Dr. Mohga Kamal-Yanni Senior policy advisor to UNAIDS and The People Vaccine Alliance. Key advisor to the NGOs reps at UNITAID Global Health and Access to Medicines

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?**

As an international agreement under an international agency, WHO, the Pandemic Accord PABS can be applied to both Parties and non-Parties in the Nagoya Protocol. According to the Nagoya Protocol *"Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol".* This clause would not prevent a complementary agreement that includes non-Protocol Parties from being included in a Pandemic Agreement. Of course, the additional parties would be bound to the terms of the Pandemic Agreement but not the Nagoya Protocol, though certain Protocol provisions might be referenced or even incorporated. As long as Parties agree to be bound to PABS terms as provided by the new Pandemic Agreement, PABS provisions could be binding on Pandemic Agreement Parties regardless of their not being a Party to the Protocol.

A key issue is that the Pandemic Agreement must ensure that it is supportive of and does not run counter to the objectives of the Convention and the Protocol. As benefit sharing is an essential feature of the Protocol, the Pandemic Agreement must support its objectives. The Pandemic Agreement should accordingly include binding commitments to benefit sharing.

There are important learning lessons from the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines, diagnostics, and other benefits. The Framework includes obligations that ensure both access to pathogens and sharing benefits that are legally binding to all signatories.

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 ?**

Criteria for Parties to CBD and the Nagoya Protocol who are Parties to the Pandemic Agreement

There must be an assessment of the PABS in the Pandemic Agreement vis-à-vis the objectives of the CBD and the Nagoya Protocol, such as the specific genetic resources covered by and the purpose of the Pandemic Agreement. Given that the Pandemic Agreement will include one system for PABS that has to be consistent with and does not run against the Nagoya Protocol, the criteria listed below will apply to signatories of the Pandemic Agreement.

In consistency with the Nagoya Protocol and the CBD, the PABS agreement must:

1. Be "supportive of and not run counter to the objectives of the Convention and of the Protocol." The concept of "mutual supportiveness entails good-faith efforts to negotiate and conclude instruments clarifying the relationship between potentially competing regimes". This is a starting condition;
2. Establish or strengthen inter-Secretariat cooperation including sharing information and joint capacity-building initiatives;
3. Keep the Nagoya Protocol COP/MOP informed of "progress in negotiations; to draft provisions in a new instrument, i.e the Pandemic Agreement, that will specifically cater to mutual supportiveness";
4. The Nagoya Protocol's COP/MOP has to consider the implications of the recognition made by the Pandemic Agreement "based on the criteria adopted and/or decide whether to recognize an international instrument as a specialized ABS agreement";
5. Includes specific obligations to support compliance with domestic legislation or regulatory requirements of the Party providing genetic resources and contractual obligations reflected in mutually agreed terms,
6. Is an intergovernmental agreement;
7. Apply to a specific set of genetic resources (and/or traditional knowledge associated with genetic resources), which would otherwise fall under the scope of the Nagoya Protocol;
8. Apply to specific uses of genetic resources and/or traditional knowledge associated with genetic resources, which would require a differentiated and hence specialized approach;
9. Commit to fairness and equity in the sharing of benefits;.
10. Have "legal certainty with respect to access to genetic resources or traditional knowledge and to benefit-sharing";
11. Contributes to sustainable development,
12. Based on international adjudication which relied on international human rights obligations and standards such as due process, non-discrimination, and proportionality.

Domestic legal arrangements 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

1. In some countries, international agreements immediately and operationally become part of national law, but this is not true in many other countries;
2. For Parties to the CBD/Nagoya Protocol, national mechanisms are needed to ensure that relevant national authorities follow the mutually supportive approach proposed by the Nagoya Protocol

COP/MOP in the context of "negotiations, interpretation and implementation efforts in the Pandemic Agreement";

3. For Parties to the CBD/Nagoya Protocol, national mechanisms to coordinate at the national level the access and benefit-sharing issues addressed in Nagoya Protocol and the Pandemic Agreement;
4. For all Parties, the national laws must have legal certainty about PIC and a clear and transparent process for obtaining PIC and must otherwise comply fully with the requirements of the Pandemic Agreement;
5. National laws need to be adapted to implement both the CBD/Nagoya Protocol and the Pandemic agreement in a mutually supportive manner;
6. National laws need to be adapted to ensure that PIC are well established and implemented in coherence between CBD, Nagoya Protocol and the Pandemic Agreement.

