

PATHOGEN ACCESS AND BENEFITS SHARING

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Objectives Rest

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Pathogen Access And Benefits Sharing: The Fulcrum On Which Equity Objectives Rest?

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Pathogen access and benefits sharing will be a near-fulcrum around which concrete provisions to address equity objectives for future health emergencies could be realized.

New rules in global health on facilitating access to pathogens and the sharing of benefits will likely feature in both - a new Pandemic Accord and in the International Health Regulations.

The form this set of provisions could take is still not clear, with a range of options being discussed including a new dedicated multilateral mechanism to govern PABS applicable to both regimes; as an annex to the Pandemic Accord; as a separate set of rules under Article 23 of the WHO constitution modeled around the Pandemic Influenza Preparedness Framework; and building on existing provisions in other legal instruments.

Irrespective of which form these rules take, the legal effect and the kinds of obligations these rules could result in, will be important in determining not just whether access to information on pathogens will be streamlined. It will have implications for guaranteed access to countermeasures in return for sharing information, promise of greater support for researchers and capacity building in weaker health systems among others.

This story looks at some of these options more closely as discussed also at an intersessional meeting on PABS organized by the INB bureau last month. Do note that some of the analysis is based on existing provisions suggested to the [Zero Draft of the Pandemic Accord](#). A new Bureau's Text of the Pandemic Accord is currently in the works, and is expected to be released on May 22, that might feature additional provisions on PABS.



Image Credit: [Photo by Mikhail Nilov](#), Pexels

WHAT HAS BEEN PROPOSED SO FAR?

Both the proposals to the amendments to the IHR and the suggestions to the Pandemic Accord feature provisions for access to pathogen information and sharing of benefits.

PABS IN THE PANDEMIC ACCORD [ZERO DRAFT]

WHO Pathogen Access and Benefit-Sharing System

Article 10 of the equity chapter is dedicated to the WHO Pathogen Access and Benefit-Sharing System. In one of the more decisive aspects of the Draft Text, a set of provisions dedicated to accessing information on pathogens and sharing resulting benefits have now been fleshed out, that will serve as a basis for negotiation.

It is not clear yet whether detailed provisions on Access and Benefits-Sharing [ABS] will be a part of this instrument, or will it follow in an annex, as many WTO agreements are structured.

The article lays down how information should be shared and suggests that it operate synergistically with other relevant access and benefit-sharing instruments. There is specific language on what should be shared; who shares it; who handles such information; prevailing laws governing such information; the frameworks or contracts that must be place to facilitate such transfer of information [a Standard Material Transfer Agreement focused on PABS].

The Draft Text suggests how benefits resulting from information on pathogens can be shared – such as sharing a percentage of all production of medical products with WHO.

(Also see more here on provisional application of rules: [The Zero Draft of the Pandemic Accord: A Discursive Journey into Equity](#))

The EU has also suggested additional provisions on ABS in a more recent submission to the Zero Draft of the Pandemic Accord. The EU for example has suggested that such rules should be concluded within two years of the instrument coming into force. (See more on this here: [Price Caps, Tiered Pricing, Stockpiling, in the EU's Textual Proposals for Pandemic Accord. Its Imprint on the WHO Medical Countermeasures Platform](#))

IHR AMENDMENTS

Similarly a number of proposals in the IHR suggest amendments to include secure and transparent exchange of genetic sequence data; refer to digital technologies to improve secure global exchange of health data; among others.

WHY DO WE NEED NEW RULES ON PABS?

Several stakeholders believe that the prevailing system of rules has no clear obligations to ensure the access to pathogens and the sharing of information. And hence countries see these on-going negotiations as an important opportunity to craft new rules on these issues specific to global health.

In general, countries and stakeholders are divided on whether the access to information on pathogens should be bartered with ensuring the sharing of benefits on account of providing such information. Largely some developed countries are not in favor of such a “transactional mechanism”, while for developing countries this is a key negotiating chip to guarantee fair access to not only countermeasures, but also to deliberate on issues of sovereignty and agency.

It is widely acknowledged that while samples and information on Sars-Cov-2 were shared during the pandemic, medical countermeasures that were developed using those samples and information were not shared resulting in serious inequities.

