INB related interactive dialogues
Topic 1. Article 12 (Pathogen Access and Benefit-Sharing System)

Tuesday 3 September 2024 from 10:00 – 13:00 and 14:00 – 17:00

Agenda

Co-chaired by Ambassador Anne-Claire Amprou and Ambassador Tovar da Silva Nunes

1. Introduction and Welcome

2. Current status and outstanding issues in Articles 12

3. Dialogue with resource persons

    - Resource persons and relevant stakeholders to address discussion questions proposed by the Bureau

    - Follow-up questions from Member States

4. Wrap up

Names of confirmed resource persons (*in alphabetical order*) as of 2 September 2024

1. Professor Frederick Abbott, Professor of Law, Florida University
2. Annaliesa Anderson, IFPMA, Senior Vice President and Head of Vaccine R&D Pfizer
3. Paula Barbosa, Associate Director, Vaccines Policy, IFPMA
4. Tiwadayo Braimoh, Policy Manager at the Medicines Patent Pool
5. Dr. Carlos María Correa, Executive Director, South Center
6. Ruxandra Draghia, Chair of the Scientific Advisory Group for the INTREPID Alliance
7. Pamela Duchars, VP Business Development @ Valneva
8. Pierre du Plessis, High Value Plant Species Expert, The Centre for Research, Information, Action in Africa – Southern Africa-Development and Consulting
9. Dr. Mark Eccleston-Turner, Senior Lecturer in Global Health Law, Director of postgraduate studies, Department of Global Health & Social Medicine, King's College London
10. Hisham Fyyaz, Head Pandemic Preparedness, Global Public affairs, Sanofi
11. Kathryn Garforth, Legal Officer at the CBD Secretariat
12. Professor Benjamin Howden, Director, Microbiological Diagnostic Unit Public Health Laboratory The Peter Doherty Institute for Infection and Immunity
13. James Love, Knowledge Ecology International
14. Martha Lucia Cepeda Hernandez, Expert in Microbial Ecology and Director of the Directorate of Research and Knowledge Transfer (DIyTC) at Central University, Brazil
15. Samantha Johnson, Director, IP and Multilateral Affairs, Global Corporate Government Affairs & Policy, GSK
16. Dr. Mohga Kamal-Yanni Senior policy advisor to UNAIDS and The People Vaccine Alliance. Key advisor to the NGOs reps at UNITAID Global Health and Access to Medicines
17. Ms. Valerie Kawangu, Board Secretary and Legal Counsel, ZNPHI
18. Tom Ksiazek, Director of High Containment Operations at the Galveston National Laboratory (GNL)
19. Chris Larkins, Senior Vice President, Global Operations, CSL Seqirus
20. Joel Lexhin, Professor Emeritus, School of Health Policy and Management, York University
21. Cedric Mahe, President, Foundation for Influenza Epidemiology
22. Dr. Makiko MATSUO, Project Associate Professor, Ph.D, Graduate School of Public Policy, The University of Tokyo
23. John McCauley, former Director of the Worldwide Influenza Centre, the Francis Crick Institute, London (retired)
24. Suerie Moon, Professor of Practice, Geneva Graduate Institute
25. Elisa Morgera, Professor of Global Environmental Law, University of Strathclyde
26. Debora Botequio Moretti, Instituto Butantan (Brazil): A leading biomedical research center in Brazil, involved in vaccine production for diseases like dengue, influenza, and COVID-19
27. Srinivas Murthy, Clinician-Scientist, Associate Professor, University of British Columbia
28. Dr Ebere Okereke, Independent Global Health Expert
29. Paul Oldham, Industrial Fellow, Manchester Institute of Innovation Research
30. Christine Pratt, Director of Operations at European Virus Archive (EVA)

31. Dr. Anne Pohlmann, Institut für Virusdiagnostik
32. WEI Qiang, Chinese Center for Disease Control and Prevention（China CDC）
33. David Reddy, Director General, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
34. Carolina dos Santos Ribeiro, Senior policy advisor, National Institute for Public Health and the Environment, the Netherlands
35. Dr Michelle Rourke, Postdoctoral Research Fellow at the Law Futures Centre, Griffith University
36. Mr. Vladimir Ryabenko, Head of the International Relations Department at the State Research Center of Virology and Biotechnology VECTOR, Rospotrebnadzor
37. Nina Schwalbe, CEO and Founder at Spark Street Advisors, Adjunct Assistant Professor at Columbia University, and Principal Fellow at United Nations University International Institute for Global Health, Associate Fellow Chatham House
38. Amber Hartman Scholz, Ph.D. Head of Science Policy & Internationalization Department Leibniz-Institut DSMZ German Collection of Microorganisms and Cell Cultures
39. Sangeeta Shashikant, Legal Adviser to the Third World Network
40. Dr Stephanie Switzer, Director, Strathclyde Law School
41. Mr. Nirmalya Syam, Senior Program Officer of the Health, Intellectual Property and Biodiversity Program at the South Centre
42. Bart Van Vooren, Independent expert