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?**

During negotiations, parties should ensure that the Pandemic Agreement:

- Emphasizes the objective of the Nagoya Protocol, which is "*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, and by appropriate funding, hereby contributing to the conservation of biological diversity and the sustainable use of its components*."
- Recognize that benefit sharing is not limited explicitly or implicitly to the Party where the genetic resources are originally identified or that initially share such resources. To comply with the right to health, the right to the benefits of scientific progress and their application, and the requirements of global public health security, aspects of benefit sharing, particularly adequate, affordable and equitably distributed medical countermeasures, should be made available to everyone, everywhere, in need. Article 8(b) of the Nagoya Protocol should be taken into account in this regard, where it is stated that: *"In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall….(b).Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries;"*

- Ensure legal certainty on benefit sharing by providing an unambiguous basis on which to determine whether actions (particularly related to access) are lawful, thereby protecting against arbitrary use of State power and their capacities to isolate pathogens or generate, share and store GSD of Pathogens. The benefit includes monetary and non-monetary aspects such as products and technology transfer, as a means of benefit-sharing that can build research and innovation capacity for adding value to genetic resources in developing countries. This can thus contribute to public health and the good of humanity.

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?**

Since Article 4.2. of protocol allows developing specialized ABS instruments, and Decision 15/9 on DSI in COP15 also allows for the development of specialized approaches by the other international organizations, it seems that there is nothing in PABS negotiations which would prejudice the negotiations on DSI in CBD forum.

It must be noted that CBD currently is only developing a mechanism for sharing benefits from the use of DSI from public databases, and which is clearly limited by other international ABS agreements and Parties' policy space to maintain their own national ABS systems for DSI. Therefore, as long as PABS identifies specific set of pathogens and specific purposes for which pathogens and their sequence information are shared, there could be no prejudice as to the CBD process.

However, the ongoing discussions on handling DSI within the CBD and the Nagoya Protocol may be prejudiced if the PABS system under negotiation at INB :

- does not commit to legally binding obligations for benefit sharing being at the same level as pathogen access.
- introduce a hierarchy that puts PABS before the Nagoya Protocol obligations.
- Ignores mutual supportiveness with Nagoya Protocol and CBD.
- Does not include obligations on transparency on ABS agreements/contracts.
- Does not include obligations on Standard Material Transfer Agreement that ensures traceability and sovereignty of the material owners.
- Does not include obligations that benefit sharing goes beyond the country that provided the material-for example on technology transfer for regional production.

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?**

The CBD and Nagoya protocol are legal instruments already signed by governments and thus the new Pandemic Agreement should be consistent with them and not contradictory to them. These legal instruments came into being after years of negotiations. Both instruments ensure national sovereignty. Therefore, whether a Party is a signatory to Nagoya Protocol or CBD or not, the actual PABS must be consistent with and not run counter to the objectives of CBD and Nagoya Protocol.

Entitlement to dispute settlement under Article 27 of the CBD is a legal issue requiring legal expertise. However, this possibility could be considered as another reason why the decision whether an international PABS instrument is an SII or not, should be left to the meeting of parties to the Nagoya Protocol. If MOP makes such determinations, then there cannot be any disputes.

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?**

There are several elements that would be inconsistent with and run counter to the objectives of the CBD and the Nagoya Protocol -if the PABS system:

- Does not legally guarantee benefit sharing obligations on the users.
- Ignores PIC, which is an absolute obligation on those wishing to access genetic resources to obtain the consent of the Contracting Party unless that Party waives that right.
- Does not define the scope of pathogens (genetic materials) covered by it and does not specify the purposes for which such pathogens and their GSD are shared.
- Does not include legal obligations to benefit sharing with local communities.
- Undermines accountability and transparency in access and benefit sharing such as allowing for anonymous sharing and use of GSD.

- Does not include clear obligations on primary users e.g. labs and databases and on secondary users including researchers, developers and manufacturers.
- Leaves decisions on benefit sharing to the charitable will of researchers, developers and manufacturers rather than inserting legal obligations on specific sharing of benefits.
- Does not define the benefits to be shared such as technology and products.
- Does not contribute to development and the right to health.

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 ongoing negotiation at the in the Ad Hoc Open-Ended Working Group on Benefit-sharing from the Use of Digital Sequence Information (DSI) on Genetic Resources. The text proposals for the DSI multilateral mechanism were first ever discussed during 12-16th August 2024 and there was no consensus. It is very unlikely that a consensus would emerge in the 16th meeting of conference of parties in October 2024. Currently, there is no proposal on the table to define DSI. CBD multilateral mechanisms can afford to do so, because there are no obligations to share DSI under CBD the Mechanism. DSI is therefore used as a placed holder terminology and nothing more.

