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CONFERENCE OF THE PARTIES TO THE
CONVENTION ON BIOLOGICAL DIVERSITY
SERVING AS THE MEETING OF THE PARTIES TO
THE NAGOYA PROTOCOL ON ACCESS TO
GENETIC RESOURCES AND THE FAIR AND
EQUITABLE SHARING OF BENEFITS ARISING
FROM THEIR UTILIZATION

Second meeting

Cancun, Mexico, 4-17 December 2016

Agenda item 8

**IMPLEMENTATION OF THE NAGOYA PROTOCOL AND PATHOGEN SHARING: PUBLIC
HEALTH IMPLICATIONS**

1. At the request of the Government of the United Kingdom of Great Britain and Northern Ireland, the advance Executive Summary of the study by the World Health Organization (WHO) entitled *Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications* is made available for the information of participants in the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol.

2. The Executive Summary is an advance copy, made available for information purposes only, and it does not prejudice any discussions of the Executive Board of WHO. While the advance copy is available in English only, the final document will be made available in all official languages of WHO.

Pending translation of this document into all official WHO languages, this is an advance copy of the document for the 140th session of the Executive Board.

Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications

Study by the Secretariat

Executive Summary

The Executive Board at its 138th session in January 2016 considered the report of the First Meeting of the Review Committee on the Role of the International Health Regulations (2005). During the discussions,¹ it was agreed that the Secretariat would prepare a study, for presentation to the Board at its 140th session, in order to analyse how the implementation of the Nagoya Protocol might affect the sharing of pathogens, and the potential public health implications. The full report by the Secretariat will be made available, in all six official languages, on the WHO website.²

This summary contains a brief statement of the methodology employed, background information, key findings and main considerations and options. It is intended as an aide to Member States in their consideration of the full report.

Methodology

Preparation of this analysis involved a multi-pronged approach to information-gathering, which included a call for written responses to key questions to all Member States, through their health and environmental sectors, and to stakeholders, as well as in-person and telephone interviews with relevant stakeholders and experts. In addition to relevant internal units of the Secretariat, various international organizations, including the secretariat of the Convention on Biological Diversity and FAO, were also consulted.

Background information

The Nagoya Protocol is a supplementary agreement to the Convention on Biological Diversity, which has as one of its main goals the fair and equitable sharing of the benefits derived

¹ See document EB138/2016/REC/3, summary record of the second meeting, section 1.

² See <http://www.who.int/influenza/pip/2016-review/en/>.

from the use of genetic resources.¹ The Protocol expands on the Convention's access and benefit-sharing provisions, aiming to create a global framework for the development of access and benefit-sharing instruments for genetic resources.

The Nagoya Protocol applies to genetic resources, and traditional knowledge associated thereto, that are covered by the Convention on Biological Diversity, and to the benefits arising from their utilization. Under the Protocol, genetic resources may be accessed subject to the "prior informed consent" of the country providing the resource, if it so requires, and once "mutually agreed terms" have been reached that include the fair and equitable sharing of benefits arising from the utilization of the concerned genetic resources.²

The Nagoya Protocol lists in its annex many benefits supportive of public health, such as technology transfers and collaboration in scientific research, which could be implemented by Parties through mutually agreed terms.

While the Nagoya Protocol sets out broad principles, such as prior informed consent and mutually agreed terms mentioned above, the details of implementing them are left to domestic legislation. In that implementation, it will be important for Nagoya State Parties to consider how to address access to pathogens, especially during public health emergencies. These decisions taken by parties on their implementing legislation for the Protocol may, individually and in the aggregate, have an impact on public health.

The public health response to infectious disease relies on ongoing surveillance, timely risk assessment, implementation of public health control measures, and broad and equitable access to medical interventions, such as vaccines and medicines.

In the context of influenza, for example, monitoring the evolution and spread of viruses, and responding to outbreaks is a continuous process, requiring constant access to samples of circulating influenza viruses. This involves the sharing of thousands of influenza virus samples every year, from as many countries as possible, with the Global Influenza Surveillance and Response System, a WHO-coordinated global network of laboratories. Based on these samples, laboratories of the Global Influenza Surveillance and Response System can then conduct risk assessment, monitor the evolution of seasonal influenza activity as well as the pandemic potential of novel influenza viruses, and

¹ Convention on Biological Diversity art. 1, *entered into force* 29 December 1993, 1760 U.N.T.S. 79. Text available at: <https://www.cbd.int/convention/articles/default.shtml?a=cbd-01>, accessed 15 November 2016.

