

INB related interactive dialogues

Topic 1. Article 12 (Pathogen Access and Benefit-Sharing System)

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These inputs reflect the experience at the Leibniz Institute DSMZ, the first [Registered Collection](#) under the Nagoya Protocol's in the European Union (EU Reg 511/2014), as co-founder of the [DSI Scientific Network](#), head of the [German Nagoya Protocol HuB](#), and Nagoya Compliance lead for the [European Virus Archive](#) project.

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?

It is our understanding that a PABS agreement would effectively supersede previous national ABS legislation or a lack thereof. Universal application of a PABS instrument is possible, but requires each country to individually decide to become a party to such PABS instrument and *how* to implement the new PABS instrument's requirements against the backdrop of their current national ABS legislation (or lack thereof. There would be two "flavors" of implementation needed:

1. Countries that currently regulate access and require benefit-sharing on a bilateral basis under the NP would shift to regulate access to pathogen genetic resources on a multilateral basis.
2. Countries that do not regulate access and do not require benefit-sharing (including non-Parties to the CBD/NP (e.g., USA) and Parties that grant "free" access under Article 6 (e.g., Germany)) would now regulate pathogen access on a multilateral basis.

In terms of process: Parties to the Nagoya Protocol (NP) have never officially recognized an SII during a COP/MOP. Nor do they know how an Art. 4.4 process would be handled. The issue of how to recognize an SII was on the COP15 agenda but was postponed to COP16. More generally, there is no requirement in the NP for such "recognition", and it remains the sovereign prerogative of NP Parties to enter into an SII, provided that such SII is in line with the obligations set out in art 4.2 and 4.4 (mutual supportiveness and no contradiction to the objectives of CBD/NP).

In many cases, the recognition of an SII is practically enabled through implementing ABS legislation. For example, Brazil's national access laws and the EU's ABS compliance laws, respectively, recognize existing

multilateral ABS instruments (PIP Framework and ITPGRFA) and indicate to users that they should follow those respective instruments where 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 ?

In the absence of ABS legislation, the default from a compliance perspective, is a pre-CBD-like “free access” (unregulated and not requiring benefit-sharing) situation. Thus, Parties that have no ABS legislation in place would need to adopt PABS at the national level. Parties that regulate access bilaterally would need to adapt their national legislation to recognize PABS procedures under the new multilateral instrument. For some countries, this will be straight forward as their national legislation already recognizes other multilateral ABS instruments. Additionally, some countries made provisions for the possibility of Article 10 (Global Multilateral Benefit-Sharing Mechanism) to be created or adopted in the future. In either of those cases, amending or expanding the list of “ABS exceptions” from national bilateral procedures could potentially be done via administrative law. In cases where no ABS legislation and no access requirements are in place, it is likely new national legislation could be needed.

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?

Parties might wish to specifically acknowledge Article 8a and Article 10 of the Nagoya Protocol.

Article 8a notes the need for expeditious access during present or imminent health emergencies and corresponding need for access to affordable treatments, especially in developing countries.

Article 10 calls for multilateral benefit-sharing in the case of transboundary situations. There can be no doubt that pathogenic outbreaks, are, by their very nature, transboundary.

On a more general note, the INB might note the CBD’s extensive use of informal processes during the development of the benefit-sharing instruments for both the NP and the DSI mechanism. The CBD has used informal processes including a Norway-South-Africa-led informal dialogue on DSI which included in-person, informal meetings under Chatham House Rules; the establishment of multiple Ad Hoc Technical Expert Groups; regular monthly online meetings of the co-chairs’ Informal Advisory Group; as well as the commissioning of studies on contentious and technical issues (e.g., scope, databases, traceability, national legislation). Parties may find that the PABS discussions could be less challenging if supplemented by additional types of input, meeting formats, and engagement with stakeholders.

Finally, there is no need to “treat both kids the same way”. Physical pathogen samples and DSI are very different. Each needs to be addressed in a specialized, separate fashion. This means that an SII under the Nagoya Protocol would handle physical pathogen samples. But it cannot handle DSI. A specialized

approach for DSI, compatible with other DSI benefit-sharing mechanisms, as noted in the chapeau of CBD Decision 15/9¹ is needed.

- 1.4. Are there any specific issues in the PABS under ongoing INB negotiations that may prejudice the ongoing discussions on the handling of DSI within the CBD and the Nagoya Protocol?

