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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? N/A

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 ?

N/A

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? N/A

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? N/A

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? N/A

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? N/A

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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?

There is no definition of DSI in the CBD. We propose that the Agreement use the term "genetic sequence data," as previously defined under the PIP Framework: "*Genetic sequences means the order of nucleotides found in a molecule of DNA or RNA. They contain the genetic information that determines the biological characteristics of an organism or a virus*" (PIP Purple Book, "4. Definitions and use of terms"). Using this definition will provide clarity and reduce the risk of misinterpretation. If the Agreement must reference "sequence information", to avoid any confusion the full term should be used to ensure alignment with the CBD: "digital sequence information".

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?

Access to pathogens and their sequence information under the Pandemic Agreement should be decoupled from benefit sharing obligations. Any other approach will be administratively cumbersome, if not impossible, hindering the quick access to pathogens needed to prepare and respond to epidemics and pandemics. We believe that a decoupled approach is the only way to enable ongoing research on pathogens as soon as they are discovered and to encourage as many researchers as possible – in both public and private sectors – to work in the infectious diseases space.

Ensuring equity in the event of future pandemics must be built from the common understanding that access to pathogens is essential for the achievement of global public health security, regardless of what country has shared the pathogen. Any future PABS instrument must help deliver the prevention and preparedness goals of the Pandemic Agreement, as well as the response goals, and address the challenges across all these pillars - which go beyond only benefit sharing.

In the event of a pandemic, the biopharmaceutical industry has committed to reserve an allocation of real-time production of vaccines, treatments, and diagnostics for priority populations in lower income countries and take measures to make them available and affordable, via legally binding commitments. Berlin Declaration: Biopharmaceutical Industry Vision for Equitable Access in Pandemics | Delivering equitable access in pandemics: Biopharmaceutical industry commitments

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

The extent and complexity of how sequence information is shared, reorganized, reshared, and utilized makes tracking and tracing extremely challenging, if not impossible, as shown by experts' discussions at the CBD level on a multilateral ABS mechanism for DSI. Attempts at tracking and tracing samples and sequence information under the Pandemic Agreement should be avoided as any efforts to do so would hamper access to both samples and information, hinder preparedness efforts, and slow responses to an epidemic or pandemic. While technically unimaginable to implement, tracking and tracing would severely hamper access to both pathogen samples and information, hinder prevention and preparedness efforts and severely slow down pandemic response. Tracking and tracing would not be necessary under a decoupled system for equitable access – which will help deliver access to all countries based on their public health need.

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?**

The private sector will need to play a critical role in preventing, preparing and responding to future pandemics. To help enable a broad and robust set of activity from companies – both big, medium and small – and academic and public researchers, the Agreement should encourage – and not penalize or discourage – researchers from working in this area.

The biopharmaceutical industry has proposed that companies could independently adopt Equitable Access Commitments in periods in between pandemics and/or during pandemics based on what each company could best contribute in view of its circumstances, such as its size, location, technology platform, research and development pipeline, or manufacturing capabilities. We believe the commitments outlined in the statement "Delivering equitable access in pandemics: Biopharmaceutical industry commitments are both significant and practical – offering a menu-based approach whereby individual companies select from a range of binding commitments, from product volume to capacity building efforts, based on their unique expertise and circumstances.

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The commitments would be part of a Pathogen Access and Benefit-Sharing (PABS) system, that – provided it is built on a broad multi-stakeholder partnership with no restrictions to accessing pathogen samples and DSI - could help maintain private, public and academic infectious disease research and

support preparedness. A broad multi-stakeholder partnership with no restrictions to accessing pathogen samples and DSI would foster global collaboration and enhance preparedness for future pandemics by ensuring that vaccines, therapeutics, and diagnostics (VTDs) are equitably distributed. To be effective, this system must be designed with careful consideration of the unique challenges facing VTD manufacturers, particularly the need to maintain incentives for innovation and flexibility in response to varying market conditions and pandemic epidemiological characteristics.

Scientists need rapid access to pathogens and data in order to quickly develop safe and effective countermeasures to save lives. The PABS system should incorporate flexible and decentralized pathogen sharing mechanisms that build on existing networks and resources. For example, platforms like the European Virus Archive (EVA-G), ATCC or the African CDC have proven successful in facilitating the rapid exchange of pathogen samples and genetic sequence data across regions. By leveraging these pre-existing networks, a decoupled and open PABS system could avoid the inefficiencies that often accompany centralized control, be established in a timely manner and encourage wider participation, including from smaller and medium-sized companies that may offer specialized technologies or research capabilities.

It is also essential that a PABS system does not impose additional financial burdens that could hinder ongoing or future efforts in pandemic prevention and preparedness. Many biopharmaceutical companies are already making significant contributions to pandemic preparedness (e.g., capacity building, product donations, manufacturing scale-up) and continue to make at-risk investments. During the COVID-19 pandemic, several companies also provided COVID vaccines at reduced prices or free of charge to low- and middle-income countries, demonstrating their commitment to equitable access. Obligating annual monetary contributions could divert resources away from these critical activities, impact the overall financial viability for companies to remain invested in emerging infectious disease R&D/manufacturing, and reduce the industry's ability to respond swiftly in future emergencies.

Overall, a PABS system should be designed to complement existing frameworks, such as the Pandemic Influenza Preparedness Framework, to avoid duplicating obligations and ensure a cohesive global response. By allowing companies to negotiate specific contributions with WHO, recognizing the diverse forms of support already provided by VTD manufacturers, and maintaining flexibility in benefit-sharing commitments, the PABS system can help strengthen global health security while continuing to foster innovation and collaboration across the industry.

