such an instrument may be considered as a SII by the COP/MOP of the Nagoya Protocol. Articles 4(2) and 4(4) of the Nagoya Protocol are clear that Parties can develop a specialized access and benefit-sharing agreement for specific genetic resource covered by and for the purpose of the specialized instrument provided that the agreement is consistent with and does not run counter to the objectives of the Convention and this Protocol. Whether or not the PABS instrument meets the objectives of the Convention and the Protocol, can only be decided by Parties to the Protocol. Accordingly, Parties to the Protocol are presently considering the criteria and the process for determining an instrument to be a 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?

Response: A PABS system adopted in the WHO can be applicable to Parties and non-Parties to the Nagoya Protocol, irrespective whether it is formally considered as SII. For example the PIP Framework adopted in WHO is applicable to all WHO Members including 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?

Response: See response to paragraph 1 and 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?

Response: Arrangements to be put in place at the national level depends on the content of the PABS instrument. To avoid additional or different PIC and MAT at the national level, it is important to ensure that WHO Members agree to Standard Material Transfer Agreement (SMTA) for the sharing of materials as well as Standard Data Access Agreement (SDAA) for the sharing of sequence information as part of the PABS system. These tools are commonly used when transferring material and sequence information. They set out standard legally binding terms and conditions, which serves as PIC and MAT for accessing the biological material and sequences.

For e.g. Section 5.1.2 of the PIP Framework states that "By providing PIP biological materials from National Influenza Centres and Other authorized laboratories to WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories as set out in section 5.1.1 above, Member States provide their consent for the onward transfer and use of PIP biological materials to institutions, organizations and entities, subject to provisions in the Standard Material Transfer Agreements.

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?

Response: The considerations that should guide the INB include:

-consistency with and not run counter to the objectives of the CBD and the Nagoya Protocol i.e. "the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies".

-Addressing PIC and MAT are central to operationalizing the objectives of the CBD and the Nagoya Protocol. Thus Members need to develop legally binding standard terms and conditions that a recipient agrees to, prior to accessing the material and sequence information. The terms and conditions will set out the rights and obligations of the provider and/or WHO and the recipient including the terms and scope of use as well as fair and equitable benefit sharing required of the recipient.

-Ensuring legal certainty with respect to fair and equitable benefit-sharing by the recipients accessing materials and sequence information.

-Use outside the scope of the PABS system should be governed by CBD and the Nagoya Protocol as implemented by national ABS laws. The PABS system should take reasonable measures to ensure that resources shared through the PABS system are not used for purposes other than those permitted under the PABS system.

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?

Response: Article 4(2) of the Nagoya Protocol is clear that the Protocol does not prevent development and implementation of specialized access and benefit sharing agreements, with the proviso that such agreements "are supportive of and do not run counter to the objectives of the Convention and the Protocol".

COP Decision, CBD/COP/DEC/15/9, which sets out the current process in CBD that handles DSI, is also clear that other fora may develop specialised approaches for the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources. Hence addressing the handling of sequence information in the ongoing INB negotiations does not prejudge discussions in the CBD and 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-Party to PABS that is affected by the conclusion of a SII entitled to dispute settlement under Article 27 of the CBD?

Response: Determination of whether an instrument is a SII will depend on the COP/MOP of the Nagoya Protocol (NP) based on the criteria and process set out by the COP/MOP of NP. Decisions in COP/MOP of NP are taken by consensus. Once an instrument has been determined to be a SII by COP/MOP of NP, it is unlikely to be contested by a Nagoya Party that has adopted such a decision.

Further if a WHO Member is not a Party to PABS, it need not comply with the requirements of the PABS system, even if the PABS instrument is considered to be a SII. Hence, why would a non-Party to PABS initiate 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?

