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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?

   Not applicable

   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 ?

   Not applicable

   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?

   Not applicable

   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?

   Not applicable

   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?

Not applicable

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?

Not applicable

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?

Not applicable

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?

Not applicable

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

Not applicable

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**?

Manufacturers being called on to set aside volumes of product - this can be construed as being a part of our role / an intuitive role in the ecosystem - Manufacturers such as ourselves invest in and pilot R&D, we manufacture products (vaccines), and provide them to

governments and other healthcare providers with preventative solutions as part of public health programs. So “in character” for the sector, and a clear signal on achieving Equity.

Provision of those products on Free of Charge (FoC)/Not For Profit (NFP) basis – could be a company choice – 2 observations: NFP can be very subjective, depending on accounting systems. Why would “donations” by a Company be a better option than via a Govt initiative? And even those do not necessarily get to achieving the ultimate goal, which is vaccination – the distribution and administration of vaccines, especially to adults remains a challenge. A PABS systems will not address that.

Turning to some of the details:

Reserving capacity pragmatically improves equity, but must be dynamic and realistic, considering factors like yields, technologies, pathogen characteristics, and population needs. We understand the desire to put a number on “X”, but it must account for the fluctuating demand-supply dynamics during pandemics and varying epidemiology of diseases (as seen with mpox versus COVID-19).

Mandatory financial contributions from companies based on sales or size are unacceptable. Aside from being beyond our role in the ecosystem, it is highly likely that such a tax would disincentivize pandemic preparedness engagement and potentially prevent the most promising technologies from being developed for pandemic uses. And I think we all agree that would not be a desired outcome.

The proposal mistakenly assumes a limited, pre-identifiable group of primary R&D actors, ignoring the diverse, unpredictable nature of global R&D efforts evident in COVID-19 response. Notably, few entities ultimately delivered Medical Counter Measures, particularly for vaccines. During the COVID-19 pandemic, over 300 projects were initiated globally, however only a small fraction of these succeeded in being licensed for use, and then deployed. Six vaccines were deployed and used globally.

Some observations as a flu company: we have contributed to the PIP PC since 2012.

The **PIP Framework** is an inadequate model for broader pandemic preparedness. It remains untested, and here are 5 issues:

1. With few (14) Supply agreements established despite numerous flu (30 according to MI4A, study) manufacturers.
2. Its PC system is flawed: a voluntary program sees the main manufacturers contributing (although falling well short of 100% of vaccine suppliers), and some sectors have never been actively encouraged so the total burden is borne by few.
3. The use of a GISRS running cost as a proxy has not brought satisfaction to the members of that network.

4. There is lack of transparency on the decision-making (or efficiency) initiatives that are financed with PIP funds to improve **Flu** pandemic preparedness at a national level. (despite efforts to publish HLIPs), with overspill (beyond flu-specific topics) and opacity (true impact of the Projects on flu preparedness).
5. Lastly, a significant proportion of PIP PC money is spent on administrative costs within the secretariat – could this be optimized using an alternative model?

Operational readiness: Critically, the INB discussions have largely overlooked the need for regulatory coordination and convergence — a glaring oversight exposed by the recent mpox outbreaks. This crucial element must be prioritized to fortify ability to respond in an equitable manner – many High Income Countries have adapted processes, while Low-Middle Income Countries have not (despite >10years of PIP activity).

Lastly, the role of public-private collaboration in the development of MCMs should not be overlooked, since most MCMs are developed under this frame, during a pandemic. Therefore, any industry commitments to set aside doses or courses must be done with the cooperation and assistance of those funders and/or collaborators. Especially in the initial period of any public health emergency when companies are simultaneously concluding clinical trials, optimizing manufacturing processes, rapidly scaling production, and executing global technology transfers as necessary.

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

Not applicable

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?

Public-private partnerships can serve as a powerful incentive for encouraging manufacturer participation.

For example, there is a clear need to enhance surveillance efforts and the WHO is making strides towards integrated surveillance. However, the proposed expansion of GISRS to GISRS+ is already facing resistance from countries and experts due to concerns over financing and resources. This opens an opportunity for PU/PR networks to capitalize on their existing successes and infrastructure, leveraging cutting-edge artificial intelligence to create a high-performing surveillance system.

Example 1: GIHSN - a worldwide network that operates across 100 hospitals in over 20 countries, screening hospitalized patients annually for influenza and other respiratory viruses, collecting clinical and virological data to inform vaccine development and public health strategies. GIHSN is the sole provider of linked clinical and virological data including DSI making it an invaluable partner for WHO's collaborating centers.

GIHSN's visibility helped several sites secure government funding, leading to capacity building with broader impacts. This aligns with the Global Fund's concept of diagonal funding, where disease-specific vertical programs contribute to overall health system strengthening. In this case, patients benefit from increased testing availability.

GIHSN demonstrates that industry contributions in kind can offer greater value than monetary funding alone. This proof of concept could be expanded and accommodated as part of a PABS system.

Example 2: Harnessing the private sector's innovation and expertise in AI and machine learning with **AIOLOS,** Sanofi co-leads a consortium that integrates real-time data from diverse sources such as wastewater surveillance, weather patterns, mobility trends, and social media to detect, monitor, and support responses to potential respiratory virus outbreaks. The prototype co-funded by German and French governments is ready to be used by relevant organizations in a public-private collaboration and can be adapted to different pathogens/threats.

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

Not applicable

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?

Not applicable

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

The timeframe for sharing VTD benefits should be dynamically assessed, aligning with the pandemic's duration and the ongoing necessity and utilization of these resources. This continuous evaluation is crucial to provide clear guidance and prevent resource waste.

Consider the COVID-19 pandemic: In 2022, Team Europe / HERA and Sanofi-GSK invested months of intensive work and substantial resources to negotiate contracts and orchestrate logistics for sharing Sanofi-GSK's COVID vaccine. Ultimately, this herculean effort proved futile as country demand had already been met, highlighting the critical importance of agility and foresight.

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?

Not applicable

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"?

Not applicable

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?

Not applicable

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?

Not applicable

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?

Not applicable