² 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 art. 5 & 6, *entered into force* 12 October 2014. Text available at: <https://www.cbd.int/abs/text/default.shtml>, accessed 15 November 2016.

recommend risk management measures including vaccines. Manufacturers use materials and information developed by the Global Influenza Surveillance and Response System to produce influenza vaccines, antivirals and diagnostics.

Further, the Pandemic Influenza Preparedness Framework, adopted in 2011 by the Health Assembly in resolution WHA64.5, aims to improve pandemic influenza preparedness and response and strengthen the Global Influenza Surveillance and Response System, “with the objective of a fair, transparent, equitable, efficient, and effective system for, on an equal footing: (i) the sharing of H5N1 and other influenza viruses with human pandemic potential; and (ii) access to vaccines and sharing of other benefits, such as diagnostics and antivirals.”¹

For non-influenza pathogens, sharing occurs in various ways: ad hoc, bilaterally, as the need arises, or through existing networks of institutions and researchers. Such networks share pathogen samples for surveillance and diagnostic activities, in order to determine, for example, epidemiological changes or the development of resistance.

In the context of polio eradication for instance, laboratories in the Global Polio Laboratory Network share samples from suspected polio cases for the purpose of rapid detection and in order to ensure rapid containment and response through the monitoring of polio virus transmission patterns.

Key findings

A central conclusion of the study is that: (1) the Nagoya Protocol has implications for the public health response to infectious diseases, including influenza; and (2) these implications include opportunities to advance both public health and principles of fair and equitable sharing of benefits.

Key points found in the responses to the questions provided to Member States and stakeholders also included the following:

- Infectious disease response requires both rapid and comprehensive sharing of pathogens and fair and equitable access by all countries in need to vaccines, medicines and diagnostics.

- The two elements, access to pathogens and equitable sharing of resulting benefits, are promoted by the Nagoya Protocol, which sets legal obligations regarding access to genetic resources, and promotes an equitable approach for sharing the benefits derived from their use.

¹ See Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011: Section 2 (http://apps.who.int/iris/bitstream/10665/44796/1/9789241503082_eng.pdf, accessed 15 November 2016).

-- By promoting the equitable sharing of benefits arising from their use, the Protocol can promote trust, thus encouraging the sharing of pathogens. In this way, the Nagoya Protocol can be supportive of public health and equity.

Considerations and options

The Nagoya Protocol's normative approach to accessing genetic resources and sharing benefits arising from their use is based on core principles such as fairness, equity and a respect for global public health as an important concern.

By clarifying and harmonizing access and benefit-sharing obligations associated with the sharing of pathogens, the Nagoya Protocol can support timely and systematic sharing, speeding up as a consequence risk assessment and the development of disease countermeasures. In addition, predictable sharing of benefits can improve access to affordable treatments and help developing countries to build capacities in such areas as disease surveillance and research and development. Accordingly, the Nagoya Protocol provides an opportunity for Member States to establish pathogen-sharing systems that support both global health equity and security.

For example, in the context of influenza, some respondents highlighted that the Protocol could help to bolster support for the Pandemic Influenza Preparedness Framework, encourage more participation in the influenza virus-sharing system and provide an opportunity to consider the equitable sharing of benefits arising from the use of seasonal influenza viruses.

In the context of non-influenza pathogens, some respondents highlighted that the Nagoya Protocol provides an opportunity for Member States to establish clear, pre-arranged benefit-sharing expectations arising from access to pathogens that will, in turn, contribute to the public health response to infectious disease outbreaks.

At the same time, concerns have been voiced that implementation of the Nagoya Protocol could slow or limit the sharing of pathogens owing to: (1) uncertainty regarding the scope and implementation of the Protocol, (2) the high transactional cost of implementing bilateral access and benefit-sharing arrangements and (3) the complexity of varying domestic access and benefit-sharing legislations. Such factors could have an impact on the comprehensiveness and speed of risk assessment as well as the timely development of vaccines, diagnostics and other medical countermeasures.