Note that the existing version of the Zero draft treats the issue of access and benefits on an equal footing. It is not clear whether this will continue to be so in the coming months. Also, experts have pointed out the access provisions as they stand in the Zero Draft are subject to compliance mechanisms more strongly than provisions to monitor the sharing of benefits (*See Article 22 of Zero Draft*).

While some countries are insisting on obligations on sharing information on pathogens, others are less enthusiastic on signing up to such obligations, particularly in the absence of clear obligations on ensuring benefits. Some even argue that there are de facto obligations to share information already, and caution against additional obligations on sharing information on pathogens. During COVID-19, information has been readily shared, experts acknowledge.

Needless to say, there are several parameters to determine such complex provisions including what constitutes pathogen information, how should it be

shared, in what form, under what circumstances, on the intellectual property implications of such information; and separately, what constitutes benefits and how can states craft obligations on the same. Several experts have also called for transparency considerations in the kind of information shared, how data flows, who owns the data, how is it stored, among other factors.

There are examples from other legal regimes in other forums, that is shaping some of the current deliberations, most notably from the Convention on Biological Diversity.

LESSONS FROM CBD

Speaking at the intersessional briefing on PABS last month, Kathryn Garforth from the Secretariat of the Convention on Biological Diversity said:

“From our experience under the Convention and the Nagoya Protocol, it is vital to have balance between commitment to access on one hand and commitment to benefit sharing on the other. There is a need to create incentives for all countries that participate in the systems that facilitate sharing of samples and data. These incentives come through benefit sharing. And by benefit sharing, I mean the sharing of monetary benefits - yes, but also capacity building, technology transfer, the development of indigenous research, capacity, collaboration on research activities and a whole range of other activities often refer to as non-monetary benefits.

It is only by having some certainty that benefits will be shared that the international community can build the trust needed to improve access to samples and data. We very much understand the importance of rapid access. Our experience, though has been that calls for rapid access and open access are most constructive if they are matched with a willingness and a commitment to share benefits. Without such sharing, open access, can reinforce inequities and create feelings of what's yours is mine, and what mine is mine.”

HOW CAN PABS BE CRAFTED?

Discussions at WHO and outside, are focused on how some of these provisions can be balanced to receive consensus from the widest group of member states.

Some believe that access to information is crucial for surveillance purposes, and to contribute to research and development at the time of emergencies. In return, the sharing of benefits should not only include access to countermeasures developed as a result of information shared, but also access to technology.

Scholars such as Suerie Moon, Co-Director of the Global Health Centre at the Geneva Graduate Institute, who addressed member states during the intersessional briefing, also suggested a committee to negotiate benefits for commercial use of samples or GSD on a case-by-case basis. She pointed to the Oceans Treaty that has established a Access and Benefits Committee. (See [The Biodiversity Beyond National Jurisdiction or the High Seas Treaty](#)). She also cited the weaknesses in the PIP Framework, where pharmaceutical companies while choosing to donate products as contractually obliged, have not chosen to share intellectual property, technology, know-how.

On intellectual property implications, Moon said, “The current limits on the ability to claim intellectual property on samples or data I find quite narrow. So, you cannot patent, for example, they cannot claim intellectual property on data or samples, as they would be shared. However, if you can imagine developing a vaccine, a diagnostic or a drug using the samples or that data, as I understand it, you could claim intellectual property protections on what you develop based on that use. Since you do not have this kind of reach through provision, that would free or ensure an open access to that kind of technology or knowledge in the event of a pandemic.”

[Art 10 (3) of Zero Draft: “(d) Recipients of materials shall not claim any intellectual property or other rights that limit the facilitated access to pathogens with pandemic potential, or their genomic sequences or components, in the form received; and (e) Access to pathogens with pandemic potential protected by intellectual and other property rights shall be consistent with relevant international agreements and with relevant national laws.”]

