

The public health implications of implementation of the Nagoya Protocol

Interim report by the Director-General

1. This report is submitted pursuant to decision WHA72(13) (2019), in which the Seventy-second World Health Assembly requested the Director-General, in order to broaden engagement with Member States, the secretariat of the Convention on Biological Diversity, relevant international organizations and relevant stakeholders: (1) to provide information on current pathogen-sharing practices and arrangements, the implementation of access and benefit-sharing measures, as well as the potential public health outcomes and other implications; and (2) to provide a report to the Seventy-fourth World Health Assembly, through the Executive Board at its 148th session, as well as an interim report to the Executive Board at its 146th session.
2. This interim report provides: background information on WHO's work to date on access and benefit-sharing arrangements; an update on the Secretariat's work in implementing decision WHA72(13) and a proposed workplan for the period February 2020 to March 2021.
3. In the light of the diverse stakeholder communities with interests in this matter and following the mandate of the Health Assembly to broaden engagement therewith, this report has been prepared in close consultation with the Secretariat of the Convention on Biological Diversity, which supports it.

BACKGROUND

Pathogen-sharing and the Nagoya Protocol

4. The Nagoya Protocol to the Convention on Biological Diversity¹ is an international agreement whose objective is the fair and equitable sharing of the benefits arising from the utilization of genetic resources. The Protocol aims, through the establishment of national legal frameworks, to create legal certainty and benefit-sharing mechanisms for the users and providers of genetic resources. Under the Protocol, genetic resources may be accessed subject to the "prior informed consent" of the country providing the resources and once "mutually agreed terms" have been reached that include the fair and equitable sharing of benefits arising from the utilization of the concerned resources.

5. Under the Nagoya Protocol, the term "genetic resources" means "genetic material of actual or potential value". "Genetic material" in turn means "any material of plant, animal, microbial or other

¹ 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).

origin containing functional units of heredity”, which has generally been understood to include human pathogens.

6. Currently, pathogen-sharing occurs in various ways: on an ad hoc basis; bilaterally, as the need arises; and through existing networks of institutions and researchers. In the case of seasonal influenza, virus-sharing is systematic through the WHO Global Influenza Surveillance and Response System, an international network of influenza laboratories that conducts year-round surveillance of influenza. For influenza viruses of pandemic potential, sharing occurs under the terms of the Pandemic Influenza Preparedness Framework.¹ Pathogen samples are shared to advance surveillance and diagnostic activities or to determine, for example, epidemiological changes or the development of resistance. One example of such sharing is in the Global Polio Laboratory Network, where laboratories share samples from suspected polio cases for the purpose of rapid detection and to ensure rapid containment and response through the monitoring of poliovirus transmission patterns.

WHO’s relevant work on biodiversity and health and on access and benefit-sharing

7. WHO and the Secretariat of the Convention on Biological Diversity have a strong history of collaboration on access and benefit-sharing as well as on other issues. Particularly since the establishment in 2012 of the joint work programme on biodiversity and health, WHO has worked closely with the Secretariat of the Convention on a number of activities, such as a 2015 joint report on biodiversity and human health² and a 2018 workshop on facilitating access and benefit-sharing for pathogens to support public health,³ as well as a number of decisions under the Convention on Biological Diversity relating to the links between health and biodiversity.⁴ A recent document prepared by the Secretariat of the Convention on Biological Diversity with the support of the interagency liaison group on health and biodiversity also explores these linkages.⁵

8. In 2015, WHO and the Secretariat of the Convention on Biological Diversity signed a memorandum of understanding to strengthen collaboration and, with relevant partners, capitalize on their respective scientific and technical expertise on the links between health and biodiversity, establishing a liaison group to exchange information and coordinate activities relating to the linkages between human health and biodiversity. To support countries in mainstreaming biodiversity and health in national strategies, programmes and plans, both parties (including WHO regional offices) and other partners have co-convened a series of regional capacity-building workshops, bringing together representatives of health ministries and those responsible for biodiversity.⁶ In addition, further to decision XIII/6 of the Conference of the Parties to the Convention on Biological Diversity (2016), joint

¹ See resolution WHA64.5 (2011).

² World Health Organization and Convention on Biological Diversity. Connecting global priorities: biodiversity and human health: a state of knowledge review. Geneva: World Health Organization; 2015 (<https://www.who.int/globalchange/publications/biodiversity-human-health/en>)

³ See http://www.who.int/influenza/ABSworkshop_June2018/en/, accessed 29 October 2019.

