



# Sharing human pathogens

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Access to biological material with human pathogenic potential is important, as research aimed at the development of new drugs and vaccines is dependent on scientific analysis of the underlying causes of disease. In the circumstance of a potential pandemic, issues surrounding access take on particular urgency.

During the past several years, Member States of WHO have negotiated toward an agreement on sharing of influenza viruses with human pandemic potential in the Intergovernmental Meeting on Pandemic Influenza Preparedness (IGM-PIP). These negotiations arose out of controversy surrounding withholding by a developing country of virus samples from WHO researchers based on concern over reciprocal access to resulting vaccines and treatments, and relevant technologies. While WHO negotiations regarding influenza viruses are progressing slowly, there is also recognition at WHO that eventually the sharing of biological materials with human pathogenic potential more broadly will need to be addressed.

Biological materials with human pathogenic potential are potentially also the subject matter of the CBD and/or the draft Protocol. At present, the treatment of such materials by the draft Protocol is problematic and, depending on the approach chosen, adoption of the Protocol could lead to a situation of substantial legal insecurity.

The current draft Protocol provides three alternatives. Either potentially pathogenic materials are included and treated largely as any other genetic resource, they are explicitly exempted, or the Protocol provides for special regulation. The draft Protocol addresses its potential integration with existing and future WHO rules in Article 6 on Emergency Situations.

Up until the most recent negotiators' meeting in Montréal, "human pathogens" was the sole alter-

native in Article 3(f). Presumably this reference was intended to refer to external pathogens that may be harmful to humans, and not to pathogens that are human. During the last resumed session of the CBD's ABS Working Group, Parties suggested an alternative text for Article 3(f). The alternative text refers to "A genetic resource when it constitutes a serious and direct danger to the health of humans as described in the International Health Regulations, and it is covered by and for the purpose of a specialised instrument as described in paragraph (b) of Article 6". Such clarification would begin to reduce the ambiguity of the exemption, but it would leave important questions unanswered.

The wording "serious and direct danger to the health of humans" entails an immediate threat, but threat assessment based on probabilities for genetic mutation is an inherently uncertain exercise, as for example in the case of the H5N1 (avian flu) virus. It would be preferable to use language that does not entail a requirement of direct immediate threat. A formulation such as "with human pathogenic potential" might serve this purpose.

Article 6 provides for a specific mechanism applicable to pathogen/genetic resources, but its relationship to Article 3(f) and to WHO mechanisms seems to raise more questions than it answers.

The first bracketed option would create a general, non-specific obligation to take external circumstances regarding pathogen materials into account in formulating and implementing national legislation. This option would do little to clarify the relationship between the ABS Protocol and/or the CBD, on one side, and interests involving WHO on the other.

The second bracketed option is substantially more specific, although it leaves significant questions. Unless pathogen materials are expressly excluded from the scope of the ABS Protocol, this provision does not remove them from regulation under the

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draft Protocol. If the new bracketed exclusion from scope under Article 3(f) is adopted, this would cross-reference Article 6(b), but the two provisions almost certainly encompass different subject matter. The first clause of Article 6(b) refers to providing “immediate access”, but it does not explain how that obligation would relate to other obligations in the draft ABS Protocol, such as the obligations in Article 5 for obtaining prior informed consent and negotiating the terms of benefit-sharing.

The phrase “in ways and for uses provided for in existing and future rules, procedures or practices on the sharing of pathogens and related benefits established under those international organisations and conventions” may be intended to signal that WHO rules will take priority over ABS Protocol rules. By leaving the relevant pathogen materials subject to the ABS Protocol, the provision appears to constitute the ABS Protocol and the CBD as the “default regime” regarding access to pathogen materials in the event Member States are unable to

reach alternative agreements at the WHO. It might also serve as a “gap filler” when WHO rules do not cover a specific issue. If pathogen materials are excluded from the scope of the ABS Protocol under the current formulation of draft Article 3(f), they might remain subject to the CBD (but not the Protocol), mooting application of Article 6 of the draft ABS protocol, with greater uncertainty all around.

While ABS Protocol negotiators have recognised some of the potential issues raised by overlapping subject matter addressed at WHO, there is a lack of clarity as to precisely what they think ought to be done about it. In that regard, before adoption, negotiators in the ABS Protocol forum and at the WHO in the IGM-PIP should focus attention on concrete ideas concerning how the two systems are expected to operate simultaneously with respect to the same subject matter. This does not appear to be a situation in which “constructive ambiguity” will operate for the public benefit.