PABS text using DSI/GSD/ Sequence Information has no bearing on the negotiations of the CBD. However, what is more important for PABS text is an operational definition of the term the Parties decide to use in Article 12.

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?

A transparent, fair and accountable system must establish the rules that enable sharing biological material including GSD and at the same time prevent potential exploitation of the system by better-resourced laboratories, developers and manufacturers.

The PIP framework sets up an example of how these targets are achieved via obligations to ensure PIC via Standard Material Transfer Agreement 1 (SMTA1) which establishes the rights and obligations of GISRS laboratories. Such contracts establish the rights of both parties: the owner of the material and the primary users and includes regulations on PIC, IPRs, sharing with secondary users, traceability of material, benefit sharing of potential products, dispute settlement arrangements and prevention of abuse.

Moreover, enabling unregulated and unaccountable sharing of GSD with both known and anonymous users, which removes any potential for countries to trace the use of their genetic resources, is deeply problematic. t is critical that "public" database has agreement with the countries that has the genetic source to ensure Prior Informed Consent (PIC) via contractual agreements of (SMTA).

The PABS system must ensures rapid access to information in order to develop relevant products, but it also secures the rights of those who provided the virus information in the first place. This can be done through standardized "templates" of legally binding contracts/agreements that can be quickly signed

without unnecessary delays. If there is a template that is well known and transparent and accepted by relevant stakeholders, it would be easily and quickly signed without hassle.

Practices like unregulated and unaccountable sharing of GSD with both known and anonymous users, which removes any potential for countries to trace the use of their genetic resources, are deeply problematic. Such practices do not comply with international law including CBD, the Nagoya Protocol and are not consistent with the UNESCO Recommendation on Open Science. These issues were highlighted in CBD Negotiations during the August 2nd week. See a CSO letter that critically analysed the proposals made by the Co-chairs of the CBD Ad Hoc Open-Ended Working Group on Benefit-sharing from the Use of Digital Sequence Information (DSI) on Genetic Resources. It is critical that "public" databases which share DSI maintain certain accountability and transparency measures in order to ensure the rights of providers are respected as well as benefit sharing.

Therefore, the INB negotiation must recognize the key problems with the current proposal as described in the CS letter above in order to ensure compliance with CBD, Nagoya Protocol, and the UNESCO Recommendation on Open Science and to protect Parties' rights to their genetic resources while promoting science and research and development.

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

The PIP provides examples of measures to ensure traceability and benefit sharing, while the current proposal of the CBD negotiation provides examples of how to obscure traceability and dilute obligations of benefit sharing. Measures to safeguard traceability can ensure that the use of material is accountable to benefit sharing obligations include:

- Obligation of PIC in SMTA.
- SMTA should include clarity on the benefit sharing obligations related to the use of the material (biological and digital) that the primary user must commit to in making the material available to developers and manufacturers and which will be legally binding on secondary recipients and users.
- Information on the users of data must be available to enable tracing. Anonymous users must not be allowed.
- Users of the GSD databases must sign SMTA 2 with the holders of the database including clear commitment to benefit sharing.
- The Pandemic Agreement must include obligations on users of databases on benefit sharing.

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?**

Positive consequences of PABS system:

- Assurance that manufacturers have legal access to pathogens and GSD in legitimate ways. As Parties sign to PABS that makes their obligation on pathogen access is dependent on sharing benefit, there would be no legal ways for manufacturers to obtain legal access without signing to benefit sharing.
- Manufacturers would contribute to global health and thus gain good PR with their investors, governments and the public. COVID-19 vaccine inequality has stained pharmaceutical companies. The public saw that scientists invented vaccines, pharmaceutical companies made enormous profit and left poor people especially in Africa without access to vaccines.
- The global economy would not be as severely impacted, meaning that governments and individuals would have more money to spend on other health needs to the benefit of manufacturers, non-pandemic health spending, and economies in general.

Negative consequences:
Although pharmaceutical companies claim that PABS system would disincentivize and delay innovation, there is no evidence to support such claim. Standardized agreements that define the obligations of parties, database holders, labs and manufacturers can be streamlined to ensure rapid access to pathogens while securing benefits for people everywhere, including in developing countries. (see above on transparent templates of contracts/agreements).

