Meeting Report

Consultation between WHO Secretariat and the Secretariat of the CBD

20-21 March 2017

Montreal, Canada

Background

1. The Executive Board at its 140th session in January 2017 considered the *Report of the 2016 Pandemic Influenza Preparedness (PIP) Framework Review Group*[1] and the Secretariat's *Study on the Public health implications of the implementation of the Nagoya Protocol*[2]. After a robust discussion of these documents, the Board adopted decision EB140(5) requesting the Director-General to continue consultations with the Secretariat of the Convention on Biological Diversity and other relevant international organizations, as appropriate, in the context of existing international commitments on access to pathogens and fair and equitable sharing of benefits, in the interest of public health, and to report thereon to the Seventieth World Health Assembly.

2. The UN Biodiversity Conference, held in December 2016, in Cancun, Mexico, recognised the importance of cooperation with relevant international processes and organisations, including the World Health Organisation, in decisions adopted by the thirteenth meeting of the Conference of the Parties (COP 13) and by the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol (COP-MOP 2).

3. In this context, the World Health Organization and the Secretariat of the Convention on Biological Diversity held a face-to-face meeting on 20-21 March 2017 in Montreal, Canada. The objectives of this meeting were to: 1) share information on relevant areas of work being conducted by the WHO Secretariat and the Secretariat of the Convention on Biological Diversity; 2) identify issues relevant to both organizations; 3) discuss potential areas of future collaboration; 4) discuss coordination of WHO-CBD collaboration and joint activities; and 5) discuss future collaboration with other relevant international organizations.

4. This report provides an overview of the outcomes of this meeting.

Information on relevant areas of work being conducted by the WHO Secretariat

5. During the meeting, the WHO Secretariat presented an overview of its work in relation to access to human pathogens and fair and equitable sharing of benefits, including its work in the following areas:

- Pandemic Influenza Preparedness Framework (PIP Framework)
- R&D Blueprint
- International Health Regulations (2005)

[1] Report of the 2016 PIP Framework Review Group. Geneva: World Health Organization; 2017: p. 40 (A70/17; http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_17-en.pdf).

[2] Implementation of the Nagoya Protocol and pathogen sharing: Public health implications – Study by the Secretariat. Geneva: World Health Organization; 2016: p. 4 (http://www.who.int/un-collaboration/partners/Nagoya_Full_Study_English.pdf)

- WHO's role in coordinating laboratory networks, such as the Global Influenza Surveillance and Response System and the Global Polio Laboratory Network

Pandemic Influenza Preparedness Framework

6. The WHO Secretariat provided information on the adoption of the PIP Framework and an overview of its objectives. Following 4 years of negotiations, the PIP Framework was adopted by a resolution of the Health Assembly in May 2011. The Framework objectives are to 1) improve the sharing of influenza viruses with human pandemic potential (IVPP) ; and 2) achieve more predictable, efficient, and equitable access to benefits arising from the sharing of such viruses, notably vaccines and antiviral medicines.

7. Under the Framework, Member States are expected to share IVPP through the Global Influenza Surveillance and Response System (GISRS), a network of public health laboratories, coordinated by WHO.

8. There are two principal benefit-sharing mechanisms under the PIP Framework: 1) the Standard Material Transfer Agreement 2 (or SMTA2), a contract concluded between WHO and non-GISRS recipients of PIP Biological Materials; such recipients notably include influenza vaccine manufacturers that are expected to commit to provide to WHO real-time access to pandemic products at the time of the next pandemic[3]; and 2) the PIP Partnership Contribution, which is an annual payment to WHO from manufacturers that use GISRS. WHO uses the funds to strengthen pandemic preparedness capacities in countries where they are weak[4].

9. The WHO Secretariat also presented background on the work conducted by the PIP Framework Advisory Group (PIP AG) since 2013, on the handling of genetic sequence data under the PIP Framework.

10. Finally, the WHO Secretariat discussed some of the findings of the *2016 Review of the PIP Framework*, including recommendation 36 that the PIP Framework be recognized as specialized international access and benefit-sharing instrument under article 4(4) of the Nagoya Protocol. The WHO Secretariat highlighted that this was the view expressed by many WHO Member States in the context of the WHO *Study on the implications of implementation of the Nagoya Protocol on public health*. The WHO Secretariat gave the example of the "*European Union Regulation on compliance measures for users from the Nagoya Protocol*", which recognizes the PIP Framework as such for pandemic influenza viruses[5]. The WHO Secretariat indicated that WHO Member States and many stakeholders are eager to follow the work to be undertaken by the CBD on this matter.

