TWN
Third World Network
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Briefing Paper

February 2021

WHO Executive Board discusses Nagoya Protocol and proposed BioHub

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On January 25th and 26th, the Executive Board (EB) of the World Health Organization (WHO) considered the public health implications of the Nagoya Protocol[1] on access and benefit sharing.

The EB agenda item stemmed from World Health Assembly (WHA) Decision 72(13) taken in 2019. With recent pandemics and major epidemics including of novel influenza, zika, Ebola, and obviously COVID-19, the issue of access and benefit sharing for pathogens is taking on increasing importance on the WHA agenda. The WHA itself will consider the same agenda item when it meets in May.

The EB discussion exhibited a tendency toward North-South divisions, with many developing countries emphasizing national sovereignty over genetic resources and the need for benefit sharing when pathogens and sequence information are collected and provided to the international community, particularly when they are then used to develop commercial products. In contrast, Northern countries tended to gloss over the benefit sharing issue, instead preferring to speak of their insistence that they always be given prompt access to pathogens and sequence information, particularly in unusual disease outbreaks.

The EB talks concluded with remarks from WHO officials that seemed out of step with the positions expressed by many Member States, and unresponsive to the concerns many developing countries raised, particularly in regard to WHO's excessive focus on pathogen access over consideration of benefit sharing. These comments, in some cases, have raised concerns that the WHO leadership is not being accurately advised about the Nagoya Protocol and access and benefit sharing issues.

The core questions

In asserting their demands for fast and unfettered pathogen access, wealthy countries invariably make reference to public health, but the reality of how shared samples and sequence information are used is more complicated, and involves major commercial interests. It is true, of course, that pathogen samples and sequence information are used for non-commercial public health purpose too, but they are also used by companies to develop proprietary and expensive diagnostics, vaccines, and other treatments.

[1] The Nagoya Protocol (129 Parties) implements the third objective of the Convention on Biological Diversity (196 Parties except the United States): fair and equitable sharing of benefits arising from the use of genetic resources.

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And therein lies the controversy – developing countries are providing, for free, materials that are transformed into pharmaceuticals and other items that often are too expensive or simply unavailable for developing countries. This reality has been brought to the fore as many developing countries struggle to obtain products to combat the SARS-CoV-2 pandemic, particularly vaccines.

During the EB discussion, many Member States also asked questions about the WHO Director-General's "BioHub" for potentially pandemic disease samples, proposed for creation in Geneva. The BioHub, which WHO formerly referred to as a "bio-bank", has raised numerous questions about access and benefit sharing related to the Nagoya Protocol. In his reply to the questions, the Director-General claimed the Nagoya Protocol is problematic, and he incorrectly suggested that it mandates long delays in shipment of viruses, and requires negotiation for each one. The reply, whose conclusion contradicted the stated views of many Member States, raised questions about the quality and impartiality of the advice the Director-General is receiving from staff.

What countries had to say

Austria, speaking on behalf of the European Union, first took the microphone. Austria praised the sequence information database GISAID and networks sharing physical virus samples, claiming that such databases and networks constitute a "global public good", which drew a quizzical reaction from some observers.

The "global public good" reference was an odd and awkward claim to advance, especially at this juncture. EU leaders publicly declared at the outbreak of the COVID-19 pandemic that COVID-19 vaccines would also be a "global public good". But instead of affordable access for all, Europe is in a self-centered panic, imposing vaccine export restrictions and fighting over doses with manufacturers and its erstwhile member the United Kingdom. Obviously Europe's pledge did not turn out to be the case as vaccine nationalism, contract disputes, proprietary claims, and other problems have instead made COVID-19 vaccines a proprietary, scarce, expensive, and unequally distributed commodity.

GISAID too is an odd duck to term a "global public good". The Germany-based database, which collaborates with the vaccine maker Sequirus and other companies, including Sanofi's charitable foundation, describes itself as a "public-private partnership". GISAID's user base is heavily private sector, and its user agreement allows companies to use the sequence information that contributors upload, often public health laboratories, in the development of propriety products. While GISAID facilitates public science, it is thus also used extensively by proprietary interests whose products are anything but "global public goods".