In the context of influenza, for instance, some respondents have mentioned that, with thousands of viruses shared with the laboratories of the Global Influenza Surveillance and Response System each year, negotiating Prior Informed Consent and Mutually Agreed Terms for individual virus samples could increase the complexity of virus sharing and could place significant demands on both resources and time. This could slow down or limit virus sharing, posing a challenge to a public health response to influenza. Similarly, for non-influenza pathogens, it was highlighted that bilateral agreements may not always be supportive of a common approach to rapidly handling a public health threat.

As noted by respondents to this study, there are tools under the Nagoya Protocol that address these concerns. The manner in which the Nagoya Protocol is implemented – both collectively through the Protocol’s Meeting of the Parties, and by individual Parties through their domestic legislation – will be vital to ensuring that the Nagoya Protocol supports public health.

Respondents to this study therefore proposed a number of options for advancing public health and for improving harmonization between the Nagoya Protocol and existing pathogen-sharing systems. These included:

- (a) establishing new “specialized international access and benefit-sharing instruments” under Article 4.4 of the Nagoya Protocol, or designating existing instruments as such;
- (b) ensuring that implementing legislation is supportive of public health; and
- (c) promoting consultation, dialogue, public awareness and international collaboration.

Many respondents expressed the view that the PIP Framework is or should be considered a specialized international access and benefit-sharing instrument. The Nagoya Protocol would not apply to the specific genetic resource subject to such instruments, in accordance with its Article 4.4, as long as the instrument is consistent with, and does not run counter to, the objectives of the Protocol. In other words, Article 4.4 can be understood as a recognition that Parties may enter into Nagoya-consistent international arrangements to facilitate access and benefit sharing on a large scale for specific classes of genetic resource. Recognition of the PIP Framework under Article 4.4 would clarify that the Nagoya Protocol’s requirements for bilateral ad-hoc access and benefit-sharing negotiation would not apply to influenza viruses with human pandemic potential shared through GISRS. This could promote ‘legal certainty’ with respect to such pathogens.

The Nagoya Protocol also includes terms which specifically address public health considerations. Article 8(b) of the Nagoya Protocol requires Parties to pay due regard to “present or imminent emergencies that threaten or damage human, animal or plant health, as determined

nationally or internationally” when developing legislation on access and benefit-sharing. Many respondents therefore focused on operationalising Article 8(b) in their implementing legislations in order to facilitate rapid access to pathogens that threaten public health in actual or likely emergency situations while ensuring equitable benefit sharing.

Other proposals discussed by respondents included the development of a code of conduct for pathogen sharing to promote access to pathogens used for public health purposes, particularly when such use was non-commercial. The idea of developing simplified and accelerated processes to obtain Prior Informed Consent and Mutually Agreed Terms for pathogens with a significant public health impact was also suggested, including through the use of standard contractual templates, as encouraged under Article 19 of the Nagoya Protocol.

Many respondents suggested that the Secretariat and Member States promote dialogue, consultation and public awareness of the issues relating to the Nagoya Protocol and pathogen sharing. They also called for international coordination on the implementation of the Nagoya Protocol and suggested efforts be undertaken to harmonize national implementing legislation to ensure that such laws are consistent with public health.

Finally, a few respondents suggested continuing discussions at future WHO meetings to allow further discussion of the public health implications of the Nagoya Protocol.

Taken as a whole, responses to this study reflect a view that access to pathogens should be governed by an approach that promotes the timely access to pathogens for global health purposes and the fair and equitable sharing of the resulting benefits. Consistent with this view, the Nagoya Protocol provides normative tools to promote efficient and equitable international access and benefit-sharing arrangements for pathogens, including through the development of specialized international instruments, the recognition of emergencies that threaten human health, and the promotion of international collaboration.

Member States may wish to consider the utility of such tools, as well as next steps for addressing the public health implications of the Nagoya Protocol, taking into account relevant developments, including the report of the PIP Framework Review Group¹.

¹ See document EB140/16.