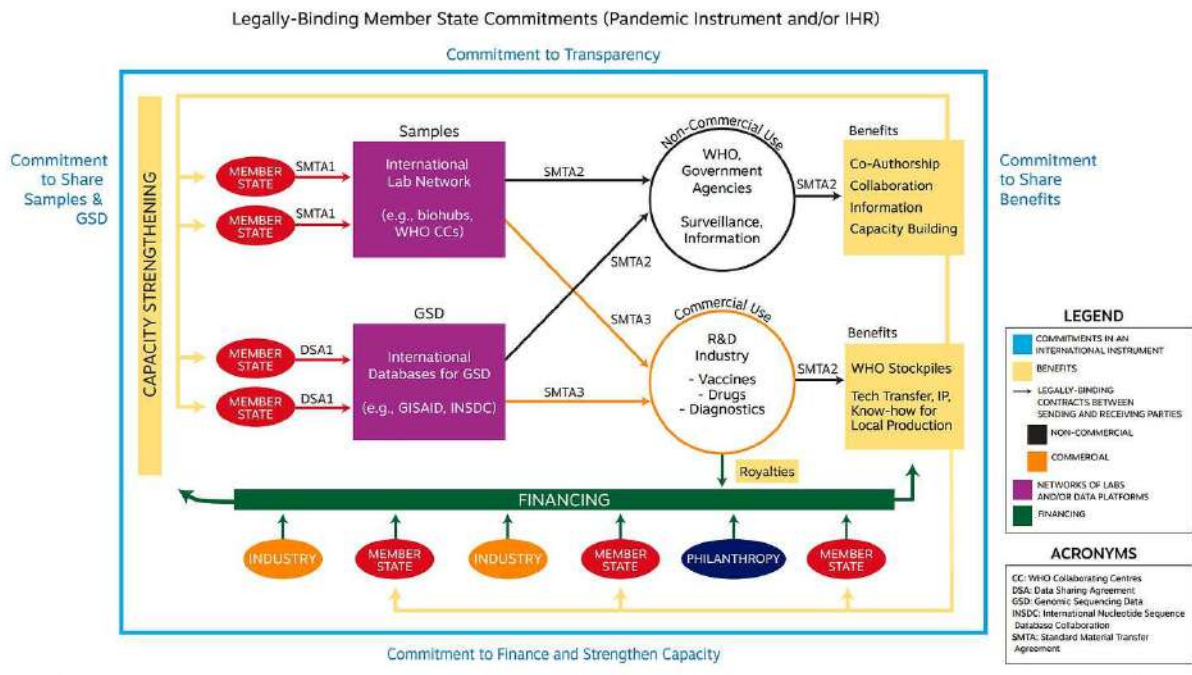
Moon also presented a schematic on potentially how a PABS system can function.

The suggestion foresees a set of commitments for governments including sharing samples, sharing GSD, sharing benefits, committing to transparency, supporting capacity building, providing sustainable financing. One option stated was to establish a multilateral, multi-pathogen system.

More information on how such a mechanism can operate has been described here in a briefing by the Geneva Graduate Institute's Global Health Centre: [*What Are the Options? Pathogen-, Gsd- And Benefit- Sharing In An International Instrument: December 2022*](#)

According to this paper, “The operation of the multilateral system would begin with the Member States sharing the pathogen samples with international lab networks and the GSD with international databases. The samples and GSD could then be shared for non-commercial use under SMTA2 with WHO and Government Agencies for the purpose of information and surveillance. The onward use of that data would be governed through SMTA2 [*Standard Material Transfer Agreement*] and could generate benefits such as co-authorship, collaboration, information and capacity building. Both samples and GSD could also be channelled to commercial actors under SMTA3 for the purposes of countermeasure R&D. The transfer for commercial use under SMTA3 could result in benefits such as commitment to share a certain part of the production with WHO, as well as tech transfer, IP and know-how for local production. It could also result in royalties which, along other streams of funding, could be used to finance the fulfilment of other commitments. Ultimately, the benefits would flow back to the Member States that provide the samples and GSD. The alternatives would be to preserve the status quo of patchwork arrangements, to expand individual instruments or to establish a minilateral (multi-pathogen) system among the likeminded countries.”

Figure 1: "Strawman": Towards Envisioning a Functioning PBS System



Source: Global Health Centre, Geneva Graduate Institute [What Are The Options? Pathogen-, Gsd- And Benefit- Sharing In An International Instrument](#): December 2022

WHAT SHOULD BENEFITS LOOK LIKE?