Europe's concluding remarks were notable for their ambiguity and included a comment that might be interpreted as a veiled threat. It said that some pathogens "*should not be treated the same way as other genetic resources*" and claimed, without evidence, that "*legal uncertainty on timely access to pathogens*" exists. This alleged uncertainly, Europe further stated, "*could cause delay in access to diagnostics, therapeutics, and vaccines.*"

The charitable interpretation of Europe's remark about impaired access to treatments would be that it is a practically-minded one about timelines. That is, if companies don't have certain pathogen samples then their product development might be slower for technical reasons until they do. In the alternative, the link drawn by Europe between access to vaccines and medicines for developing countries and "timely access" to pathogens and sequence information could be understood as a subtle threat to cut off developing countries from medical supplies.

China noted its sharing of influenza and SARS-CoV-2 isolates and sequence information and, using the language of the Nagoya Protocol, said that a fair and equitable benefit sharing mechanism for pathogens was "urgently needed". In contrast with Europe's endorsement of trying to sidestep the Nagoya Protocol, China emphasized the importance of "respecting sovereignty" and the need to develop pathogen access and benefit sharing approaches in the context of Nagoya Protocol implementation.

Indonesia, a country that played a key role in the development of the successful benefit sharing approach of WHO's Pandemic Influenza Preparedness Framework (PIP Framework) followed. It noted that the WHO Secretariat's report on a survey conducted about pathogen access and benefit sharing contained omissions and selective depictions of the data gathered. By overstating aspects of the study, which had a disappointingly small number of responses, especially from Member States, WHO earned Indonesia's advice to "be careful" about how it depicted the results. On the basis of the limited information provided in the Secretariat's paper, Indonesia noted that it "could not confirm the validity of the results."

Indonesia noted the importance of the Nagoya Protocol and national sovereignty for sharing of pathogen samples. On the potential development at WHO of new pathogen access and benefit sharing mechanisms, Indonesia was of the opinion that "*such mechanisms should be done through an intergovernmental process with active and inclusive participation of Member States*".

The United States, which only days before had announced it would reverse its plan to leave the WHO, then briefly intervened. True to Northern form that emphasizes access to pathogens over benefits sharing, the US said that "*rapid sharing of pathogens, clinical materials and information, including genetic sequence data … is critical for surveillance, rapid development, and deployment of diagnostics, therapeutics, and vaccines*…" What the US did not mention is that those diagnostics, therapeutics, and vaccines that depend on pathogen sharing are typically proprietary products with price tags that developing countries often cannot afford, if they are available at all.

Where the US position was more widely consonant was its expression of caution, and request for more information, about the Director-General's proposed BioHub. The US said it wanted to know what gap(s) the BioHub sought to cover, and said "*We caution that this is a complex issue to navigate in normal circumstances let alone* [in] *a severe pandemic.*"

In particular, the US signaled its concern about "biosecurity" issues in relation to the BioHub. As the facility is proposed to be located at a well-protected Swiss government laboratory, the US concern is unlikely to be about the physical security of samples in Geneva. Rather, the US reference to "biosecurity" here is a reference to its national export control law and the Australia Group system, an informal network of governments, dominated by developed countries, that cooperates to limit access to pathogens (and other items) for some countries on grounds of national security concerns.

Most developed countries are members of the Australia Group, and those governments may be seeking the creation of a double standard at the WHO facility, in which WHO and its BioHub host Switzerland (itself an Australia Group member), will not treat all Member States equally in their access to deposits at the BioHub, and will deny samples to some governments but not others. Such practices would be difficult to reconcile with the principles that underlie global public health efforts and the operation of the World Health Assembly.

Ghana, on behalf of Africa, emphasized the importance of the Convention on Biological Diversity (CBD) and its Nagoya Protocol and reiterated that sovereign rights over genetic resources, including pathogens, means that there a need for users to obtain prior informed consent of the providing government and for there to be mutually agreed terms for benefit sharing.

Africa was disappointed that "*pathogen and sequence information sharing for public health has often lacked fairness and equity,*" and noted that treatments developed from pathogens and sequence information were frequently patented, in limited supply, and sold at monopoly prices – a description that certainly applies in the present pandemic. Noting WHO's recent establishment of a COVID-19 laboratory network, Africa asked what its benefit sharing terms were.