The PABS drafts to-date have primarily focused on the relationship of the PABS instrument to the Nagoya Protocol. The PABS instrument has not yet referenced CBD Decision 15/9 in which Parties agreed to “establish a multilateral benefit-sharing mechanism for DSI on GR including a global fund”. This is a critical gap that overlooks the distinct handling of GR and DSI. CBD Parties decided at COP14, that DSI negotiations would not be conducted “under” the Nagoya Protocol. Instead DSI was negotiated as part of the CBD Global Biodiversity Framework. Decision 15/9² was a CBD COP decision and the NP only recognized that CBD made a decision on DSI³.

A multilateral CBD mechanism for DSI means that a PABS system (with both GR and DSI) needs to account for both the bilateral Nagoya Protocol and the multilateral CBD DSI instrument (currently being operationalized).

The rhetoric expressed by some Parties that they are “waiving their right to bilateral benefit-sharing” if they agree to a PABS instrument, is incomplete. This may be true (depending on the national ABS situation) for pathogen genetic resources (i.e. physical sample), but it is not true for genetic sequence data.

Because Parties have agreed to establish a multilateral benefit-sharing mechanism for DSI, the choice for sequence data is only whether it is handled multilaterally under CBD or multilaterally under PABS. A bilateral path for DSI/GSD is not under discussion at the CBD, although, of course, initial access to GR should be compliant with the Nagoya Protocol. Furthermore, in Decision 15/9, Parties agreed that the multilateral DSI benefit-sharing mechanism should be consistent with open access to data, not hinder research and innovation, be mutually supportive of other ABS instruments (para. 9e,f, h) and that tracking and tracing is not practical (para. 5).

- 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?

Given the Nagoya Protocol’s Article 8a and 10 (mentioned above) it is hard to understand how PABS and its recognition as an SII would be inconsistent with and/or counter to the objectives of the CBD/NP. Furthermore, a PABS non-Party would still retain sovereign rights over its pathogen genetic resources.

¹ Recognizing further that any solution for the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources should be mutually supportive of and adaptable to other instruments and fora while recognizing that other fora may develop specialized approaches,

² <https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-09-en.pdf>

³ <https://www.cbd.int/doc/decisions/np-mop-04/np-mop-04-dec-06-en.pdf>

One issue that could undermine the PABS system would be if a Party to the Nagoya Protocol (or non-Party) were to grant “free access” to their pathogen genetic resources (as many already do under Article 6 and/or 8b). This would create a competitive marketplace between unregulated access and PABS-access which could generate unintended consequences and outcomes including avoidance of the PABS system. For PABS to work, there can be no “free” pathogen material available in parallel. All PABS material and data must trigger benefit-sharing requirements and participation in the PABS system should be effectively unavoidable.

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?

- Tracking and tracing of DSI would be inconsistent with CBD Decision 15/9 para.5
- Closed access to DSI would be inconsistent with CBD Decision 15/9 para.9f
- Hindrances on research and innovation would be inconsistent with CBD Decision 15/9 para.9e
- Incompatibility with other ABS instruments would be inconsistent with CBD Decision 15/9 para.9h
- Delayed access to pathogen genetic resources would be inconsistent with Article 8b of the NP
- Bilateral benefit-sharing during transboundary situations would be inconsistent with Article 10 of the NP
- A failure to deliver benefits (perhaps due to the design of the system, avoidance opportunities, complexity, incompatibility with scientific practice, and/or a lack of future-proofing against new GR/DSI-related technologies such as artificial intelligence).

2. Issues related to access to PABS materials and sequence information

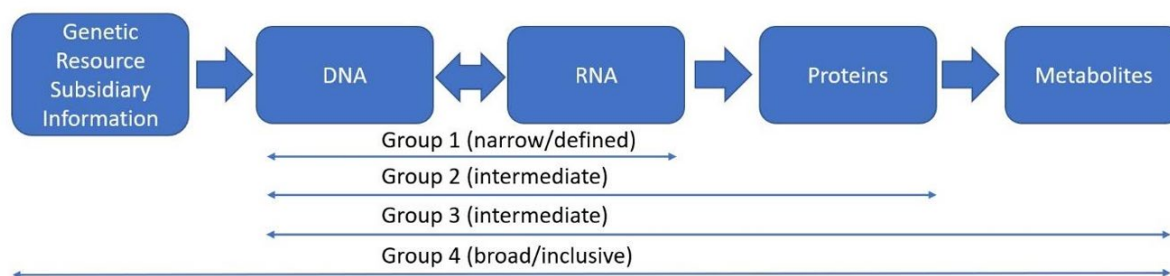
2.1. What are the current most up-to-date progresses in CBD on definition and scope of digital sequence data (DSI)? Will the current negotiated text using “sequence information” contradict/hamper the ongoing negotiation of the CBD?