While these are relatively early days in these negotiations, there are already a lot of questions on the specificity around the kinds of benefits that must flow from the sharing of information on pathogens.

There is appetite among countries and stakeholders to move beyond prevailing non-monetary benefits sharing including academic credits, research collaborations, although such practice should also be standardized and codified under new rules.

(See our earlier interview with Bangladeshi scholar ["The idea of pathogen sharing is based on power dynamics": Q&A with Senjuti Saha](#), September 2021 by Divya Venkatesh)

The current negotiations present a real opportunity to put in place obligations for monetary benefits. But this will be subject to a number of factors, including governance, financing and many other considerations as other legal

regimes show. *(See more below on benefits-sharing on digital sequence information in the context of CBD.)*

To illustrate just how much is at stake when it comes to monetary benefits, Moon explained why this can be so complicated. "...Where things get more challenging is around the commercial benefits....this can be money, it can be intellectual property, it can be sales of products, reduced prices, stockpiles, know-how," Moon said.

Two scenarios were presented: one where a company is able to supply to WHO and affected countries in the event of a small outbreak, and the second, such as the pandemic of COVID-19 with a global demand for medical products, one that cannot be serviced by a few entities. It is in the latter case that technology transfer and related benefits become critical, Moon said. The suggestion is to establish governance mechanism and to have a benefits committee to determine how this could function in the event of an emergency. She also cautioned that while there have been precedents on obliging tech transfer in other forums including at the WTO, these have been difficult to monitor.

It was also pointed out that when an outbreak becomes a large-scale epidemic, the market is enormous and hence it is very difficult to induce technology transfer given the huge upside for companies. And therefore the need for governments to establish rules on benefits, given also that public money funds research and development.

Sangeeta Shashikant, a legal advisor at Third World Network with extensive experience of working on these issues, pointed out at the intersessional meeting, emphasized the need to have a commitment on sharing technology and medical products right at the beginning and not after a crisis has hit. She called on member states to negotiate benefits before contracts become operational.

"It will be too late for a benefits committee to decide when a crisis hits, because we know for a fact, as we have seen [during COVID-19], manufacturers may not agree to sign any kind of agreement at that point. For instance, the manufacturers did not want to commit to contribute to the

WHO COVID Technology Access Pool. So, these are not issues that should be left at the later stage. These are issues that can be determined, as we have seen in the PIP framework, while improving on the contracts...but these are all decisions that have to be negotiated by the WHO membership.”

FINANCING AND INCENTIVES

Another key area countries will address is on financing such a mechanism. Some have suggested a “subscription model” based on user fees.

Incentivizing participation from the private sector to make the PABS system work is another area that is being discussed. Experts highlighted that given the large scale investments by governments such as during the COVID-19 pandemic, the question of incentives, while important, has been addressed to an extent.

At the briefing, Moon said, “...it's public funding that largely pays for R&D prior to an outbreak. This is a good thing; this is what should happen. There is too much risk and uncertainty for the private sector to take this on that's why the public sector takes it on but because there is public money paying for this, this is the incentive. Essentially, governments are paying companies to do this, and you have a number of particularly small and medium enterprises. They are the dominant actors in this area, it is where most of the innovation is coming from and this is where these companies basically many of them rely on government funds. That is their bread-and-butter source of revenue until an outbreak occurs, and they can sell a product and make money. So, I think there are already financing mechanisms and incentives in place for companies to engage in R&D.”

WHAT DOES INDUSTRY SAY?

For the pharmaceutical industry, the rapid access to pathogens is a priority. The industry also believes that pathogens should not fall under the scope of CBD, since the instrument focuses on the conservation of biodiversity. In the context of these discussions it [has lamented](#) the politicization of the sharing pathogens.

(See industry commissioned report: [Global Disease Surveillance and Pathogen Sharing](#); and also [‘Transactional’ Pathogen Sharing Undermines Global Health Security](#): Health Policy Watch)

THE INFRASTRUCTURE OF PABS: THE INTEGRITY OF DATABASES

These negotiations on PABS also bring into sharp focus the role of databases in the system of accessing and sharing information. WHO member states will need to address this in the context of these discussions to improve transparency, accountability and governance mechanisms to undergird the PABS system.