Africa sought more information about the BioHub and expressed caution, saying that Member States should evaluate the merits of the proposal, and how it would protect sovereign rights and address benefit sharing. Africa did not think this was the time for the EB to draw any major conclusions on the issue of pathogens and benefit sharing.

The United Arab Emirates, on behalf of the Eastern Mediterranean region, noted the importance of virus sharing during public health emergencies and emphasized the need for more benefit sharing. In this regard, it noted that the CBD and Nagoya Protocol are legally binding and emphasized the need for Members to take steps to more equitably share benefits from pathogens through their "*legislative, administrative, and policy measures*" to implement the Protocol.

Bangladesh saw the WHO Secretariat's report as excessively focused on pathogen sharing to the detriment of properly discussing benefit sharing. It agreed with other developing countries on the importance of the Nagoya Protocol and the principles of prior informed consent and fair and equitable benefit sharing. Bangladesh saw the PIP Framework as a useful example of how a WHO approach can offer transparency and governance for pathogens and benefit sharing while upholding the CBD and Nagoya Protocol.

Bangladesh thought the report should have more information on benefit sharing, including how WHO's existing laboratory networks distribute pathogens and ensure benefit sharing. It also noted the need for a better understanding of the prevalence and impacts of intellectual property claims related to shared pathogens and sequence information, including on diagnostics, vaccines, and pharmaceuticals.

Bangladesh further requested information on how national "biosecurity" and export control laws impact pathogen sharing. In conclusion, it noted that Member States should lead any WHO effort to develop policy options and suggested that, in addition to further information on the issues it noted, that an intergovernmental working group could be a possible way forward.

Argentina placed implementation of the Nagoya Protocol squarely at the center of benefit sharing for pathogens and sequence information. Argentina said its law to implement the Nagoya Protocol incorporates concerns about public health emergencies while simultaneously ensuring benefit sharing. Argentina was not concerned that access and benefit sharing laws create too much bureaucracy, and said that its own regulatory framework concretely demonstrates that access to pathogens can be swift while ensuring fair and equitable benefit sharing.

Like Bangladesh, Argentina felt the WHO discussion was too focused on access to pathogens and not enough on benefit sharing. It also made reference to the success of the PIP Framework as an example of how benefit sharing can help developing countries.

Argentina said that any new move should be made by Member States and be undertaken in light of Article 4.4 of the Nagoya Protocol, on Specialized International Instruments for access and benefit sharing. Argentina said the genetic resources covered in the scope of any WHO effort needed to be specifically defined and that, in accordance with Article 4.4, the overall agreement must be consistent with, and not contrary to, the objectives of the CBD.

Like the rest of the North, **Canada** unsurprisingly emphasized rapid sharing of pathogens, and devoted most of its intervention to the BioHub proposal. Canada had an interesting question for the Director-General. It wanted to know about the scope of the BioHub's planned functionality. Would it, Canada asked, include the activities of genome sequencing and analysis?

Canada echoed US national security concerns, but also implied a greater willingness to discuss benefit sharing when it said that there should be Member State consultations on the BioHub, including "*on its scope, proposed material transfer agreements, access and benefit sharing plan, and safety and security considerations of both the facility and pathogen transfers…*" Canada requested that this be available before the WHA in May.

Switzerland noted that the Nagoya Protocol does not obligate countries to place conditions on access on pathogens, thereby suggesting that Members might want to freely share pathogens without asking for any benefit sharing in return. The somewhat tone-deaf Swiss suggestion might obviously be more attractive to a very wealthy nation such as itself that is the headquarters and a research and development center for many

biomedical companies … rather than a developing country struggling to locate and pay for essential vaccines and other supplies.

Switzerland said that consultations with Member States and other international organizations were "very important" on the issue of pathogens and benefit sharing. It then said that it is a partner in the BioHub that has been announced by the Director-General but has not been the subject of consultations.

Sending more mixed messages on process, Switzerland referred to the BioHub as if it were a decided matter, saying the it "will" be voluntary, at least "initially", a remark suggesting that Switzerland has a longer term goal to make participation mandatory, a goal that raises conflicts with the Nagoya Protocol. After referring to the BioHub's establishment as a *fait accompli,* Switzerland doubled back and said a "*formal framework … will be developed in close consultation with Member States,*" without offering any details on the form, timing, and breadth of the participation that it envisages in this "*close consultation*".