To date, Parties to the CBD have agreed to continue to use the expression “digital sequence information” as a placeholder term. However, the 2020 Ad Hoc Technical Expert Group on DSI received a study on the potential definition of DSI and formulated a range of options of how DSI could be understood⁴.

In its most narrow definition (group 1), DSI would be defined as nucleic acid sequences, which include both DNA and RNA, and constitute the core genetic information of an organism. The intermediate definition (group 2) would include amino acid (protein) sequences that, when folded inside a living cell, take on structure and become the “machines” of the cell carrying out the daily work of making,

⁴ CBD/DSI/AHTEG/2020/1/3 Digital Sequence Information on Genetic Resources: Concept, Scope and Current Use <https://www.cbd.int/doc/c/fe9/2f90/70f037ccc5da885dfb293e88/dsi-ahteg-2020-01-03-en.pdf>

breaking, transporting, activating and recognizing other molecules. The definition of DSI could be expanded further (group 3) to include metabolites and biologically-active molecules as well. The AHTEG recommended that subsidiary information should not be included in the definition.



Grouping proposed for digital data of molecular information derived from genetic resources (adapted from footnote 1).

As “digital sequence information” has become a term-of-art albeit a placeholder, we believe that PABS should use an identical term to that used by both CBD and the new High Seas Treaty (BBNJ). This will increase legal certainty and indicate the intention of PABS Parties to promote compatibility between various ABS instruments.

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?

Under the ITPGRFA, an online system has proved extremely effective at capturing the exchange of plant genetic resources under the SMTA: <https://mls.planttreaty.org/itt/index.php>. The statistics page captures nearly 7 million SMTA plant germplasm accessions and the locations of both the provider and user countries by regions.

For DSI, citation of sequence data in scientific publications and in patents is routine practice. Under the WILDSI project, a number of global, quantitative analyses were performed to assess how DSI is cited and used in scientific publications: <https://apex.ipk-gatersleben.de/apex/wildsi/r/wildsi/home>. Scholz et al. found that DSI users tend to use locally- or regionally-sourced DSI more than they use foreign DSI.⁵ These kinds of indicators could be potentially supportive of a monitoring framework under PABS.

Using existing public data sources on the use of pathogen GR and DSI as indicators could increase transparency and trust. Empirical, unbiased data can be used to review whether the PABS system is delivering or not in an overarching, global manner. Indicators based on publicly-available data sources allow Parties to adapt course and based their decisions on data from the real world, but they do not disrupt the scientific ecosystem. Closed, control-based approaches (such as island databases, blanket

⁵ <https://doi.org/10.1093/gigascience/giab085>

user registrations, or closed access) that have been under consideration will lead to avoidance and low uptake by the same users that are needed to deliver PABS benefits.

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

As noted in CBD Decision 15/9, tracking and tracing of individual data exchanges is neither an efficient nor effective use of resources where hundreds of millions of sequences, tens of millions of users worldwide, and thousands of databases are involved. Instead, monitoring at key points in the R&D value chain is likely to be far more effective and efficient than a tracking and tracing approach.

The CBD *Combined study on digital sequence information in public and private databases and traceability* by Rohden et al.⁶ for the 2020 DSI AHTEG notes a number of opportunities within the existing scientific infrastructure to consider traceability but also a variety of challenges associated with these kinds of approaches.

Many approaches were considered during previous CBD inter-sessional periods such as Blockchain-based tracking and tracing, closed-access databases, or bilateral approaches to DSI benefit-sharing. However, these were ultimately deemed too disruptive to the inter-connected DSI scientific infrastructure. This infrastructure not only generates basic knowledge, it also generates non-monetary benefits in the domains of conservation, sustainable use, food security, public health and the bioeconomy. In particular, the requirement of government funding agencies (in all UN regions)⁷ for open data, the need for interconnectivity of datasets and databases, the ability to transform and re-use DSI into many other kinds of data, and the terabyte-scale of all of these scientific activities is simply incompatible with tracking and tracing. It is also not “future-proof” as DSI-related analyses shift to artificial intelligence approaches and outcomes are based on millions of data points where tracking and tracing will always fail.