There have been [concerns on the integrity of databases](#), and the protection offered by prevailing systems. Experts are now calling for oversight of WHO member states in these processes before committing on obligations for global sharing of sequence data. Questions on data ownership and permissions will also need to be negotiated.

Some experts point out that while the emphasis on benefits is important, the focus on access conditions is also crucial. There is a price to access, and a number of determinations on what kind of access and the types of information that countries will be obliged to share under these potential new rules.

WHAT NEEDS TO BE RESOLVED?

Some of the most important questions, of the many, facing negotiators, is what constitutes digital sequence information, how should they be governed in the realm of global health.

Also important will be the status of the new set of rules in relation to the Nagoya protocol.

DIGITAL SEQUENCE INFORMATION

In December last year, the Conference of the Parties to the Convention on Biodiversity, [adopted a decision](#) on digital sequence information on genetic resources or DSI, similar to genetic sequence data. CBD experts at the intersessional explained that under this decision, the parties agreed that

benefits from the use of digital sequence information should be shared fairly and equitably. Further, there was consensus to develop a solution for the sharing of benefits arising from the use of DSI. The decision (para 9 & 10) contains criteria that such a solution should meet including that it should not hinder research and innovation and that it should be consistent with open access to data.

The expert from CBD also discussed a multilateral mechanism for benefit sharing from the use of DSI, including a global fund, that was decided by the COP. The [Kunming-Montreal Global Biodiversity Framework](#) sets out a process to further develop and operationalize the mechanism which is to be finalized at the COP's next meeting in October 2024. Work on this process is now under way.

THE IMPORTANCE OF TERMINOLOGY

WHAT IS DSI

In the zero draft of the Pandemic Accord, (a) “genomic sequences” means the order of nucleotides identified in a molecule of DNA or RNA. They contain the full genetic information that determines the biological characteristics of an organism or a virus”. (This definition is already under negotiation among WHO member states)

In comparison, Garforth explained that in the context of the CBD, the COP agreed to keep using the term digital sequence information on genetic resources, but did not define the term. “There isn't an agreed definition of it. So then, what it means, I think, it is up to interpretation,” Garforth said.

She also described that these discussions have progressed in the CBD, also steered by a technical expert group that has categorized different definitions to capture the complexity and breadth of genetic information including related to DNA and RNA, proteins, metabolites and macro molecules, traditional knowledge associated with genetic resources and other biotic factors in the environment.

A broader definition leaves scope for implementation when it comes to sharing of benefits.

Garforth said, “...I can certainly see that a definition of the as it is in the Zero draft which is quite specific, it does give an indication of for the limits of the type of information the use of which would require benefit sharing; whereas with these some of these other broader groups that I have identified as possibly being part of digital sequence information that that could be a broader scope.”

There is also another practical implication that does not favor defining information in such clinical terms. Garforth said, “Certainly, part of our negotiations, there was a very conscious awareness among the Parties, of a desire not to try and start with sub-dividing digital sequence information into different categories, because that is not how the ecosystem of digital sequence information functions in practice in the databases where this information is stored or not distinguishing between different types of digital sequence information coming from different sources, and to be used for different purposes. They tend to be very integrated.”

She therefore underscored the need for consistency in the way such information is treated across instruments and forums. (See more below on the link between the Nagoya Protocol and a potential new system on PABS at WHO.)

BENEFITS-SHARING FROM DIGITAL SEQUENCE INFORMATION

Notwithstanding the somewhat broad understanding of such information, Parties to the COP at CBD have agreed that benefits from the use of DSI should be shared.

Garforth also drew attention to the provisions on benefit sharing in the recently concluded Treaty on Biodiversity in Areas Beyond National Jurisdiction, that also recognizes that the modalities of monetary benefits sharing under that agreement should be mutually supportive of and adaptable to other ABS instruments.

