
The public health implications of implementation of the Nagoya Protocol

Report by the Director-General

1. The Executive Board at its 144th session in January 2019, agreed to include an item on the public health implications of implementation of the Nagoya Protocol on the draft provisional agenda of the Seventy-second World Health Assembly.¹
2. This report provides considerations of this matter. It draws upon 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 2017.² 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. In addition, the report *inter alia* outlined the importance of timely pathogen sharing to global public health, and examined how the sharing of benefits arising from their use has been, and will increasingly be, important both for public health reasons and in light of the entry into force and implementation of the Nagoya Protocol.
3. Developments since the Board's discussion in January have underscored the importance of access to pathogens and benefit sharing both to "ensure healthy lives and promote well-being for all at all ages", the objective of Sustainable Development Goal 3, and to achieving all three of WHO's triple-billion goals under its Thirteenth General Programme of Work, 2019–2023.
4. Many of the attendant issues are multidimensional, involving: diverse ministerial and stakeholder communities; developments in biotechnology, health technology and information technology; as well as questions of international and domestic policy, law and procedure. Because of their inherent complexities, there is no space to address them fully in this report. Accordingly, links to additional background materials and information have been included. The Secretariat has also organized

¹ See the summary records of the Executive Board at its 144th session, seventeenth meeting, section 1.

² See document EB140/2017/REC/2, summary records of the Executive Board at its 140th session, tenth meeting, section 2.

information sessions open to Member States and stakeholders to provide additional background. Supporting material for those sessions are available through the WHO website.¹

KEY ISSUES

5. Timely sharing of pathogens and benefits enables identification of the pathogen, a sound risk assessment, initiation of evidence-based interventions and the subsequent development and deployment of countermeasures such as diagnostics, vaccines and therapeutics. This is important during declared or imminent health emergencies and as a core component of routine surveillance and public health preparedness.

6. The Nagoya Protocol to the Convention on Biological Diversity² is a treaty that supports these objectives and that offers opportunities to further them. The aim of the Protocol is the implementation of the Convention's third objective of the fair and equitable sharing of benefits arising from the use of genetic resources. Benefits may include monetary and non-monetary benefits. The Protocol includes, inter alia, a recognition of the importance of genetic resources to public health; it requires its Parties, in their implementation, to pay due regard to cases of present or imminent public health emergencies; and it makes reference to the International Health Regulations (2005). The Protocol has the potential to increase equity, promote trust and improve both access to pathogens and their benefits, including access to medical interventions and countermeasures for countries in need supporting the attainment of health-related Sustainable Development Goals. National implementation of the Nagoya Protocol involves multiple government sectors. In this context, engagement of the health sector is crucial to ensuring that public health considerations are duly taken into account.

7. Governments can make arrangements for access and benefit sharing to facilitate the sharing of pathogens and corresponding benefits, by means that include multilateral arrangements. The timely sharing of pathogens, and corresponding benefits, is crucial for public health, notably, for instance, in the areas of food safety, antimicrobial resistance, tuberculosis, HIV infection, malaria, and emerging high-threat pathogens like the Middle East respiratory syndrome coronavirus, and Zika, Ebola and Lassa viruses, as well as unknown future threats.

8. The principles of global public health, including those enshrined in the Constitution of the World Health Organization, and the critical importance of timely access and fair and equitable benefit sharing can serve as a reference for future steps in developing collaborative arrangements to promote: both access and benefits; surveillance of pathogens; effective international response to outbreaks; and appropriate collective use of benefits and their distribution based on global public health needs.

¹ Supporting documents include: Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications (https://www.who.int/influenza/Nagoya_Full_Study_English.pdf); WHO workshop report: Facilitating Access and Benefit-Sharing (ABS) for Pathogens to Support Public Health, Geneva: World Health Organization, 2018 (https://www.who.int/influenza/ABS_Workshop_Report_7Sep_hyperlinks.pdf?ua=1); Implementation of the Nagoya Protocol in the context of human and animal health, and food safety: Access to pathogens and fair and equitable sharing of benefits, Questions and Answers. May 2018 (https://www.who.int/influenza/pip/QA_NP_Public_Health.pdf); and WHO comments on the fact-finding and scoping study on the emergence and growth of digital sequence information in research and development" (<https://www.who.int/influenza/whocommentscbddsi.pdf>) – all URLs accessed 13 March 2019.

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: text and annex. Montreal, Quebec, Canada: Secretariat of the Convention on Biological Diversity; 2011 (<https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>, accessed 13 March 2019).

9. Addressing access and benefit sharing for pathogens may involve consideration of other topics, including, inter alia, intellectual property aspects of the sharing of pathogens,¹ genetic sequence data, research² and publication of results, traceability, biosecurity, monetary and non-monetary benefit-sharing elements, as well as international and domestic law and process matters.

TAKING THE ISSUES FORWARD

10. The importance of ensuring timely access to human pathogens for public health preparedness and response purposes is clear and is reiterated in the Nagoya Protocol's preamble. Importantly, the Protocol includes provisions with potential application for collaborative approaches to accessing pathogens and sharing benefits arising from their use, furthering core principles of fairness, equity and the protection of global public health.

11. Such approaches can help to advance timely sharing, and speed up risk assessment as well as the development of disease countermeasures. In addition, predictable sharing of benefits creates possibilities for improving access to affordable treatments, and helping countries, particularly those in need, to build capacities in such areas as disease surveillance, preparedness and response, and research and development.

12. To ensure that access and benefit-sharing legislation and implementation plans take into account the imperatives of public health, Member States should take proactive steps to ensure that health ministries are represented and engaged in discussions and planning.

13. To support the foregoing, WHO is ready to explore, in close dialogue and collaboration with all relevant partners, possible options, including codes of conduct, guidelines and best practices, and global multilateral mechanisms, for pathogen access and benefit sharing. Such work would be done in harmony with the Nagoya Protocol and its principles, under the overarching framework of reaching the objectives of the health-related Sustainable Development Goals, and in furtherance of the objectives of the International Health Regulations (2005) and WHO's Thirteenth General Programme of Work, 2019–2023. It would focus on:

- (1) preserving and promoting the ability to respond to future outbreaks of disease in the best interest of global public health by ensuring timely sharing of pathogens according to appropriate biosafety and biosecurity standards;
- (2) increasing the fairness and equity of benefit sharing in order to further support public health surveillance, preparedness and response;
- (3) advancing implementation of the International Health Regulations (2005), especially the strengthening of core capacities in countries, particularly those in need.

¹ See Public consultation – pathogen genetic sequence data: WHO's draft code of conduct for open and timely sharing of pathogen genetic sequence data during outbreaks of infectious disease (<https://www.who.int/blueprint/what/norms-standards/gsdsharing/en/>, accessed 14 March 2019).

² See A research and development Blueprint for action to prevent epidemics (<https://www.who.int/blueprint/en/>, accessed 14 March 2019).

ACTION BY THE HEALTH ASSEMBLY

14. The Health Assembly is invited to note the report and to provide further guidance.

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