To preserve the generation of these public good outcomes, a de-coupled approach to benefit-sharing, where the end of the value-chain (e.g. VTD) rather than the point of access, is expected to be the trigger for DSI benefit-sharing under the CBD.

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?

⁶ <https://www.cbd.int/documents/CBD/DSI/AHTEG/2020/1/4>

⁷ <https://zenodo.org/records/5849643>. Page 19-23.

N/A

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 lessons of the Nagoya Protocol have taught us that if it is possible to legally avoid a benefit-sharing system by accessing material that is not under ABS requirements (because of temporal and material scope) many users will indeed do so. For example, after the implementation of the Nagoya Protocol in the EU (Reg. 511/2014), many commercial entities simply “Nagoya-proofed” their supply chains, that is, they ensured that any access to genetic resources involved free access (non-ABS-regulating) countries or material that was out of material or temporal scope. The primary compliance mechanism, for these entities, was to avoid Nagoya Protocol-regulating countries AND this is completely legal. This is a lose-lose situation that delivers less-than-ideal R&D outcomes and lower benefits.

Benefit-sharing systems that have broad, all-encompassing scope and do not enable avoidance and also have simple, de-coupled benefit-sharing are those that will deliver. This requires fundamentally different approaches than the traditional control-based types of benefit-sharing. See Halewood et al⁸ for a deeper discussion. For this reason, we remain concerned that a narrow definition of “pathogen” (i.e. only PHEIC-causing organisms) will lead to avoidance. For example, if closely related viruses that do not cause PHEICs are used to develop countermeasures or older material excluded, then the PABS system could be avoided and benefits will not be delivered. The scope must be as inclusive as possible to minimize avoidance.

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?

Based on the outcomes of the covid-19 pandemic, it seems that society is broadly capable of sharing samples and sequence information (and related biological data) to deliver rapid diagnostics and counter measures. However, we completely failed at vaccine, therapeutics, and diagnostic equity. The question would be whether linking the morally unambiguous need for VTD with access to pathogen samples and data is the correct connection and legal precedent? Why not just make rules about each of these topics separately and let commercial and non-commercial scientists do their jobs (i.e. share their data, samples)?

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

⁸ Halewood et al., New benefit-sharing principles for digital sequence information. Science. 382,520-522(2023).DOI:10.1126/science.adj1331; <https://www.science.org/stoken/author-tokens/ST-1528/full>

Putting medical countermeasures on the market that would treat, diagnose or inoculate against a pathogen-caused disease.

- 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?

All of the above.

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

N/A

- 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?

Biosecurity concerns abound in the world of pathogens as well as the use of biological diversity although it is unclear how these issues are directly relevant to PABS. For bad actors, pathogens are not the only source of nefarious options to create bioweapons and toxins. For example, non-infectious cyanobacteria⁹ (pond scum) and fungi¹⁰ (found in every spoonful of soil) would not be under any potential definition of “pathogen” under PABS because they do not infect humans (i.e. they do not reproduce in our bodies). These organisms are nevertheless capable of producing some of the most toxic substances known to mankind. As such, pathogens should not be considered uniquely dangerous in their capacity to be weaponized.

Nevertheless, most PHEIC-causing organisms are on, for example, the Australia Group¹¹ of organisms and any research activities done on them should be denoted dual use research of concern (DURC) by national authorities responsible for these issues. One particular issue that was challenging during last year’s mpox outbreak, was the transport of material across borders including between European Union Member States. The PABS instrument may want to encourage responsible authorities to improve inefficiencies and bureaucratic challenges to efficiently and safely exchange pathogen material which can lead to delays in outbreak response.

In summary, mis-use of biological research is a critical biosecurity issue. But it is not directly related to PABS. Biosecurity issues should be handled by those national and international¹² bodies with the competency and expertise to holistically address these issues.

⁹ <https://en.wikipedia.org/wiki/Cyanotoxin>

¹⁰ <https://en.wikipedia.org/wiki/Aflatoxin>

¹¹ https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/human_animal_pathogens.html

¹² <https://www.nti.org/about/programs-projects/project/global-biosecurity-dialogue/>; <https://ghsagenda.org/>; <https://www.gpwmd.com/>

- 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"?

