THE ABS CAPACITY DEVELOPMENT INITIATIVE

L'INITIATIVE DE RENFORCEMENT DES CAPACITES POUR L'APA

Webinar report:
"Expeditious access in case of emergencies"
Thursday, 24 September at 14h CET

History, importance, relevance for COVID-19 pandemic and links to wider ABS issues around pathogens

- Article 8 NP (special considerations) was meant as "parking lot" for important but highly contentious matters on which there was little consensus during the negotiations of the Nagoya Protocol.
- 8(a) deals with non-commercial research, 8(c) with food and agriculture. Article 8 is closely related to Article 4 which deals with international agreements and instruments, especially Art.4.4 on specialised international ABS instruments.
- The WHO Pandemic Influenza Preparedness Framework (PIP Framework) was adopted by 64th World Health Assembly on 24 May 2011 (after Nagoya). This ABS instrument delivers around US$30 million a year in monetary benefits (to the WHO framework, not individual provider countries). But the money is actually generated by seasonal influenza vaccines, although seasonal flu viruses are not included. There is pressure from industry to expand the scope. Some companies are accessing DSI to by-pass the system.
- COVID-19 is a genuine emergency. The coronavirus genome was shared quickly by China (as DSI). Chinese scientists submitted the gene sequencing data for posting on Virological.org, a hub for prepublication data designed to assist with public health activities and research. This enabled the development of diagnostic tests and an early start on developing vaccines and treatments. The coronavirus genome is small, quick and easy to sequence. There are no reports of ABS measures stopping access anywhere.
- The COVID-19 Vaccines Global Access Facility (COVAX) is being led by the WHO, the Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi, the Vaccine Alliance and aims to deliver some two billion vaccine doses around the world by the end of 2021. An initiative to ensure any future vaccine against COVID-19 is fairly shared throughout the world has secured the backing of 156 countries and territories, but the USA and China have yet to sign up. There are many open questions, e.g. concerning benefit-sharing.

- The pharmaceutical industry unsuccessfully tried to argue that pathogens are not genetic resources. The debate about access to pathogens remains contentious. Most ABS authorities have not managed to include pathogens in their national measures in practice – Health Ministries do as they like, or as they've always done ("community of practice"). In most countries, there are no established connections and exchange mechanisms between Health Ministries and ABS authorities.
- COVID-19 will be used to increase pressure for free access to all pathogens and their DSI. Perhaps it is time to negotiate a multilateral specialised international ABS instrument?

Nagoya Protocol Article 8b – some starting observations

- Pathogens are both the problem and the solution. They are the basis of a vaccine, or, at the minimum, they provide crucial genes for vaccines. Pathogens are critical for the development of monoclonal antibody drugs ("biologicals"). Even small molecule drugs require testing use wild type pathogen isolates. Typically, treatments cannot be developed and will not obtain regulatory approval without use of viral isolates. Therapeutics are enormously expensive and unfairly distributed.
- Article 8 NP applies to cases of "present or imminent emergencies". "As determined nationally or internationally" means national law can define the circumstances in which an alternative access procedure is applied. The WHO Director-General may declare a "Public Health Emergency of International Concern" under the International Health Regulations (IHR)
- The term Public Health Emergency of International Concern is defined in the IHR (2005) as "an extraordinary event which is determined, as provided in these Regulations:
    - to constitute a public health risk to other States through the international spread of disease; and
    - to potentially require a coordinated international response"

  This definition implies a situation that: is serious, unusual or unexpected; carries implications for public health beyond the affected State's national border; and may require immediate international action.
- The IHR does not require sharing of pathogens or sequence data. But it is a trigger to consider.
- Balancing acts are required: SPEED versus RIGHTS (of provider countries); NATIONAL versus GLOBAL concerns. Important questions to be addressed: how to provide access quickly, if necessary, without giving up rights? How to balance national versus global health concerns?
- Novel pathogens generate political pressure and leave little time for negotiation. Health and biodiversity authorities need to be in tune. A possible approach could be the use of Standard Material Transfer Agreements (SMTA) for Article 8b. They could be national or regional; should developed ahead of time; quickly executed, with little or no negotiation. SMTAs should limit recipient to specific public health uses, prohibiting everything else, including onward transfer and commercial use.
- The treatment of DSI is important because most pathogens are being synthesized from sequence data in labs. If DSI is shared without terms and conditions, pathogens will be generated and it will be used without benefit sharing. Example: An Ebola monoclonal antibody drug successfully tested in DRC was developed from a West African Ebola sequence data from GenBank. The company avoided signing an MTA and thus avoided

any benefit sharing requirements. It has received over US$ 400 million in contracts to produce the drug (over US$ 10,000 a dose) for the US national stockpile.