Brazil returned the discussion to focus on the Nagoya Protocol. It noted the near universality of the CBD and that most WHO Member States had ratified the Protocol, to which they had dedicated a decade of negotiation to reach a carefully balanced internationally-agreed approach for access and benefit sharing. It said WHO could not take the obligations of the Nagoya Protocol lightly and that the CBD and Nagoya Protocol were not hindering sharing of pathogens.

Brazil was concerned, however, about a lack of benefit sharing for pathogens, and encouraged WHO to "*delve into the reasons why regular sharing of samples and pathogens have not resulted in affordable and efficacious medical countermeasures…*" It concluded saying that while timely sharing of pathogens for public health purposes is important, that it should "*take place in conformity with each country's sovereign rights over their genetic resources*."

Japan concluded interventions by Members with an unsurprising endorsement of the importance of pathogen sharing. It then offered some confusing observations about "global public goods". Japan said that the "health benefits" that stem from virus sharing are "global public goods," without reference to the fact that the goods whose development relies on virus sharing – diagnostics, vaccines, and therapeutics – are proprietary, scarce, and high priced. Like Europe, Japan awkwardly stretched credulity by seeming to claim that these scarce, patented and unaffordable health products were, somehow, "global public goods".

Japan called for a WHO-led mechanism for "rapid and equitable" sample sharing in response to public health emergencies, but it said this should be "outside the scope of the Nagoya Protocol." The latter bit is difficult to make sense of, however, since pathogens are unequivocally inside the scope of the Nagoya Protocol, and Nagoya Protocol Parties are required to share benefits from their use. Was Japan's proposal for the WHO to go "outside" the Nagoya Protocol a proposal to not share benefits? Japan's meaning was not clear.

In reality, as explained by Argentina, any new international instrument developed by WHO on pathogen access and benefit sharing would need to fit Article 4.4. of the Nagoya Protocol, on specialized international instruments. That means that any WHO effort needs to be consistent with and not contrary to the CBD and Protocol's aims. Japan's intervention thus appeared to reflect a rejection, or perhaps lack of understanding, of the Protocol concluded on its own soil.

The EB consideration concluded with comments from WHO leadership.

WHO's Chief Scientist, Soumya Swaminathan, began by recounting details of the conduct and outcomes of WHO's survey on pathogen access and benefit sharing, which was the source material for a large proportion of the Secretariat's report for the meeting. Swaminathan largely reiterated information found in the report and did not respond in a substantive and detailed way to the concerns about selectivity and lack of detail in the report that were raised by Member States in the preceding discussion.

A reply that was one apparent reaction to criticism that the report excessively focused on pathogen sharing and not benefit sharing, was that "*21 of the 43 questions* [in the survey] *were about the implementation of access and benefit sharing arrangements, so we did try to keep a balance between pathogen sharing and access and benefit sharing, which many of you have pointed out*." But the criticism was not of the questions in the survey but rather WHO's editing and presentation of the result.

Of course pathogen sharing is the "access" part of access and benefit sharing and not a distinct item from it. That is, countries provide access ("pathogen sharing"), and negotiate benefit sharing in return. What meaning Swaminathan intended when she drew a distinction between "pathogen sharing" on the one hand, and "access and benefit sharing" on the other was quite unclear.

Swaminathan claimed that there was "a good regional representation" of survey respondents that identified themselves as Member States, but there were only 21 such respondents. She termed the survey a "qualified success" but admitted it was difficult to draw conclusions on such limited data, even though the report did so. She did not explain why the Secretariat did not enumerate that different types of respondents – governments, companies, academics, etc. – in its presentation of the data, and disaggregate the results between groups, rather than lumping them all together.

Swaminathan said that the comments from Member States about the need for more consultations – with and among Member States - were "*very well taken*." She then said that "*further work will definitely continue to be balanced*," despite the fact that a number of Member States had just observed that the work output was imbalanced and excessively focused on access to pathogens.

Thus what WHO's practical response will be to calls for more government involvement in development of options, and greater balance in emphasis was unclear.