⁴ See decision XIII/6 (<https://www.cbd.int/doc/decisions/cop-13/cop-13-dec-06-en.pdf>, accessed 29 October 2019) and decision 14/4 (<https://www.cbd.int/doc/decisions/cop-14/cop-14-dec-04-en.pdf>, accessed 29 October 2019).

⁵ Document CBD/SBSTTA/21/4 (<https://www.cbd.int/doc/c/72d6/b5bb/9244e977048688ec45735d2c/sbstta-21-04-en.pdf>, accessed 29 October 2019).

⁶ Workshops were held in the Region of the Americas (Manaus, Brazil, 4–6 September 2012), the African Region (Maputo, 2–5 April 2013) and the European Region (Helsinki, 23–25 October 2017), with participation from more than 80 countries.

guidance has been prepared to support the consideration of biodiversity and ecosystem management in the One Health approach. The Convention's Subsidiary Body on Scientific, Technical and Technological Advice approved this guidance and a summary of recent activities carried out under the joint work programme was submitted to the Conference of the Parties at its fourteenth meeting, held in November 2018.

9. At its 138th session in January 2016, the Executive Board agreed that the WHO Secretariat should undertake an analysis of how implementation of the Nagoya Protocol might affect the sharing of pathogens and the potential public health implications.¹ The study was presented to the Executive Board at its 140th session, in January 2017;² a key conclusion was that the Nagoya Protocol has implications for the public health response to infectious diseases.

10. A delegation from the WHO Secretariat visited the Secretariat of the Convention on Biological Diversity in March 2017 and exchanged information and discussed coordination of activities. The two sides agreed on mutual areas of work and future collaboration and identified key linkages between the Nagoya Protocol and WHO's work on access and benefit-sharing for human pathogens, including (a) implementation of the Nagoya Protocol in the context of health emergencies, notably under Article 8(b) of the Nagoya Protocol; (b) reference to specialized international access and benefit-sharing instruments under Article 4(4) of the Nagoya Protocol; (c) digital sequence information and access and benefit-sharing under the Convention on Biological Diversity/Nagoya Protocol and the Pandemic Influenza Preparedness Framework; and (d) linkages with other provisions of the Nagoya Protocol, such as Articles 19 and 20, especially as they may apply to the sharing of pathogens.

11. In May 2018, WHO, the Secretariat of the Convention on Biological Diversity, FAO and the OIE collaborated on the development of a question-and-answer document, entitled "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".

12. Finally, it should be noted that the Seventy-second World Health Assembly requested the Secretariat to prepare, inter alia, a report on how existing relevant legislation and regulatory measures, including those implementing the Nagoya Protocol, treat influenza virus-sharing and the public considerations thereof, in consultation with the Secretariat of the Convention on Biological Diversity, as appropriate.³ More information in this regard is available in document EB146/18.

Progress in implementing decision WHA72(13)

13. As at 1 October 2019, WHO has advanced its internal coordination on pathogen-sharing, particularly in the context of the Nagoya Protocol, across all three levels of the Organization. WHO has reached out to partners, including other United Nations agencies, funds and programmes, as well as non-State actors, including the private sector.

Internal coordination

14. WHO is coordinating across its divisions and actively reaching out to all technical units that may have experience with or knowledge of pathogen-sharing, including the Secretariat of the Pandemic

¹ See document EB136/2011/REC/2, summary records of the first meeting, section 4, and the second meeting, section 1.

² Document EB140/15.

³ See decision WHA72(12) (2019).

Influenza Preparedness Framework, focal points for the International Health Regulations (2005) and food safety and communicable disease teams.

Collaborating and networking with partners

15. In collaboration with the Secretariat of the Convention on Biological Diversity in the implementation of decision WHA72(13), the WHO Secretariat has developed a survey to collect information on (a) current pathogen-sharing practices and arrangements and (b) implementation of access and benefit-sharing measures. The survey will also gather perspectives on potential public health outcomes and other implications, as requested by Member States in decision WHA72(13). The survey was designed to collect data that are both quantitative (for example, the number of countries with Nagoya-implementing legislation) and qualitative (analysing, for example, the experience of implementing access and benefit-sharing measures). The survey involves multiple choice and written responses to key questions. It is anticipated that in-person and telephone interviews with relevant stakeholders and experts will be conducted to follow up the survey when responses indicate that it is necessary. In addition to relevant internal units of the WHO Secretariat, the Secretariat of the Convention on Biological Diversity provided input to the survey questionnaire and supports its contents and approach, while various international organizations, including the FAO and the OIE, were consulted.

16. The survey will be made available on the WHO website and, as appropriate, on the Convention on Biological Diversity website as well. With a view to obtaining as broad a data set as possible, the WHO Secretariat will encourage Member States, international and national agencies, WHO collaborating centres, non-State actors in official relations with WHO, the private sector and other relevant stakeholders to provide their responses.