Response:

-delinking of access from benefit sharing and/or treating access and benefit sharing unequally (e.g. making provision of materials and sequences obligatory while benefit sharing is considered voluntary)

-lack of clarity on scope and terms of use;

-vague, unspecific benefit sharing as well as legal uncertainty with respect to compliance by recipients of materials and sequences with benefit-sharing obligations;

-absence of mechanisms that address PIC and MAT i.e. absence of legally binding terms and conditions setting out the terms of use including fair and equitable benefit-sharing

obligations with respect to shared PABS materials and sequence information, that specify the rights and obligations of the provider/WHO and the recipients;

-unknown recipients of PABS materials or sequence information or allowing anonymous access to materials or sequence information;

-absence of measures and mechanism that ensure transparency and accountability and avoids free-riders and conflicts of interests;

-failing to put in place effective measures to avoid/reduce/address leakage of resources outside of PABS system;

-allowing databases to host PABS sequence information when such databases have not legally committed to implement measures that require recipients of sequence information to comply with the PABS system;

-recognizing as SII, an outline or a framework of a PABS system that is not fully developed and functional and that does not legally guarantee fair and equitable benefit-sharing;

-failing to put in place effective measures to ensure that all recipients of PABS materials and sequence information agree to legally binding terms and conditions including fair and equitable obligations with respect to use of the materials and sequence information.

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?

CBD Decision 15/9 - does not provide definition and scope of DSI. Any further decision in COP is also unlikely to provide definition and scope, as a tacit convergence has emerged that CBD can live without a definition and scope, since there can be no general obligation on Parties to share DSI with others.

Having said that, an Ad-hoc Technical Expert Group (AHTEG) in 2020 has attempted to provide guidance on defining the concept and scope of the term DSI. The Group provided four different ways of scoping the terminology, from narrow most to broadest possible scope. The narrowest definition and scope is limited to nucleotide sequence data associated with transcription of DNA and RNA. The broadest possible scope includes behavioral data, information on ecological relationships and traditional knowledge relating to genetic material, thus comprising information associated with transcription, translation and biosynthesis as well as subsidiary information such as relevant metadata. However, there is no consensus among Parties as to the definition and scope, when they considered the conclusions of the AHTEG .

Using "sequence information", or for that matter using "DSI" or "GSD" will not hamper any ongoing negotiations in the context of CBD, provided that there is an operational definition for the term which is finally decided as part of the PABS text.

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?

Response to questions 2.2 and 2.3:

1. It is crucial to have legally binding standard terms and conditions that a recipient agrees to prior to or on accessing the materials and sequence information. While this is important to operationalize benefit sharing, it is equally important for setting out the scope and terms of use of the materials and sequence information (e.g. with respect to transfer of materials and information, biosafety considerations etc.) and ensuring transparency and accountability of the PABS system from a public health and biosecurity perspective.
2. The name, contact details of the recipient should be known and verified. Anonymous access or download of sequence information should not be allowed.
3. A recipient should not transfer any material or sequence information to a third party unless the third party has also agreed to be bound by the same terms and conditions.
4. Databases wishing to host sequence information coming through the PABS system should formally agree with WHO to comply with the requirements of the PABS system. The terms of this agreement should also be standardised.

Following from the above, in my view effective "traceability" measures, as a matter of governance/ accountability principle, must be accepted in the PABS text and should in addition to the above include:

(a) for Materials

Transfer of any materials under the PABS system should be recorded and such records made publicly available. Recipients of materials will be known as these recipients would have agreed to legally binding terms and conditions prior to receiving materials that include benefit sharing and biosafety considerations. There is a precedent for such recording in the context of the PIP Framework for the sharing of influenza virus of pandemic potential, whereby a influenza virus tracking mechanism (IVTM) has been set up. (section 5.3 of the PIP Framework)

(b) for Sequence Information

-Data access agreements - i.e. anyone wishing to access sequence information can obtain access provided its credentials has been verified by WHO and the recipient has virtually signed a data access agreement, the terms of which are standardised. Through this way the details of the recipient are known and the recipient commits to comply with the terms of use of the sequence information received and to share fair and equitable benefit sharing.

- Unique Identifiers/ labelling of Sequence Information - databases should attach unique identifiers or labels on the sequence information units making it explicitly known the source/provider of information as well as country of origin of the material from which sequence information was extracted. This will also improve traceability.

