

Implementation of the International Health Regulations (2005)

Public health implications of the implementation of the Nagoya Protocol

Report by the Secretariat

Executive summary

1. 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).¹ During the discussions,² 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 due course, in all six official languages, on the WHO website.³

2. The present summary contains the following: a brief statement of the methodology employed; background information; key findings; and main considerations raised and options proposed by Member States and stakeholders. It is intended as an aid to Member States in their consideration of the full report.

Methodology

3. This analysis was prepared using a multi-pronged approach to information-gathering, which included a call to Member States, through their health and environmental sectors, and to stakeholders, for written responses to key questions, 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.

¹ Document EB138/20.

² See document EB138/2016/REC/2, summary record of the second meeting, section 1.

³ The relevant section can be found at <http://www.who.int/influenza/pip/2016-review/en/>.

Background information

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

5. 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 of origin 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

6. 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.

7. Although the Nagoya Protocol sets out broad principles, many details are left to domestic jurisdictions, including how to address pathogens in implementing legislation and how to implement health emergency measures. These decisions will have an impact on public health.

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

9. 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 recommend risk management measures, including vaccines. Vaccine manufacturers use materials and information developed by the Global Influenza Surveillance and Response System to produce influenza vaccines.

10. 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

¹ Convention on Biological Diversity Art. 1, entered into force 29 December 1993, 1760 UNTS 79. Text available at: <https://www.cbd.int/convention/articles/default.shtml?a=cbd-01>, accessed 5 December 2016.

² Convention on Biological Diversity Art. 5, entered into force 29 December 1993, 1760 UNTS 79. Text available at: <https://www.cbd.int/convention/articles/default.shtml?a=cbd-05>, accessed 5 December 2016.

and other influenza viruses with human pandemic potential; and (ii) access to vaccines and sharing of other benefits, such as diagnostics and antivirals.”¹

11. 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.

12. 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

13. 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.

14. The responses to the questions provided to Member States and stakeholders also clarified a number of issues.

- Infectious disease response relies on ongoing surveillance, timely risk assessment, public health control measures, and access to diagnostics, vaccines and treatments. This requires both rapid and comprehensive sharing of pathogens and fair and equitable access to diagnostics, vaccines and treatments.
- The two elements, which are equally important, are both promoted by the Nagoya Protocol, which clarifies and harmonizes legal obligations regarding access to genetic resources, and establishes a more equitable approach for sharing the benefits derived from their use.
- In this way, the Nagoya Protocol can be supportive of pathogen-sharing. It can promote trust and encourage more countries to share pathogens, and it provides a normative basis for addressing the equitable sharing of benefits arising from their use.

Considerations and options

15. The Nagoya Protocol’s provision of a foundation for a normative approach to accessing pathogens and sharing benefits arising from their use is based on core principles such as fairness, equity and the protection of global public health.

16. By clarifying and harmonizing access and benefit-sharing obligations associated with the sharing of pathogens, the Nagoya Protocol can support the promotion of timely sharing and speed up risk assessment as well as 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

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).

Nagoya Protocol provides an opportunity for Member States to establish pathogen-sharing systems that support global health equity.

17. 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.

18. 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 for access to pathogens that will contribute to the public health response to infectious disease outbreaks.

19. 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 Nagoya Protocol, (2) the high transactional cost of implementing a bilateral system for access and benefit sharing 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.

20. 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, the procedures for individual negotiations for Prior Informed Consent and Mutually Agreed Terms could increase the complexity of virus sharing and could make 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 handling a public health threat.

21. 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.

22. 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, or identifying existing “specialised international access and benefit-sharing instruments” under Nagoya Protocol Article 4.4; (b) suggestions to ensure that implementing legislation is supportive of public health; and (c) consultation, dialogue, public awareness and international collaboration.

23. Many respondents expressed the view that the Pandemic Influenza Preparedness (PIP) Framework for virus and benefit sharing is or should be considered an Article 4.4 specialized international access and benefit-sharing instrument. Such recognition would mean that the Nagoya Protocol’s requirements for case-by-case Prior Informed Consent and Mutually Agreed Terms would not apply with respect to influenza viruses with human pandemic potential. This could promote “legal certainty” with respect to such pathogens, strengthening the mechanisms of the PIP Framework.

24. Further, 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 operationalizing Article 8(b) in their implementing legislations in order to facilitate rapid access to pathogens that threaten public health while ensuring equitable benefit sharing.

25. 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 Protocol.

26. 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 a WHO-led effort to harmonize national implementing legislations to ensure that such laws are consistent with public health.

27. Lastly, a few respondents suggested adding agenda items to future WHO meetings to allow further discussion of the public health implications of the Nagoya Protocol.

28. Taken as a whole, responses to this study reflect a view that access to pathogens should be governed by an approach that promotes the rapid sharing of 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 instruments, the recognition of emergencies that threaten human health, and the promotion of international collaboration.

29. Member States may wish to consider the feasibility of such tools, as well as the next steps for addressing the public health implications of the Nagoya Protocol, including opportunities to advance both public health and the principle of equitable sharing of benefits.

ACTION BY THE EXECUTIVE BOARD

30. The Board is invited to note the report and to provide guidance.

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