The proposed % in different versions of the Pandemic Agreement draft is actually too small: 20% for 80% of the world population is grossly disproportionate to need, but at least it ensures that some "at risk groups" in the Global South can have these products at the same time as people at risk in the Global North. During COVID-19, health workers in Africa and many LMICs were waiting for the 1st dose of the vaccine while watching groups at lower risk in the North taking their 2nd dose. The Agreement must guard against this inequality. The percentage of set-aside proposed in the draft Pandemic Agreement should at the very least be increased substantially, though the preferred approach is one that guarantees equitable access for all. This is better achieved via mandatory IP licensing and technology transfer to qualified producers to more rapidly enable adequate. secure, and more affordable and equitable access to VTD and other pandemic-related health products.

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

If Countries approved and signed a fair equitable and transparent PABS agreement that has obligation on Parties and manufacturers, then manufactures would not have other legal ways to obtain access to pathogens. But, more realistically, manufacturers will always have an incentive to engage in pandemic-related R&D for medical products that might be needed in high-income countries that are willing and able both or help subsidize and derisk R&D, enter into advance purchase agreements at risk, and pay commercially attractive and profitable prices. The issue historically is that manufacturers have less incentive to significantly expand manufacturing capacity to meet immediate needs in developing countries and that they can prioritize sales to more commercially profitable procurers.

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?**

WHO Pandemic Influenza Preparedness Framework (PIP Framework) provides a system for access to influenza pathogens of pandemic potential and the sharing of benefits arising from the utilization of pathogen material. It took governments years to negotiate a fairer system than what was there before: companies get free access without any obligations on sharing the benefit of them sharing the pathogen. Free access to pathogen information of COVID-19 (and now mpox) without benefit sharing obligations resulted in huge inequality in access to medical products especially vaccines and diagnostics. What is clear in mpox is that access to vaccines is mainly dependent on companies good will rather than obligations under a global system of PABS.

Therefore, a clear, transparent and legally binding PABS agreement is the way to ensure that researchers, developers and manufacturers access the needed pathogens and with equal importance, people in developing countries do not wait in queues for the charity of those who obtained their genetic resources in the first place.

PABS is also critical as part of other globally legally binding treaties including CBD and the Nagoya Protocol.

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

The triggers depend on the public health needs of a health crisis. A key lesson from the crisis of HIV, Avian flu, COVID-19 and now mpox, is the critical importance of preparedness and of quick response with timely and equitable access to medical technologies including VTD. However, the current crisis of mpox clearly shows that the world is walking into another COVID-19 where vaccines are produced and stockpiled in the Global North while the critical need is in Africa. Moreover, lack of diagnostic tools is impeding prevention efforts, leading to uncontrolled transmission rates.

Therefore, the triggers are:

- An outbreak with a threat of spreading.
- WHO declaring a situation of PHEIC.
- WHO declares a situation of pandemic emergency or pandemic.

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?**

Yes. However, PABS should not only cover PHEIC and pandemic emergency and pandemics but should be able to provide equitable access to vulnerable communities living in outbreak areas, much ahead of outbreak becoming a PHEIC. Prevention of international spread of disease is the major goal of IHR and Pandemic Agreement and therefore it does not make sense to wait for an outbreak to become PHEIC to trigger benefit sharing. The alternative is repeating the huge vaccine inequality of COVID-19. Had COVID-19 been a more dangerous virus (like MERS), millions more would have died in the Global South and only people in the Global North protected. The agreement must prevent inequitable access to medical products during such health emergencies.

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

The duration of benefit sharing should be determined by the time needed to serve public health needs in terms of:

- The duration of the crisis, where countries need to prepare and respond to a pathogen attack.
- Setting up sustainable supply of products as the ending of a global crisis does not mean simultaneous ending in all countries. For example, in 2023, WHO declared the end of mpox pandemic. Yet the infection continued and was rising in DRC. In such case DRC (and countries in similar situations) would continue to need access to VTDs. Sustainable supply is served by sharing technology as part of PABS and removing IP barriers as well as supporting regional production as part of other articles in the Pandemic Agreement.
- It is also critical to consider the importance of the economic sustainability of new regional producers in LMIC regions. This supply is important to self-sufficiency and regional health capacity more broadly. It is also important to surge capacity to produce pandemic-related products quickly and safely. Support from the public sector, donor, and international procurer (e.g., GAVI, UNICEF, PEPFAR, Global Fund) is needed to enable sustainability, and the continuation of production, supply and distribution of pandemic related products even after the formal end of public health emergencies or pandemics.

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?**

The Pandemic Agreement can refer to the Biological and Toxin Weapons Convention perhaps in the preamble as recognizing the obligations to "*never in any circumstances to develop, produce, stockpile or otherwise acquire or retain microbial or other biological agents, or toxins or weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict*". Article 12 can suggest, if necessary, that the shared materials or information should only be used for peaceful purposes consistent with BWC convention.

