Notice and Request for Comments on the Implications of Access and Benefit-Sharing (ABS) Regimes on Global Health and Biomedical Research

US Department of State [Public Notice: 10789]

Submission by the GISAID Initiative

GISAID's Submission to DOS Notification 10789

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The Global Initiative on Sharing All Influenza Data (GISAID) appreciates the invitation by the U.S. Department of State (DOS) to comment on the effects of the Nagoya Protocol and other ABS implementation on public health systems.

On the eve of the 72nd annual World Health Assembly, GISAID commented on a WHO Report on the 'Public Health Implications of Implementation of the Nagoya Protocol', highlighting recent problems around sharing of seasonal influenza viruses, the consequences of delays in virus sharing, and the connection to the discussion at the Convention on Biological Diversity. GISAID respectfully submits these comments at the end of this document, to provide critical evidence for the discussion on the implications of ABS regimes on Global Health and Biomedical Research.

Previously, GISAID responded to an invitation by the CBD Secretariat to comment on any potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention and the Nagoya Protocol, as communicated in notification 2017-37 (see https://www.cbd.int/abs/DSI-views/GISAID-DSI.pdf). A subsequent peer-reviewed fact-finding and scoping study on digital sequence information on genetic resources in the context of the Convention on Biological Diversity and the Nagoya Protocol, found *'GISAID might provide useful lessons and insight to ABS discussions*', highlighting key advantages of GISAID's sharing mechanism and a fair and equitable benefit-sharing resulting from access to data (see CBD/DSI/AHTEG/2018/1/3).

There is a huge collective global benefit of robust influenza virus surveillance which is achieved in part through the sharing of all influenza GSD in a timely manner. Further examples of monetary or non-monetary benefits to the global public health system resulting from the sharing of GSD and/or relevant metadata through GISAID, defined in the 'Annex - Monetary and Non-monetary Benefits to the Nagoya Protocol' include but are not limited to:

1. Monetary Benefits:
   (i) Joint ventures;
   (j) Joint ownership of relevant intellectual property rights.

2. Non-monetary Benefits:
   (a) Sharing of research and development results;
   (b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;
   (d) Collaboration, cooperation and contribution in education and training;
   (e) Admittance to ex situ facilities of genetic resources and to databases;

(continued on next page)

Non-monetary Benefits (continued):
(f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
(g) Strengthening capacities for technology transfer;
(h) Institutional capacity-building;
(j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;
(k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
(m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources; (n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
(o) Food and livelihood security benefits;
(p) Social recognition;
(q) Joint ownership of relevant intellectual property rights.

GISAID remains committed to the timely, ethical, equitable and transparent sharing of influenza data, and willing to assist the US Department of State in its deliberations on this important topic.

GISAID's Comments on the WHO Report of
The Public Health Implications of Implementation of the Nagoya Protocol

The Report[i] on the "*public health implications of implementation of the Nagoya Protocol*" raises a number of major concerns. While the Report speaks about '*principles of global public health'* enshrined in the Constitution of the World Health Organization (WHO) it does not state one of its key objectives that is *"… to eradicate epidemic, endemic and other diseases;"*[ii]. (see No.8)

From the outset, and throughout, the Report appears to assume that the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization* (NP) is a gain for pathogen sample-sharing and public health, without providing any substantive support for this viewpoint. This is concerning since it represents a fundamental misunderstanding about how 'access and benefit sharing' under the NP was conceived, and how it has been applied to other (non-pathogenic) genetic resources.

The NP is a supplementary agreement to the *Convention on Biological Diversity* (CBD), an instrument that was originally designed to conserve and sustainably use the components of biodiversity, equitably and fairly. The CBD reaffirms that nations have sovereignty over their genetic resources and encourages them to implement domestic laws to regulate access to those resources. The CBD states (and the NP reaffirms) that access to genetic resources shall occur with the prior informed consent (PIC) of the originating country and on mutually agreed terms (MAT) by the provider and user. This 'access and benefit sharing' mechanism of bilateral exchange between provider countries and user parties was supposed to generate benefits to channel into environmental conservation efforts, but after more than 25 years this goal has yet to be realized.

Needless to say, 'access and benefit sharing' as developed under the CBD is oriented towards extremely different goals than the exchange of pathogens that the world shares for scientific purposes and emergency response, but would probably rather see eradicated. The exchange of pathogens involves time pressure, and global cooperation, neither of which is typical to the exchange of genetic resources envisioned under the CBD.

The Report does not consider the incompatibility of the objective of the CBD to conserve biodiversity and WHO's mandate to eradicate disease, and whether the Nagoya Protocol on access and benefit sharing actually has a great deal to offer the public health community in the way of guidance on how to develop timely pathogen sharing systems, and benefit sharing.

The Report also does not adequately reflect the range of views expressed by WHO Member States (MS), or the literature, including the CBD's own peer-reviewed fact-finding study[iii] on these issues, e.g. the CBD commissioned study. The Report refers instead only to Pandemic Influenza Preparedness (PIP) Framework Q&A and Secretariat's comments on the CBD study, and other documents the Secretariat has produced.

The overall impression of this Report is that it seeks to make a particular argument, rather than a balanced and accurate reflection of the views expressed on numerous occasions over the last few years by the MS. For example:

> '… *the report by the Secretariat on the public health implications of the implementation of the Nagoya Protocol (document EB140/15), which was noted by the Executive Board at its 140th session in January 2017. …. A central conclusion of that report was that the Nagoya Protocol has public health implications, and that these implications include opportunities to advance both public health and principles of fair and equitable sharing of benefits*.' (see No.2)

Those having followed MS deliberations during EB144 will recall that some MS expressed concern, calling for a more thorough and far-reaching review of issues about advancing public health through the NP.