R&D Blueprint

11. The WHO Secretariat presented the R&D Blueprint[6], a global strategy and preparedness plan that allows the rapid activation of R&D activities during epidemics. Its aim is to fast-track the availability of effective tests, vaccines and medicines that can be used to save lives and avert large scale crises. The WHO Secretariat summarized some of the work undertaken since the launching of

[3] See PIP Framework Annex 2 for the model SMTA2 and http://www.who.int/influenza/pip/benefit_sharing/smta2_signed/en/ to see all SMTA2s signed to date.
[4] To learn more about the PIP Partnership Contribution, visit the Portal at https://extranet.who.int/pip-pc-implementation/
[5] See Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union Text with EEA relevance, recital 16.
[6] WHO, A research and development Blueprint for action to prevent epidemics, http://www.who.int/csr/research-and-development/en/

the Blueprint in 2015. This has included the development of global norms for sharing data and results, and the elaboration of mechanisms for collaboration and data sharing during public health emergencies, such as a Material Transfer Agreement capacity-building tool. The WHO Secretariat highlighted that access and benefit-sharing principles were important considerations in the work carried out under the R&D Blueprint.

International Health Regulations (2005)

12. The WHO Secretariat provided background on the International Health Regulations (2005) and explained some of the areas where access and benefit-sharing principles have been discussed, including the publication of the 2016 "*Policy Statement on Data Sharing by the World Health Organization in the Context of Public Health Emergencies*" and the development of the draft global implementation plan. The WHO Secretariat also presented key findings and recommendations of the Review Committee on the Role of the IHR (2005) in the Ebola Outbreak and Response[7], in particular recommendations to improve the sharing of data of biological samples and sequence data and the benefits arising from their use "on an equal footing"[8].

Coordination and support of laboratory networks

13. The WHO Secretariat described WHO's role in coordinating laboratory networks. Such networks are responsible for sharing pathogen samples in a rapid manner for surveillance and diagnostic activities both before and during public health emergencies. As an example, the WHO Secretariat provided an overview of the Global Influenza Surveillance and Response System (GISRS), a network of more than 150 public health laboratories through which seasonal, zoonotic and pandemic influenza viruses have been shared for almost 65 years. The Secretariat explained how GISRS is structured, how laboratories are designated or recognized, virus sharing and benefit-sharing expectations, as well as the contributions GISRS makes to seasonal and pandemic influenza preparedness and response.

Information on relevant work being conducted by the Secretariat of the Convention on Biological Diversity

14. The CBD Secretariat presented background information on the CBD and the Nagoya Protocol, including a description of ABS principles and the main components of the Nagoya Protocol. Key provisions of the Protocol of relevance to public health and WHO were also highlighted, including:

- Article 8b), which relates to special considerations in the development and implementation of ABS legislation or regulatory requirements to pay due regard to cases of present or imminent health emergencies;
- Article 4, which addresses the relationship between the Nagoya Protocol and other international agreements and instruments;
- Other relevant provisions, in particular Articles 19 and 20, which address the development, update and use of model contractual clauses, codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing.

[7] WHO, Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response, http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_21-en.pdf?ua=1

[8] WHO, Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response, Recommendation 11, p.12.

15. The CBD Secretariat also summarized the main outcomes of COP 13 and COP-MOP 2 of particular relevance to pathogen-sharing, human health and digital sequence information on genetic resources, and described the activities planned for the next biennium in light of these outcomes (2017-2018).

Follow-up to WHO *Study on the implications of implementation of the Nagoya Protocol on public health*

16. COP-MOP decision NP-2/5 on cooperation with other international organizations, conventions and initiatives, requested the Executive Secretary to liaise with the WHO on the outcomes of the WHO study on the potential public health implications of implementation of the Nagoya Protocol and to transmit information on the study to COP-MOP 3.

National reports

17. In accordance with COP-MOP decision NP 1/3, Parties to the Nagoya Protocol are requested to submit an interim national report on implementation of the Nagoya Protocol, as called for in Article 29 of the Protocol, and to share experiences and challenges in relation to such implementation. As part of this report, Parties are to provide information on the implementation of Article 8(b).

18. In this respect, it was pointed out that national coordination amongst relevant ministries, including the ministry of health, could usefully inform the preparation of the interim national report, in particular with respect to the implementation of Article 8 (b).

19. The WHO could draw to the attention of its Member States the existence of this process, and Governments may wish to involve their ministries of health in the preparation of these reports, as appropriate. The CBD Secretariat noted that the deadline to submit these interim national reports is 1 November 2017.