Further Article 10 of the BWC provides for "*the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes*" and for international cooperation for "*further development and application of scientific discoveries in the field of bacteriology (biology) for the prevention of disease, or for other peaceful purposes*"

Thus, ensuring technology transfer as a benefit sharing component under Article 12 would enhance consistency of PABS with Article 10, BWC.

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"?**

They may be used synonymously but they have different implications.

The "benefits arising from the sharing" refers specifically to the outcomes of sharing pathogen materials and sequence information, involving the direct participants in that sharing process. For example, this includes obligation on database sites and labs to commit to sharing benefits resulting from sharing the pathogen material (biological or GSD). So even though these labs/databases may not produce a vaccine,

they would have to oblige the lab/database users to have obligations to share the products (e.g. a vaccine) with the Parties that shared the pathogen material (biological or digital) in the first place.

The "benefits covered by the PABS system" is a broader term that includes all benefits defined and managed under the PABS framework, involving all parties to the system, and may include additional commitments and benefits beyond those directly tied to material and information sharing.

However, what is critical here is the aim in the Pandemic Agreement to set up a legally binding PABS system that clearly defines the obligations for benefit sharing by all the users of the biological and digital material. The system must cover the benefits arising from sharing the material, both biological and digital information.

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?**

It is important that the PABS system ensures mutual complementarity with the Nagoya Protocol and the Pandemic Influenza Preparedness Framework.

The PIP framework sets up an example of how benefit sharing obligations can be implemented via provisions to ensure PIC in Standard Material Transfer Agreement 1 (SMTA1) which establishes the rights and obligations of GISRS laboratories. Such contracts establish the rights of both parties: the owner of the material and the primary users and includes regulations on PIC, IPRs, sharing with secondary user, traceability of material, benefit sharing of potential products, dispute settlement arrangements and prevention of abuse.

In that way the PIP provides a practical example of how to achieve the objective of the Nagoya Protocol.

The concept of “benefits arising from sharing” as in PIP is explained in question 3.8. and in that sense s broader than the terminology of “benefits arising from the utilization”.

While sharing creates opportunities for others to gain access to knowledge, utilization refers to outcomes /benefits that results from using the shared material. However, the Nagoya Protocol concept of benefits arising from “the utilization" covers any use of the material, which could include research, developing, manufacturing or sharing it with others who can do these activities.

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?**

According to the WTO, international trade is crucial to ensuring access to medicines and other medical products. However, each WTO member is *“free to determine what is necessary to protect its citizens and take the measures it deems appropriate*”. This includes import and export bans, quantitative restrictions on imports and exports, and non-automatic import licensing. However, such measures “*should be applied in a manner that does not discriminate between WTO members and should not constitute a disguised restriction on international trade*”.

However, for the international Pandemic Agreement system to work to protect public health for all Parties during a health crisis, Parties need to work to increase supply of products via actions such as technology transfer, removing IP barriers, allowing export, and investing in regional R&D and manufacturing centers, ideally during preparedness stage. The Pandemic Agreement could and should include terms that bind Parties, irrespective of WTO permissions, to support export of VTDs needed to fulfill benefit sharing obligations.

Although this question does not address WTO rules more broadly, the Pandemic Agreement should. include broader provisions providing for a temporary waiver of WTO TRIPS rules during a pandemic to help facilitate local/regional production that results in expanded supply, more affordable prices, and more equitable distribution.

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?

An APBS system should be a legally binding rule where all Parties have clear obligations to be fulfilled irrespective of under which WHO article it is set up.

Bibliography

The Convention of Biomedical Diversity: https://www.cbd.int/convention
Nagoya Protocol n Access and benefit sharing :*https://www.cbd.int/abs/default.shtml*
https://www.cbd.int/doc/c/0467/f15b/8d9256aea9ae53240e3da979/sbi-03-21-en.pdf
IUCN An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing https://portals.iucn.org/library/efiles/documents/EPLP-083.pdf
The WHO CA+ Discussions on Pathogen Access and Benefit Sharing: State of Play *By Nirmalya Syam** https://www.southcentre.int/wp-content/uploads/2023/12/PB123_The-WHO-CAPlus-Discussions-on-Pathogen-Access-and-Benefit-Sharing_EN.pdf

Klünker, Irma and Richter, Heiko (2022) Digital Sequence Information between Benefit-Sharing and Open Data https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4135144