While this Report strongly suggests the NP provides '*an opportunity to advance public health*', it does not consider the significant risks and that indeed there have already been significant delays in the sharing of seasonal influenza virus samples associated with implementation of the Nagoya Protocol. In late 2018 alone, several cases involving delays in sharing influenza viruses emerged, comprising national influenza centers in Southeast Asia and South America with a long-standing record of timely sharing as required under the terms of reference in the Global Influenza Surveillance and Response System (GISRS). Those national influenza centers found themselves having to delay the sharing of influenza viruses due to conflict with national legislation on ABS arising from the recent implementation of the NP and consequently missed the timing for the seasonal vaccine composition meeting.

A similar situation occurred in Europe as well, where WHO Collaborating Centers of GISRS experienced a delay of 3 months before a candidate vaccine virus, falling under France's NP legislation, could be shipped to manufacturers. In another case, in Switzerland, there was a delay of 3 weeks in the ability to use a WHO recommended candidate vaccine virus for manufacturing due to a lack of clarity of the consent process to be followed and who the "user" of the strain was; furthermore, it was not clear whether seasonal influenza fell under the scope of Swiss ABS legislation or not. The Swiss case should have been a "best case", as no benefits were required for sharing, neither PICs or MATs; nevertheless, a delay ensued.

The selection of influenza viruses for the seasonal vaccine is a time sensitive process. For example, the recent delay of 30 days in selecting one of the vaccine strains will likely cause a delay in the flu vaccine supply for the 2019-2020 Northern Hemisphere season. Any delays in virus sharing will have a negative impact on the ability to ensure the "best-matched" and "best-suitable-for-production" viruses are selected for the vaccine and timely vaccine supply.

It can be argued that, considering the recent delay in countries from various regions in sharing seasonal influenza viruses, the GISRS network is in danger of losing its long-established quality traits: timeliness and comprehensiveness, which is critical not only to ensuring the best-matched vaccines are developed, but also to detect emerging pandemic influenza strains in time.

The access and benefit sharing principles of the CBD and NP should not incentivize countries to restrict access to their pathogen samples in order to leverage a financial benefit from their use. This is not a practice that the WHO should be encouraging, particularly since for decades WHO has convened meetings, produced literature, and facilitated the creation of global systems that share benefits in ways that best serve the goals of public health – e.g. sharing of pathogens and development of medical countermeasures etc. Access to medicines should not be linked to the provision of pathogen samples.

Unfortunately, the Report over-emphasizes the opportunities of the NP while omitting its potential risks to public health. The Report avoids to address concerns expressed by MS and stakeholders in a balanced way and lacks focus on the WHO's mandate to '*eradicate epidemic, endemic and other diseases*'. It is likely to fall short in providing MS with a clear view on the problems and possible solutions commensurate with WHO principles.

Instead, the Report states: '*The Protocol has the potential to increase equity, promote trust, and improve both access to pathogens and their benefits…*' (see No.6) and goes on to emphasize the critical importance of '*timely sharing of pathogens*' at various points, implying that the NP will somehow assist with making pathogen sharing timely and benefit sharing fair. The CBD and NP have been largely unsuccessful in achieving their goals when it comes to non-pathogenic genetic resources, making it difficult to imagine how the NP will turn access and benefit sharing into a successful mechanism for the sharing of pathogens, and the Report provides little in the way of detail in this regard.

Implementation of the NP is in the early stages, and policy makers are still working through many challenges. For example, exploration of issues associated with accessing and sharing Genetic Sequence Data (GSD) (referred to as Digital Sequence Information, or DSI, within the CBD), and associated benefit sharing, are in their infancy within the CBD and NP policy process. The '*multilateral mechanisms'* the Report refers to (see No.13) are a vague concept at present within the NP, promoted by some, opposed by others, but fully unexplored by all, and certainly not a panacea.

To be clear, MS and other stakeholders fully support fair and equitable sharing of benefits associated with the sharing of pathogens, but do not think that the NP, however well intentioned, is the most effective model for how the public health community should do this. If anything, other public-private partnership models, where MS and scientists collaborate on practical solutions, such as initiatives like GISAID, are farther along in practically realizing the goals of fair and equitable sharing from GSD and genetic resources than the NP. It is not even clear, based on CBD presentations and publications, that the CBD policy process views the NP as an important element of benefit sharing associated with public health. Indeed, when pathogens and public health arise within CBD access and benefit sharing discussions it is usually to emphasize the importance of not risking the timely sharing of critical samples and data.

We applaud the WHO Director General for his substantial commitment to improve WHO's capacity to promote health research[iv] and for raising the important issue of access to pathogens and benefit sharing. We sincerely hope that MS will be provided ample time within their countries to fully understand and address risks posed by the Nagoya Protocol to pathogen sharing and public health, and that this issue is the subject of reasoned and vigorous public discussion.

We hope that the Director General will consider a more thorough and far-reaching review of these issues.

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[i] Seventy-Second World Health Assembly | Provisional agenda item 12.10 (A72/32) Report on the public health implications of implementation of the Nagoya Protocol | 18 April 2019

[ii] Constitution of the World Health Organization | *United Nations* | Article 2.g | 22 July 1946

[iii] Peer review of the fact-finding and scoping study on digital sequence Information on genetic resources in the context of the Convention on Biological Diversity and the Nagoya Protocol | *CBD Secretariat* | 12 January 2018

[iv] How to shape research to advance global health | *Nature* | doi: 10.1038/d41586-019-01235-1 | 25 April 2019