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

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 system must support the delivery of the prevention, preparedness and response goals of the Pandemic Agreement, as well as 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 (VTDs) 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

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 is technically unimaginable to implement and should be avoided, as any efforts to do so would

hamper access to both samples and information, hinder prevention and preparedness efforts, and severely slow responses to an epidemic or pandemic. 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 activities from companies, whether big, medium or small, as well as academic and public researchers, the Agreement should encourage, 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. This offers 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. These would be part of a PABS system, which 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. This would also foster global collaboration and enhance preparedness for future pandemics by ensuring that 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 their 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 which successfully facilitate the rapid exchange of pathogen samples and genetic sequence data across regions.

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, such as investments in disease surveillance through existing public-private partnerships, at-risk R&D activities (including expensive clinical trials), capacity building, product donations and maintenance and scale up of warm-based infrastructure that can be transitioned to support pandemic countermeasures development if necessary. The high attrition rate of

products in the development pipeline should also be acknowledged. Obligating annual monetary contributions could disincentivize innovation, 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, and other relevant access and benefit sharing instruments *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.*

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

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. Imposing inflexible obligations could discourage participation, impact the overall financial viability for companies to remain invested in emerging infectious disease R&D/manufacturing, and ultimately reduce the effectiveness of the PABS system and preparedness. 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.
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.

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?**

The biopharmaceutical industry remains fully committed to helping ensure equitable access to VTDs in times of pandemics, regardless of whether a PABS system is in place and manufacturers have reiterated their willingness to reserve an allocation of production volumes for low- and middle-income countries, as highlighted in the Berlin Declaration. A more effective alternative to a rigid PABS system could involve establishing a multi-stakeholder Partnership for Equitable Access which would allow companies to voluntarily participate by adopting 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 (e.g. tiered pricing, donations, or voluntary technology transfers on mutually agreed terms), are aligned with the capabilities and capacities of companies and are shared equitably.

Non-monetary benefit contributions should be decided by manufacturers and could include voluntary technical transfers. Public health benefits are best assured when innovator manufacturers have the latitude to determine whether and how to engage in technology transfer to enable manufacturing of their products. This minimizes the potential for issues that could undermine product safety, efficacy, quality, regulatory compliance, and ultimately public confidence in pandemic countermeasures.

Non-voluntary technology transfer is an unacceptable risk for manufacturers, and inclusion of such provisions in an international pandemic instrument could discourage otherwise interested parties from participating in countermeasures development.

CSL Seqirus and CSL group companies acted as a contract manufacturer to produce AstraZeneca's COVID-19 vaccine in collaboration with AstraZeneca and with strong support from the Australian government, successfully delivering more than 50 million doses of COVID-19 vaccine for the Australian population and other regional countries, including several LICs and LMICs, on an accelerated timeline. This was achieved through leveraging CSL's foundational capabilities including, existing product manufacturing infrastructure, established supply chains, trained and experienced staff, and knowledge of products utilizing similar technology, and the efforts of over 700 employees. It also required intense coordination and cooperation between parties who were experienced with commercial-scale vaccine development and manufacturing, including corporate decision making across nine different governance forums. More than 500 technology transfer team meetings were executed over the 17-month campaign.

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

A declaration of a pandemic emergency with clarity on which products would fall in/out of scope of PABS

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?**

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. PHEICs have historically been met with rapid and effective response targeted to the affected region and/or populations.

The requirements during a PHEIC and a pandemic emergency will be different and the criteria used to distinguish between these situations need to be further clarified if counter-productive or suboptimal measures are to be avoided. Also, as in the IHR definition of a pandemic emergency, if this includes the "high risk of a pandemic" as well as a pandemic, the criteria used to

determine these must be clarified and there needs to be a clear and definitive global trigger to switch to pandemic manufacturing, coupled with clear demand to provide certainty and justify the resource invested at-risk in the operational transition .
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. 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 our 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 consider that benefit sharing of VTDs should cover PHEICs.

3.6. **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 / pandemic lasts, the epidemiological characteristics of the pandemic and whether/where the VTDs are still needed and are being administered.

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?

N/A

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"?

N/A

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?

N/A

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?

N/A

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