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

Open access to pathogen sequence information was critical to the development of COVID-19 vaccines and treatments. Measures that would impede this and thus the ability to conduct R&D and bring future pandemic products to patients would severely undermine equity. For example, the development of the Pfizer-BioNTech COVID-19 vaccine was initiated on January 10, 2020 – the same day the SARS-CoV-2 genetic sequence was released by the Chinese CDC and disseminated globally by GISAID, and before WHO had declared COVID-19 a pandemic. Estimates indicate that a delay of just one month in accessing the SARS-CoV-2 virus samples could have led to an additional 400,000 lives lost from COVID-19.

The biopharmaceutical industry has demonstrated its commitment to equitable access and maintains the perspective that any PABS system must offer flexibility to accommodate the diverse capabilities and capacities of different companies. Manufacturers and commercial users may consider opting out of a PABS system if the required contributions are too rigid or impact the overall financial viability for companies to remain invested in emerging infectious disease R&D/manufacturing

In general, unlike influenza there is no known seasonal market for other pandemic diseases. This means that annual monetary contributions are being suggested from companies whose efforts may never give rise to a product - this means they would pay three times, for their R&D, for the PABS fee and the opportunity cost of doing R&D towards a pathogen that may never materialize or where a product may never result (versus another disease area where there are no such encumbrances and where risk is lower).

Imposing inflexible obligations could discourage participation, hinder R&D investments in pandemic-related diseases, and ultimately reduce the effectiveness of the PABS system and preparedness. Ensuring we have the right VTDs when they are needed requires to make the infectious diseases field attractive enough for companies to start or at the very least continue investing in R&D for pandemic diseases. Unfortunately, we have already seen several important manufacturers decide to leave that field.

To ensure broad engagement, a more adaptable approach, such as offering a “menu of options,” is necessary, allowing companies to tailor their commitments based on their unique resources and expertise.

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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 biopharmaceutical industry remains fully committed to helping ensure equitable access to vaccines, therapeutics, and diagnostics in times of pandemics, regardless of whether a PABS system is in place. This commitment is demonstrated through the statement on "Delivering equitable access in pandemics: Biopharmaceutical industry commitments" in which manufacturers reiterated their willingness to reserve an allocation of production volumes for low- and middle-income countries, as highlighted in the Berlin Declaration. These commitments are designed to be flexible and adaptable, allowing companies to engage in ways that align with their capacities, such as through tiered pricing, donations, or voluntary technology transfers on mutually agreed terms.

Rather than a rigid PABS system, a more effective alternative could involve establishing a multi-stakeholder Partnership for Equitable Access. This partnership would allow companies to voluntarily participate by adopting Equitable Access Commitments that are legally binding and enforceable through contracts. This approach not only facilitates the rapid and timely sharing of materials and genetic sequence information but also ensures that benefits—both monetary and non-monetary—are shared equitably.

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

Declaration of a pandemic emergency. Manufacturers need clarity on which products would fall in/out of scope of PABS - and that "pathogens of pandemic potential" should not be tied to a PHEIC.

3.4. **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?**

We understand that the IHR has replaced "pandemic" with "pandemic emergency". The requirements during a PHEIC and a pandemic emergency will be different and the criteria used to distinguish between these two situations need to be further clarified. In general, the pandemic agreement scope should strictly focus on pandemics and specifically aim to catalyze the unique level of global response, coordination and cooperation required to manage such significant public health challenges. To make the Pandemic Agreement a useful and agile tool, we should avoid overextending its scope. PHEIC has historically been met with rapid and effective response targeted to the affected region and/or populations. Not clearly distinguishing pandemics and PHEIC will trigger counter-productive or suboptimal measures. For example, in the majority of cases the same manufacturing facilities are used for both routine and pandemic related products, so switching to produce the latter would impact the supply of other routine or seasonal products and requires a definitive signal coupled with clear demand

to provide certainty and justify the resource invested at-risk in the operational transition. For example, for CSL Seqirus, if there was a requirement to supply pandemic influenza vaccines at the stage of a PHEIC, this would significantly impact their ability to supply a sufficient number of doses of seasonal influenza vaccine, which would most likely still be required in several regions of the world. For this reason, we do not think that benefit sharing of VTDs should cover PHEICs.

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

The duration of benefit sharing of VTDs should be regularly reviewed and determined by how long the pandemic emergency lasts, the epidemiological characteristics of the pandemic and whether/where the VTDs are still needed and are being administered.

We have observed that in early phases and later phases of an outbreak, the uptake is often poor even when VTDs are made available. In order to optimize the use of available VTDs, it is therefore important to take into account the various stages of supply and demand. For that reason, the percentage of set aside needs to include flexibility, and the amount of time the set aside is reserved before it can be reallocated somewhere else and the general duration of the commitment should be limited.

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?N/A

3.6. 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"? N/A

3.7. 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? N/A

3.8. 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?

The WTO aims to set rules that promote open and free trade. Member States would need to implement any potential PABS system (and the entire Agreement) in a manner that complies with their obligations under existing international instruments, regulations and treaties. The Agreement must be consistent with Members' WTO obligations, including Most Favored Nation and National Treatment obligations.

With respect to restrictions on movement of goods, a potential PABS system would have to be in compliance with the General Agreement on Trade and Tariffs (GATT), noting that any restriction should be specific, time limited and temporary, and in particular need to comply with GATT Article XI, which prohibits Members from adopting export restrictions, with limited exceptions.
Notably, WTO Members agreed in 2022 to exercise "due restraint" with respect to export restrictions and affirmed that any emergency trade measures designed to tackle COVID-19, if deemed necessary, must be targeted, proportionate, transparent, temporary, and should not create unnecessary barriers to trade or unnecessary disruptions in supply chains.
It should also be noted that several attempts are being made, at a national and regional levels to ensure open borders and free movement of goods and services needed during pandemics.

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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?

N/A