Sylvie Briand, WHO Director of Pandemic and Epidemic Diseases, then offered more information about the BioHub. Echoing Switzerland, Briand described the BioHub as "*voluntary, at the beginning*", a comment that again begged questions about the apparent intent of BioHub supporters to create what will become a binding agreement – without a mandate from the World Health Assembly and in a far less than fully participatory forum. Briand said that in the coming months there would be "*a pilot, or demonstration project*" to assess the idea. Rejecting immediate involvement by more Member States, Briand asked for the Executive Board's patience while the unidentified group developing the hub moved forward with "*technical aspects.*"

On benefit sharing, Briand said that WHO began with technical aspects *"because somehow it's easier, but this benefit sharing will obviously be tackled in due time."* She did not say when and by whom but when she returned to the subject at the end of her remarks, Briand said WHO "hoped" that benefit sharing discussion including Member States would begin "*in the coming weeks*," without more detail.

In a surprising and inexplicably inaccurate observation, Briand also claimed, incorrectly, that there is no clear commercial aspect associated with sharing pathogens at the beginning of a pandemic. This assertion by the senior WHO official is, unfortunately, simply untrue. For example, very early West African Ebola epidemic viral isolates – from clinical samples collected before Ebola was even fully confirmed as the cause of disease – have proved critical to development commercial Ebola treatments, including the first approved monoclonal antibody drug to treat Ebola disease, Inmazeb, made by the US company Regeneron.

With COVID-19, several vaccine and diagnostic makers immediately moved to capitalize when SARS-CoV-2 sequence information was being posted on the internet at the outset of the present pandemic. The US company Moderna boasted of creating its vaccine from pathogen sequence information in about two days. Another vaccine company, Inovio, said it used sequence information to make a vaccine in only a few hours. Research and development contracts and product orders for these vaccines now total several billion US dollars.

There is simply no question that early emerging samples of novel potentially pandemic pathogens, and their sequences, often have potentially huge commercial value. Why the WHO leadership is asserting otherwise is a very difficult to understand.

To end the discussion, the WHO Director-General Dr Tedros Adhanom Ghebreyesus offered brief comments. In addition to Switzerland, he said Thailand, Italy, and South Africa had joined the BioHub "voluntary program".

Raising concern that the Director-General is being poorly advised on the Nagoya Protocol, his comments reflected an incomplete understanding of the wide variety of potential access and benefit sharing arrangements that are consistent with and supportive of the Nagoya Protocol, including multilateral arrangements. In his remarks, Tedros notably did not make reference to the obvious and successful example of the Nagoya-compliant standard material transfer agreements used by WHO's own PIP Framework, which has raised US$200 million for WHO public health efforts. Instead, Tedros reflected an understanding of Nagoya dominated by a negative caricature. He contrasted the "simple" BioHub that he envisions against a distorted vision of the Nagoya Protocol that Tedros incorrectly understands to be inherently excessively complicated for every virus transfer, inalterably bilateral, and unable to permit rapid pathogen sharing.

The Director-General unfortunately remarked "*if you take the Nagoya Protocol, all the complexities, including the sharing and so on … that will be for the regular sharing, but this BioHub will be for a very specific category as part of pandemic preparedness. And the sharing of benefits, of course it has to be outlined properly, but it's the benefit that all countries get by preventing epidemics or controlling an outbreak as quickly as possible. So there is the global benefit. So on the BioHub we see it in relation to the common good, the common benefit, rather than country by country.*"

Of course many of the perceptions that appear to underpin the Director-General's remarks are misunderstandings. But the biggest concern about how the WHO leadership sees the issue is that, even as WHO-led efforts to secure access to COVID-19 vaccines and other items for developing countries are faltering due to WHO's weak hand, the Organization still does not seem to understand how its endorsement of attempts to abnegate national sovereignty over potentially pandemic pathogens will only help perpetuate the weakness that has characterized the global public health response to this pandemic. And result in future failure.

Rather than understanding the Nagoya Protocol and national sovereignty as tools that, when harnessed for public health in efforts like the PIP Framework, can make large contributions to public health through concrete and substantial cash and other benefit sharing, the leaders of the WHO appear to have been poorly advised to treat the Nagoya Protocol as an enemy. If this poor judgement persists, the result will be that WHO's leadership will encourage the continued misappropriation of pathogens and their sequences to make proprietary products that are expensive and inequitably available. That is, by supporting efforts to undermine developing countries bargaining power, WHO could wind up harming, rather than helping, global public health, and harming access to treatments for infectious disease in developing countries in particular.

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