The decision by the CBD COP lays out criteria on what such benefits could look like. For a fair and equitable benefit sharing on the use of DSI, solutions should be efficient, feasible, and practical, Garforth said. It should generate more benefits, including both monetary and non-monetary benefits, than

costs. It should be effective; it should provide certainty and legal clarity for providers and users of DSI. It should not harm research and innovation. It should be consistent with open access to data, she added. There is also language in the decision around capacity building, technology, transfer and technical and scientific cooperation.

A potential establishment of a multilateral approach for benefit sharing from the use of DSI will take into account a wide range considerations such as governance of such a fund; trigger points for benefit sharing; contributions to the funds; the potential to voluntarily extend the multilateral mechanism to genetic resources; questions on the disbursements of monetary benefits; on non-monetary benefit sharing; working with industry and academia; rights, and interests of indigenous peoples and local communities; linkages between research and technology and the multilateral mechanism; principles of data governance among others, Garforth explained.

DSI ACROSS INSTRUMENTS

Garforth from CBD also explained that the COP decision also recognized that any solution for the fair and equitable sharing of benefits from the use of DSI should be usually supportive of an adaptable to other instruments and fora, for recognizing that other forum may develop specialized approaches.

THE NAGOYA PROTOCOL AND A NEW PABS SYSTEM

One of the legal questions facing negotiators at WHO, is also the status of a new set of PABS rules relative to the commitments of states under the Nagoya Protocol affiliated with the CBD.

[The Nagoya Protocol](#) on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity is an international agreement which aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way.

[Article 4 of the protocol](#) addresses the relationship of the Protocol with international agreements and instruments. (This appears to be causing some heart-ache amongst global health lawyers.)

The crux is in defining the “nature” of the other instruments that might be considered a specialized international ABS instrument. Experts suggest that Nagoya Protocol will not apply in so far as “a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol” as per Art 4 of Nagoya.

So, whether a new PABS system will be considered a specialized international instrument (the concept of *lex specialis*), will need to be addressed. Experts say that the Nagoya Protocol accounts for different and special considerations that Parties are to take into account in their implementation of the Protocol. It has been pointed out that the IHR for example has been referred to in the Preamble of the Protocol.

Some believe that a new PABS system could be an opportunity to improve upon how benefit-sharing is articulated for global health. “Nagoya is not great on benefits. So, it should not be referred as a standard while discussing PABS in global health,” one international law expert told us.

THE LEGAL BASIS OF THE PABS

Some countries are seeking an independent multilateral mechanism on ABS, that can be referenced in both the IHR and the INB instruments.

Some legal experts suggest Article 23 of the WHO Constitution for the new ABS mechanism, as opposed to Article 21, that underpins the IHR. (Article 23 is the basis of the Pandemic Influenza Preparedness Framework, often cited as a potential model for a new ABS framework)

We [reported in detail last week](#) on the importance of the legal basis of PABS – what kind of provisions should support such a mechanism, to what extent should it be binding. One proposal is to have a separate set of regulations for PABS, as we discussed [here](#).

Some suggest on agreeing to principles on PABS and to negotiate on the details later. They also point to the interconnectedness of the PABS provisions to other aspects such as on research and development, intellectual property and tech transfer.

Shashikant, from TWN pointed out, "...if you look at the how the PIP framework was negotiated, and the benefit sharing was negotiated, all the details, access and benefit sharing were actually negotiated together and I think this is why we have a rather unique framework. So, I would say that equal footing principle is to be upheld and equity is to be developed. We should actually negotiate the details of access and the details of benefit, sharing at the same time, and not to leave it to be developed at a much later stage."

(While the PIP Framework is being held out as a model for the PABS, experts also acknowledge the need to tighten contracts in the PIP system to ensure better benefits and stronger commitments from the private sector. GSD for example does not feature in PIP contracts.)

TAILPIECE: HOW HISTORY IS RECOUNTED.

It is also interesting to observe how history is recounted. For many, Indonesia withholding samples of H5N1 in 2007, has been a painful reminder of why obligations on access are important.

And for others, they see the episode as a decisive turning point in the way the world talks about access to information and the sharing of benefits.

So, the way you read history, or consume history is very determined by where you are from. This has implications on how countries approach negotiations on PABS.