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?

Response to questions 3.1 and 3.2:

Development of an effective, transparent, accountable PABS system that is consistent with the CBD and the Nagoya Protocol with legally binding terms and conditions including on benefit sharing requirements is positive for manufacturers. Requiring benefit-sharing of manufacturers i.e. allocating a certain percentage of VTD to be provided to WHO as well as making annual monetary contributions has been done in the context of the PIP Framework. A robust PABS system offers manufacturers several advantages, such as access to materials and sequences, which facilitates development of VTDs. Additionally, it provides legal certainty regarding compliance with ABS obligations. Without such a system, manufacturers would face the cumbersome task of negotiating access to biological materials and sequences on a country-by-country basis, with the added complexity of adhering to varying ABS requirements in each jurisdiction.

The PIP Framework underscores the value of a PABS system for manufacturers. Adopted in May 2011, the PIP Framework governs the sharing of influenza viruses with pandemic potential. Over its first decade, celebrated by the WHO in May 2021, the framework has facilitated the sharing of more than 1,200 biomedical samples and the identification of numerous virus sub-types, which have been instrumental in advancing VTD development for influenza. Notably, manufacturers have entered into 16 Standard Material Transfer Agreements (SMTAs), legally committing to provide VTDs to the WHO during an influenza pandemic. Moreover, they have contributed approximately US$309 million in monetary benefit-sharing which in turn has been used for capacity building including surveillance and laboratory capacity. Notably, the benefit-sharing provisions of the PIP Framework have not deterred its use, demonstrating the feasibility and effectiveness of such requirements.

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?

Response: A PABS system consistent with the principles and elements of the CBD and the Nagoya Protocol is the best option for facilitating timely sharing of materials and sequence information and on an equal footing, fair and equitable benefit-sharing. A transparent, accountable, PABS system that sets out clearly and with legal certainty the scope and terms of use including provision of fair and equitable benefit sharing will definitely motivate sharing of materials and sequence information. This sharing will in turn

offer manufacturers access to diverse pathogens including the variants, supporting their R&D efforts (which are usually heavily subsidised by public funding) while providing legal certainty in terms of compliance with ABS requirements. A transparent, accountable PABS system also supports rapid response to prevent and address a health emergency including a pandemic. In the absence of a multilateral PABS system, manufacturers will have to wait for access to novel pathogens/variants country by country, ensure compliance with ABS requirements which varies from country to country, and consequently face legal uncertainty. There will also be unpredictability with respect to access to medical products needed to address the health emergency.
The PABS system offers a win-win situation for all WHO Members as well as the private sector and more importantly global public health.

WHO Members should be very cautious of options that that delink access from benefit sharing, options that do not require all recipients/users to agree to legally binding terms and conditions on access and benefit sharing and instead narrowly focus in getting a few major manufacturers to voluntarily provide benefit sharing, options that do not put in place measures for accountability and transparency with respect to access to materials and/or sequences etc. These options will deliver a system that is not consistent with the CBD and the Nagoya Protocol and an ineffective system that will create legal uncertainty for those wishing timely access to materials and sequences and unpredictability in access to VTDs and other benefit sharing, to the detriment of global public health.

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?

Response to questions 3.4 and 3.5:

Firstly, annual monetary benefit sharing is essential from relevant users of the PABS system such as any entity generating revenue from using the PABS system and commercial users.

Further benefit sharing of VTDs should *inter alia* cover the following situations:

1. Prevention of PHEIC: This will require provision of VTDs for WHO stockpiles as well as on request of WHO's DG, where such stockpiles do not exist. The impact of this element is to prevent a PHEIC.
2. In the event of a PHEIC, to prevent the event becoming a pandemic emergency
3. In the event of a pandemic emergency. Once a pandemic emergency is declared the amount of VTDs that should be provided to meet the needs of developing countries has to be substantially scaled up since a pandemic emergency is an event with a wide geographical spread and can overwhelm health systems and cause substantial social and/or economic disruption, and requires rapid, equitable and enhanced coordinated international action.
4. Post PHEIC and a pandemic emergency especially if the disease is such that novel variants of pandemic potential are continuously emerging, making it essential to curb the spread of the disease by continuously making available VTDs.