20. As requested in decision NP 2/5, the CBD Secretariat will share with the World Health Organization relevant information provided by Parties in their national reports on implementation of the Nagoya Protocol, including its Article 8(b).

Specialised international ABS instruments

21. The CBD Secretariat referred to Article 4, paragraph 4, of the Nagoya Protocol which addresses specialized international ABS instruments. The provision states in part that "Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention [on Biological Diversity] and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument."

22. The WHO Secretariat asked if any instruments had been recognized under Article 4(4) and how such instruments would be identified. The CBD Secretariat explained that specific criteria or a process for determining what constitutes a specialised international ABS instrument had not been established by the Nagoya Protocol.

23. The CBD Secretariat further explained that, 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*" had been made available for the information of participants at

COP-MOP 2. As noted in the Executive Summary, respondents to the study proposed a number of options for advancing public health and for improving harmonization between the Nagoya Protocol and existing pathogen-sharing systems, including establishing new "specialized international access and benefit-sharing instruments" under Article 4.4 of the Nagoya Protocol, or designating existing instruments as such.

24. Against this background, the Parties to the Protocol requested the CBD Executive Secretary to conduct a study into criteria that could be used to identify what constitutes a specialized international ABS instrument and what could be a possible process for recognizing such an instrument (decision NP-2/5).

25. This study will be made available for consideration by the Subsidiary Body on Implementation at its second meeting in July 2018 and by COP-MOP 3.

Digital sequence information on genetic resources

26. The issue of digital sequence information on genetic resources emerged as a cross cutting issue during the UN Biodiversity Conference and resulted in two decisions: COP decision XIII/16 and COP-MOP decision NP-2/14. In these decisions, the Parties agreed to consider at COP 14 and COP-MOP 3, in 2018, any potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention and the objective of the Nagoya Protocol.

27. Further to these decisions, a coordinated and non-duplicative process for further work on digital sequence information on genetic resource was established, which included the following:

- The submission of views and relevant information by Parties, other Governments, indigenous peoples and local communities, and relevant organisations and stakeholders, to be compiled and synthesized by the Executive Secretary;
- The commissioning of a study to clarify terminology and concepts, and to assess the extent and terms and conditions of use of digital sequence information on genetic resources;
- A meeting of an Ad Hoc Technical Expert Group;
- Consideration of this matter by the 22nd meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) to be held in July 2018.

Developments in other relevant processes

28. The CBD Secretariat will follow developments and continue to engage with relevant processes and policy debates, including at the WHO, in order to:

- Collect information on current discussions on the relationship between the use of digital sequence information on genetic resources and access and benefit-sharing arising out of the utilization of genetic resources in accordance with COP decision XIII/16 and COP-MOP decision NP 2/14; and
- Inform future discussions on Article 10 of the Nagoya Protocol related to a global multilateral benefit-sharing mechanism in accordance with COP-MOP decision NP 2/10.

Mutual areas of work and future collaboration

29. Based on the foregoing, the two Secretariats identified key linkages between the Nagoya Protocol and the WHO work on access and benefit-sharing for human pathogens, including:

- Implementation of the Nagoya Protocol in the context of health emergencies, notably under Article 8(b);
- Reference to specialized international access and benefit-sharing instruments under Article 4(4) of the Nagoya Protocol;
- Digital sequence information and access and benefit-sharing under the CBD/Nagoya Protocol and the PIP Framework;
- Linkages with other provisions of the Nagoya Protocol, such as articles 19 and 20, especially as they may apply to the sharing of pathogens.

30. The Secretariats identified possible areas for future collaboration in order to promote coordination at both the international and national levels in relation to the sharing of human pathogens and implementation of the Nagoya Protocol, including:

- Continued sharing of information relevant to the work of both organizations;
- Continued engagement with relevant ongoing processes and policy debates within both organizations;
- The development of awareness raising materials, *inter alia*, fact sheets and policy briefs; and,
- Organizing joint activities, such as workshops on implementation of the Nagoya Protocol in relation to pathogen sharing and public health emergencies.

Method of collaboration

31. Recognizing the complexity of these issues and the need for closer collaboration in order to address them, the WHO Secretariat and the Secretariat of the CBD further discussed a strategy for future collaboration.

32. It was noted that a memorandum of understanding was concluded between the CBD Secretariat and WHO in July 2015 to collaborate on activities of mutual interest. Collaborative activities related to ABS could be undertaken under the terms of this memorandum of understanding, subject to availability of funds.

33. Collaboration with other relevant international organisations will be considered, in light of future developments.