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Discussion questions proposed by the Bureau for resource persons

1. PABS and Nagoya Protocol related matters

If Member States reach consensus on the PABS instrument during the negotiation, including that its design is consistent with, and does not run counter to the objectives of the Convention on Biological Diversity and the Nagoya Protocol, and the INB decides that PABS can be recognized as a specialized international access and benefit-sharing instrument (SII):

1.1. Can PABS, as SII, be universally applied to all Parties to the Pandemic Agreement, i.e. both Parties and non-Parties to the Nagoya Protocol?

1.2. What criteria and/or mechanism(s) are to be used for the recognition of PABS as a SII?

- For Parties to CBD and the Nagoya Protocol who are Parties to the Pandemic Agreement?
- For non-Parties to CBD and the Nagoya Protocol who are Parties to the Pandemic Agreement?
- What domestic legal arrangements are needed, such as amendment of national ABS laws, to recognize PABS and ensure that PABS materials are not subject to additional or different PIC and MAT ?

1.3. During the INB negotiations, what are the considerations that should guide the INB so as to maintain coherence between the future PABS and the Nagoya Protocol?

1.4. Are there any specific issues in the PABS under ongoing INB negotiations that may prejudge the ongoing discussions on the handling of DSI within the CBD and the Nagoya Protocol?

1.5. In principle a non-Party to PABS who is a Party to the Nagoya Protocol could view that PABS is not 'consistent with and not run counter to the objectives of the CBD and the NP'. In this case, is the non-Partiy to PABS that is affected by the conclusion of a SII entitled to dispute settlement under Article 27 of the CBD?

1.6. What are elements or designs of PABS that would be inconsistent with and run counter to the objectives of the CBD and the Nagoya Protocol?

2. Issues related to access to PABS materials and sequence information

2.1. What are the current most up-to-date progresses in CBD on definition and scope of digital sequence data (DSI)? Will the current negotiated text using "sequence information" contradict/hamper the ongoing negotiation of the CBD?

2.2. What are the effective technical or operational measures to ensure all users (primary users and secondary users shared by primary users) of materials and sequence information account to benefit sharing arise from the use of them?

2.3. What are the effective "traceability" measures which ensure users of materials and sequence information account to benefit sharing obligations?

3. Issues related to benefit sharing

3.1. What are the positive or negative consequences to manufacturers should a PABS system be established in which there are a legally binding benefit sharing requirements to allocate certain percentage of vaccines, therapeutics and diagnostics (VTD) on a free-of-charge basis and at not-for-profit prices, as well as annual monetary contribution?

3.2. Would the manufacturers and commercial users of materials and sequence information consider not using the PABS system because of this required contribution?

3.3. If not a PABS system, are there other options which could facilitate rapid and timely sharing of materials and sequence information, and on an equal footing, sharing of monetary and non-monetary benefits arising from the use of materials and sequence information, and incentivize greater manufacturer participation? Would any of these options be preferable to a PABS system?

3.4. What would be appropriate and sufficient triggers for such benefit sharing under a PABS system?

3.5. Should benefit sharing of VTDs cover: a) PHEIC, b) pandemic emergency, c) pandemic? What would be the public health impact of each of these options?

3.6. How should the duration of the benefit sharing of VTDs be determined?

3.7. Is it necessary to make a reference to the Biological and Toxin Weapons Convention and, if so, what would need to be considered for the development of a PABS system that is consistent with the objectives of this Convention, in particular its article 10?

3.8. What are the differences, in terms of legal obligations of those participating in a PABS system, between two terms: a) "benefits arising from the sharing (of material and sequence information)"; and b) "benefits covered by the PABS system"?

3.9. Are the expressions "benefits arising from the sharing", used in the PIP Framework, and "benefits arising from the utilization", used in the Nagoya Protocol synonymous? If not, what are the consequences of each for the PABS system?

3.10. What are the WTO rules that should be taken into consideration, if any, in the design of a PABS system? Can Member States limit the export of VTDs that are identified as benefits arising from the PABS system, in light not only of the obligations agreed upon by parties to this system, but also of the public health goals emanating from it?

4. Legal issues related to the adoption of PABS system

4.1. What are the implications of adopting a PABS system under articles 19 (e.g. as a Protocol), 21 or 23 of the WHO Constitution?