17. In anticipation of the review and decision regarding work to be conducted between the issuance of this interim report and the final report that will be submitted to the Seventy-fourth World Health Assembly in 2021, the WHO Secretariat will continue the work initiated immediately following the Seventy-second World Health Assembly. Specifically, it will analyse and follow up the results of the initial survey as described in paragraphs 15 and 16 above, and will conduct further follow-up research if analysis of the initial survey data provides evidence of gaps in the knowledge base.

18. It is also anticipated that Member State and stakeholder briefings on progress to date in implementing decision WHA72(13) will be conducted in late October and early November 2019. Feedback, suggestions and guidance will be gathered during these briefings and will be considered in continued implementation.

19. Analysis of existing data is also being carried out, including via the Access and Benefit-Sharing Clearing-House (ABSCH),¹ a platform for exchanging information on access and benefit-sharing and a key tool for facilitating the implementation of the Nagoya Protocol. It contains country profile information relating to, inter alia, the competent national authority and legislative, administrative or policy measures under the Protocol, as well as the reports submitted by the Parties to the Protocol on progress made in implementing obligations under the Protocol, including information on the

¹ See <https://absch.cbd.int/> (accessed 29 October 2019).

development of access and benefit-sharing measures and progress made in implementing Article 8(b) of the Protocol.¹ This information will supplement the survey analysis.

NEXT STEPS IN IMPLEMENTING DECISION WHA72(13)

20. As provided in decision WHA72(13), the WHO Director-General will provide a report to the Seventy-fourth World Health Assembly, through the Executive Board at its 148th session, providing information on current pathogen-sharing practices and arrangements, the implementation of access and benefit-sharing measures, and potential public health outcomes and other implications. To ensure the completeness and thoroughness of this report, the Secretariat has developed a workplan for the period between February 2020 and March 2021 as proposed in this section.

Continued research and analysis

21. Based on the outcomes of the initial survey and subsequent in-depth research, the Secretariat, in collaboration with the Secretariat of the Convention on Biological Diversity and in consultation with other partners, may issue a secondary survey to stakeholders to address any gaps in data collection or in stakeholder response. Should this be necessary, the survey would be made available on the WHO website and, as appropriate, on the Secretariat of the Convention on Biological Diversity's websites. If necessary, the WHO Secretariat would also reach out to stakeholder groups to encourage participation.

Further engagement with Member States and stakeholders

22. Throughout the course of 2020, the Secretariat will convene regular Member State briefings at WHO headquarters in Geneva and will, on request, provide briefings at other Member State meetings (including the World Health Assembly and Regional Committees). The Secretariat will also convene stakeholder briefings to ensure that all interested parties are kept apprised of progress in implementing decision WHA72(13).

23. The Secretariat will continue its close collaboration with the Secretariat of the Convention on Biological Diversity and the Secretariats of the FAO and OIE. Other United Nations agencies, funds and programmes will be consulted, as indicated by the data obtained, as well as other non-State actor stakeholders, as appropriate. Feedback on meetings and cooperation with partners will be included in Member State and other stakeholder briefings.

24. As part of its collaboration with the Secretariat of the Convention on Biological Diversity and the States party to the Nagoya Protocol, the WHO Secretariat will also provide a briefing of its progress to the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol at its next (fourth) meeting, currently scheduled for the last quarter of 2020.

25. The full report by the WHO Secretariat will be made available in advance of the 148th session of the Executive Board, in all six official languages, on the WHO website. The report will build on this interim report, responding to the request in decision WHA72(13) by providing information on existing practices and arrangements for pathogen-sharing, access and benefit-sharing measures and potential

¹ A note containing relevant information provided by parties through their national reports on national implementation of the Nagoya Protocol, including its Article 8(b), was prepared by the CBD Secretariat and shared with WHO; see document CBD/NP/MOP/3/INF/4, in particular the annex, paragraph. 3, (<https://www.cbd.int/doc/c/d59c/1f59/360a556de30e9e7026b82bae/np-mop-03-inf-04-en.pdf>, accessed on 22 November 2019)

public health outcomes and other implications. A summary of the final report, containing a brief statement of the methodology employed, background information, key findings and main considerations raised and options proposed by Member States and stakeholders, will be made available in mid-2020 to aid Member States in their consideration of the full report.

ACTION BY THE EXECUTIVE BOARD

26. The Executive Board is invited to note this report and to endorse the proposed next steps presented in paragraphs 20–25 above. The Board is also invited to provide any further guidance that it may deem necessary on this matter.

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