With respect to the percentage of VTDs to be provided we are extremely concerned that the suggested amount of 10% or 20% is insufficient to meet the needs of developing countries that make up 80% of the world population. Suggestions such as 3-10% and “up to 20%” are even more unsuitable to meet the equity objective of the Pandemic Agreement.

Further it is critical that a firm benefit to be provided is manufacturing licenses to developing country manufacturers as the provision of such licenses will be the most expeditious way to scale-up manufacturing and to expand supply options, as normally during a PHEIC or a pandemic emergency demand will outstrip supply.

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

Response: Duration of the benefit sharing of VTDs should be decided taking into account the objective of the pandemic agreement i.e. to prevent, prepare for and respond to pandemic, guided by equity.

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?

Response: There are two reasons why PABS should refer to BWC, and in particular its Article 10. Firstly, the purposes served by PABS resources should be peaceful. There should be clear limitations placed on PABS users not to divert resources they access under PABS to non-peaceful purposes or to actors that are likely to use such resources for non-peaceful purposes.

Secondly, Article 10 of BWC also mandates Parties to the Convention to co-operate in contributing individually or together with other States or international organisations to the further development and application of scientific discoveries in the field of bacteriology (biology) for the prevention of disease. This is clearly a reason by which PABS benefits should be shared in an expeditious manner so as to prevent the spread of disease at the earliest point of time.

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"?

Response: The PABS system is about developing and implementing a multilateral ABS system for PABS materials and sequence information, consistent with the CBD and the Nagoya Protocol. The CBD and NP pertain to access and benefit sharing of arising from the utilization of genetic resources. Accordingly (a) is the appropriate text for the purpose of Article 12 and 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?

Response: “Sharing” under the PIP Framework is for the purpose of utilisation by the GISRS laboratories as per their terms of reference and by entities outside the GISRS 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?

Response: To ensure benefit sharing is delivered by manufacturers as envisaged under the contracts of the PABS system, WHO Members should agree as part of the Pandemic Agreement as well as the PABS instrument to legal commitments to facilitate the manufacturing and export of VTDs by manufacturers, as required by contracts under the PABS system. The legal commitment should extend to all WHO Members with facilities involved in the production and export of VTDs including production of active ingredients and excipients needed for manufacture of the VTDs. This is essential to operationalize access and benefit sharing on an equal footing and thereby maintain trust in the PABS system, and realise objectives of the Pandemic Agreement. If WHO Members restrict or erect barriers to the manufacture and export of VTDs, there will be reluctance on the part of other Members to share materials and sequence, which in turn may affect testing of VTDs against novel pathogens/variants or development of more effective VTDs. WTO rules do not preclude placing certain obligations on WHO Members.

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?

Response:

<u>Implications of adopting the PABS system under Article 19</u>

Under Article 19 of the Constitution, the Health Assembly has authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. Such agreements shall come into force for each Member when accepted by it in accordance with its constitutional processes.

Adoption of a PABS system under Article 19 means that only those WHO Members that have ratified the PABS instrument will be Parties to the instrument. It also means that some

WHO Members will be Parties and bound by the provisions of the PABS instrument while other WHO Members will not be bound by the provisions of the PABS system. This situation raises several challenges.