WHO–PIP Framework: Options for benefit-sharing clauses

- The Pandemic Influenza Preparedness Framework (PIP Framework) brings together WHO Member States, industry, academic and research institutions and the WHO Secretariat to implement a global approach to pandemic influenza preparedness and response. It is built on 3 fundamental pillars: virus sharing, benefit sharing and governance.
- The SMTA2 contract is the primary benefit-sharing mechanism, and is signed by WHO and users of PIP Biological Materials. It is a legally-binding contract between WHO and an influenza product manufacturer, research institution, or other entity that receives PIP Biological Materials, such as influenza viruses with pandemic potential (IVPP), from a laboratory which is part of the Global Influenza Surveillance and Response System (GISRS). In exchange for access to PIP Biological Materials, the entity commits to provide WHO with agreed-to benefits.
- The benefit-sharing component of the PIP Framework is the Partnership Contribution, which is an annual contribution of funds to the WHO from industry partners, such as influenza vaccine, diagnostic and pharmaceutical manufacturers, that utilize the WHO Global Influenza Surveillance and Response System (GISRS).

Experiences regarding the implementation of Art. 8b NP from the Democratic Republic of Congo (DRC) and Ethiopia

Democratic Republic of Congo (DRC)

- DRC has ratified the Nagoya Protocol, but still lacks an ABS regulatory framework. The implementing decrees have yet to be signed. DRC is receiving many access demands in the absence of such measures.
- The national state research institute requested access for Anopheles for research on malaria. Analyses were conducted at country level, including exports abroad to further deepen research. The Competent National Authority issued a PIC and a “special permit” due to the emergency situation. It was agreed that in case of a change of intent or utilization, the user must come back to negotiate. So far, DRC has not yet had any feedback regarding the progress of the research. In the case of emergency situations, a number of issues (i.e. safeguards, procedures) need to be considered.

Ethiopia

- Ethiopia has a provision that provides for facilitated access in emergency situations. Access is facilitated, but not free. An emergency exists when it is defined as such at national, regional or international level.

Brazilian examples and experiences regarding the implementation of Art. 8b NP

- Brazilian ABS Legislation was enacted in May 2015 and regulated by Decree in May 2016. Genetic Heritage is defined as genetic information from Brazilian species. A microorganism is part of the existing national genetic heritage when it has been

isolated from national territory substrates. Human pathogenic microorganisms, obtained from Brazilian patient samples are considered as Brazilian Genetic Heritage.

- In Nov 2015, the Ministry of Health declared a public health emergency due to the outbreak of the Zika virus in Brazil. There was a need to transfer Zika samples abroad, which created the opportunity to regulate an expeditious procedure for remittances in emergency situations. A Joint Ordinance (ABS Decree Art. 115) regulates a simplified procedure for the remittance of Genetic Heritage related to the Health Emergency (exclusively for research and technological development linked to the epidemiological situation). The benefits resulting from the economic exploitation will be shared in accordance with the ABS legislation.
- The corona virus was also declared a public health emergency in Brazil. The Joint Ordinance allows for a simplified procedure. Shipments can be carried out without the need for prior registration of the activity. However, shipments still depend on the signature of the MTA. The results of R&D activities are not be used for the application of any intellectual property right, until the registration and other procedures required by Law have been carried out.

Crucial issues that require further discussion; role of the AU Commission

(1) What is an emergency and who defines it?
(2) Issue of standardisation – what can we standardise and how could an SMTA look like?
(3) If an SMTA exists, what options are there to monitor compliance?
(4) Interface between genetic resources and DSI

- The AU Commission (AUC) encourages countries to put in place relevant measures for access in emergency situations. Countries require adequate support to implement Article 8 NP.
- The AUC is engaging in high priority tasks to address the COVID-19 outbreak, such as equipping and training public health officials; developing and strengthening laboratories to perform next generation sequencing on COVID-19 specimen; as well as quality insurance.