Under option b, a more de-coupled approach would be understood. This would imply, for example, that even older pathogen material and data, could potentially lead to a requirement to share benefits. Option b seems more likely to be fully-encompassing and have less opportunity for avoidance or jurisdiction shopping.

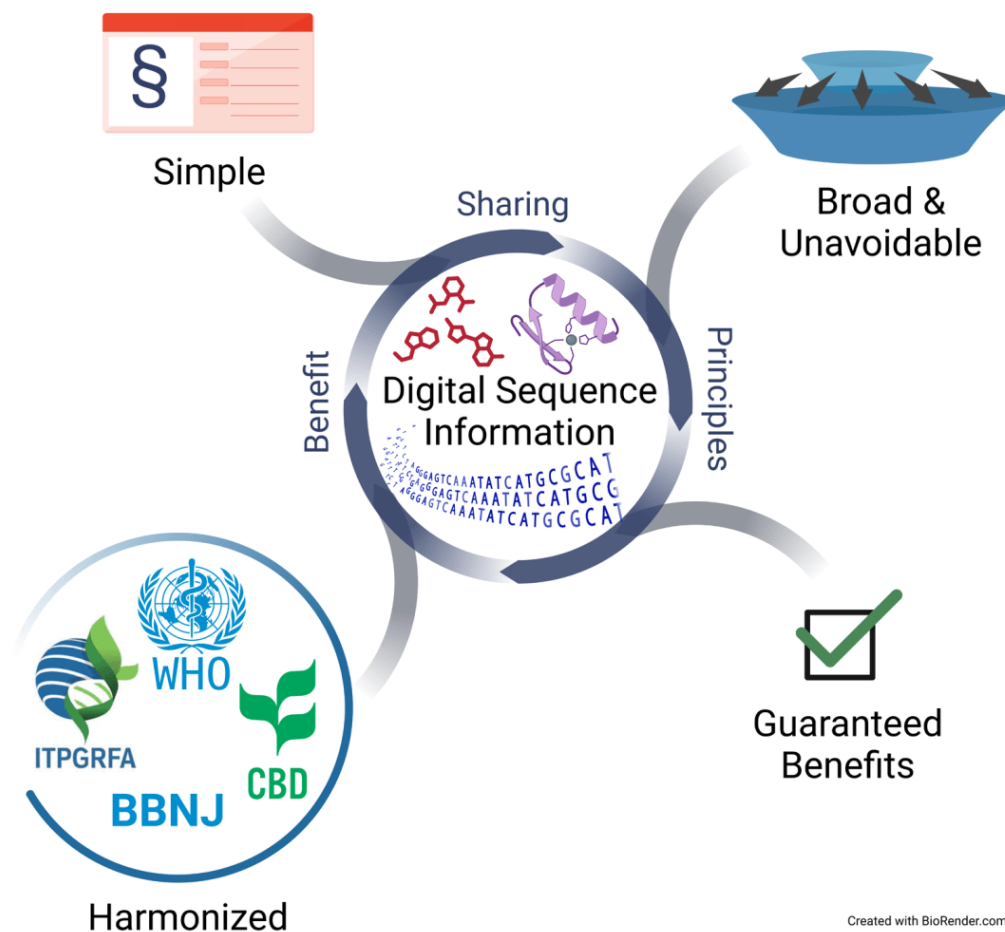
Option a is a more coupled approach and if a user were to avoid using PABS material or sequence data, then they would not be required to share benefits.

- 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?

These terms are not synonymous. Under the NP, benefit-sharing is only required if genetic resources are utilized. This means that for example, use of genetic resources for commodity purposes (like buying and selling a banana or using wood to make furniture) do not trigger benefit-sharing requirements. Only "utilization", i.e., R&D activities trigger benefit-sharing. However, not all R&D delivers clear benefits. Sometimes science hits dead-ends.

"Benefits arising from sharing" would mean that any clinician sharing pathogen samples (for example for diagnostic purposes or for identification or other kinds of routine medical testing) would also be simultaneously triggering the obligation to share benefits. This could be a desired outcome of PABS but could bring many clinical users of PABS-material/information into scope in an unintended way.

Most importantly, the chosen language for a functioning PABS system should make clear that the system is "all-in" – no avoidance opportunities available. Benefits must be shared, but the system must be simple and easy-to-use and easy-to-understand and compatible with daily scientific practices.



- 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