(a) If only some WHO Members are bound by the provisions of the PABS system, it would mean that only materials and sequences of pathogens circulating in those Members will be shared. This will make it more difficult to obtain a global assessment of pathogens and related variants circulating. In addition to complying with the PABS requirements, recipients/users will also have to comply with national ABS arrangements of Members that are not Parties to the PABS instrument.
(b) Further if the PABS system only applies to some Parties, then it will create a situation where some parties are legally bound to share materials and others are not. This may create tension among WHO Members (parties vs non-parties) e.g. when it comes to sharing of benefits. Will non-Parties have access to benefits arising from the use of the materials and sequences?
(c) In addition, if a Member is not a Party to the PABS instrument, the question arises whether its national laboratories and other users should be allowed to access the materials and sequences that have been shared by a Party. If allowed, it may create an unequal situation as users from a Party will not have access to materials and sequences from a non-Party (as the non-Party has no obligations to share materials and sequences).
(d) Another important consideration is that when an Article 19 instrument is amended, the amendment will have to be accepted by each Party by depositing an instrument of acceptance and the amendment will only enter into force on the 90th day after the date of receipt by instrument of acceptance by at least two thirds of the Parties of the PABS instrument. And the amendment only applies to Parties that have accepted the amendment. Clearly the amendment process is much more complicated if the PABS instrument is adopted under Article 19.

<u>Implications of adopting the PABS system under Article 21 of the WHO Constitution</u>

Under Article 21, the Health Assembly may adopt regulations and these regulations come into force for all Members except for those Members that notify the DG of rejection or reservations within a particular period. The IHR is an Article 21 instrument.

A PABS instrument adopted under Article 21 will be binding on all WHO Members, except for those Members that reject or express reservations within a particular period. Although perhaps less likely, a few WHO Members may reject or register their reservations over certain provisions (e.g. commitments to facilitate the manufacture and export of VTDs by manufacturers in their jurisdiction that have contractual obligations under the PABS system, commitments to ensure non-state actors operating in their jurisdiction comply with the requirements of the PABS system etc.) .This situation can also create challenges and tensions mentioned above.

However, generally, if entities that access materials and sequences have accepted the terms and conditions of use by way of standard legally binding contracts, they will continue to be bound by the terms and conditions of the contracts.

Further amendment of an Article 21 instrument and entry into force of such amendment for all WHO Members is a less complicated process, as the amendment applies to all WHO Members after a particular period of time, unless the Member expresses rejection or reservation within that period of time.

<u>Implication of adopting the PABS system under Article 23 of the WHO Constitution</u>

Adoption of a PABS system under Article 23 suggests adoption of the PABS instrument through a resolution adopted by the Health Assembly. Article 23 states that the "Health Assembly shall have authority to make recommendations to Members with respect to any matter within the competence of the Organization".

As the instrument is adopted via a resolution, it is a recommendation to WHO Members, while applicable to all WHO Members, from a legal perspective it is not legally binding as a Article 19 or Article 21 instrument would be. The PIP Framework was adopted under Article 23, and is a functioning multilateral ABS instrument for influenza viruses of pandemic potential. While the Framework was adopted via a resolution, the standard material transfer agreements between the provider/WHO and recipient of PIP materials, places legally binding contractual obligations including with respect to provision of benefits by the recipient.

Amending an Article 23 PABS instrument can be done via a resolution and the amendments are applicable on adoption of the resolution.

A disadvantage of this approach is the lack of legally binding provisions applicable to WHO Members (e.g. commitments to facilitate the manufacture and export of VTDs by manufacturers in their jurisdiction that have contractual obligations under the PABS system, commitments to ensure non-state actors operating in their jurisdiction comply with the requirements of the PABS system etc.)

From our view, the objective of the Pandemic Agreement i.e. to prevent, prepare for and respond to pandemics, is one that is relevant to all WHO Members. Hence the PABS system should be applicable to all WHO Members and to recipients of PABS materials and sequence information in all WHO Members. It is important to create a fair, transparent, accountable PABS system that motivates all WHO Members to share materials and sequences from "pathogens with pandemic potential", which is relevant for scientific analyses as well as development of VTDs and at the same time it is critical to ensure the system promptly delivers VTDs to countries at risk and in need as well as monetary benefit sharing.

If some WHO Members do not accept the PABS system (under Article 19) or opt out of the PABS system (under Article 21), it will create an unequal PABS system and tensions among WHO Members will emerge. Given the global objective of the Agreement, the PABS system should be one that applies to all WHO Members and to recipients of PABS materials and sequence information in all WHO Members. Such a system would be equal for all WHO Members, fairer, and more useful to recipients/users of the PABS system. To achieve this effect creative legal solutions will be required. .