IFPMA

Pathogen sharing and global health security

Responding to the impact of the Nagoya Protocol on Access and Benefit Sharing

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The Nagoya Protocol unintentionally gives countries the authority to block access to pathogens, such as the SARS-CoV-2 virus that caused COVID-19, by other countries and the global health community. When this happens, researchers are denied the essential information to produce diagnostics, therapeutics, and vaccines to combat viruses that can kill millions.

During the COVID-19 pandemic, countries including China, South Africa, and the UK rapidly shared the SARS-CoV-2 virus and its digital sequence information. This ability, and willingness, to work together was one of the positive aspects of the pandemic response.

But, since 12 October 2014, when the Nagoya Protocol, a supplementary agreement to the UN Convention on Biological Diversity (CBD), came into force, some countries have started withholding or delaying access to pathogen samples.

Today, there is the possibility that the CBD might extend to digital sequence information. In a future pandemic, this could be disastrous.

The Nagoya Protocol

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization is commonly referred to as the Nagoya Protocol on Access and Benefit Sharing. As mentioned above, it is a supplementary agreement to the CBD that provides guidance on how to implement the principle of access and benefit sharing.

Biodiversity means the variety of life on earth, from genes to ecosystems. Apart from its importance for our continued existence, it offers us vital and valuable resources for medicine, food, fuel, and shelter. Biodiversity is threatened by the loss of habitats, the unsustainable use of resources, pollution, and climate change.

As a powerful international legal instrument to encourage countries to conserve, sustainably use, and share benefits accrued from biodiversity, the Nagoya Protocol is good, and necessary.

But, surprisingly, pathogens like the influenza virus have not been specifically excluded from the definition of biodiversity that should be conserved or used sustainably. This enables biodiversity protection for pathogens, which should be eliminated rather than preserved.

While there are provisions in the Nagoya Protocol designed to ease possible conflicts between its rules and public health needs – for instance, Article 8(b) - most countries have not acted upon them.

Due to its environmental focus, most countries party to the Protocol have applied access and benefit sharing rules to pathogens without considering the implications for public health. From country to country, laws and procedures governing access differ enormously. In worst cases, considerable time, and often money, are needed to just access a sample.

In some countries, bureaucratic hurdles and legal uncertainty make it virtually impossible to share pathogens.

How the Nagoya Protocol might work in practice

- A researcher located in country B wants access to a rare plant that grows only in country A
- A researcher located in country B needs the informed consent of country A to allow access
- The Nagoya Protocol requires that a mutual agreement be reached to make sure country A receives its fair share of any benefits derived from the plant's use
- If not, the Protocol allows country A to deny access to the plant.

Nagoya and pathogen digital sequence information

Even more worrying, negotiations are underway to extend Nagoya Protocol-inspired access and benefit sharing regulations to digital sequence information, with complete disregard for the unique properties of pathogen digital sequence information.

It was sequence information, and not physical samples so much, that enabled researchers around the world to share SARS-CoV-2 data to quickly develop diagnostics, therapeutics, and vaccines against COVID-19.

If access to digital sequence information becomes even more difficult, the threat to global health security, especially pandemic preparedness, becomes far more serious.

Pathogen sharing and achieving the G7 100 Days Mission

As a result of the COVID-19 pandemic, G7 countries asked vaccine manufacturers to aspire to meet a goal of developing and producing vaccines, along with diagnostics and therapeutics, within 100 days in any future pandemic. This is the 100 Days Mission.

IFPMA member companies have pledged to meet this goal. But, without rapid and predictable access to pathogen samples and sequences, it will be impossible to do so. Right now, there are often delays of far more than 100 days when it comes to accessing certain pathogens.

For example:

→ Influenza: Delays of between three weeks to nine months have been experienced in five countries

- → Ebola: Samples of Ebola virus were not shared during the previous outbreaks in Africa
- → Zika: During the 2015-2016 Zika virus outbreak in Latin America, at least one country did not share the virus with the international scientific community.

If the innovative pharmaceutical industry is to achieve the 100 Days Mission, it must have fast, easy access to pathogens and their digital sequence information.

This is the only way to detect emerging threats, understand disease epidemiology and evolution, infection patterns and emerging new variants fast, and develop medical countermeasures that match the pathogen and its characteristics.

> **"The first ingredient for the 100 Days Mission to succeed is the immediate sharing of pathogens and their data. We should embed unrestricted pathogen sharing in any global agreement on pandemic prevention, preparedness, and response."**
> **Thomas Cueni, Director-General, IFPMA**

IFPMA's response: The Berlin Declaration

Since 2014, innovative pharmaceutical companies have had to take part in lengthy, burdensome negotiations for access to pathogens that are made more difficult by ABS rules that are simply not oriented to the specific needs of public health.

COVID-19 has showcased the innovative pharmaceutical industry's ability to adapt and work together to develop and scale-up production of the diagnostics, vaccines, and treatments needed to end the pandemic. But COVID-19 also brought to light the many difficulties in achieving equitable distribution and access to these countermeasures.

The Berlin Declaration is IFPMA's response to such challenges. By pledging to allocate real-time production of vaccines in the event of a pandemic, IFPMA member companies seek to fulfil and strongly contribute to equitable access in pandemic situations.

Among other things, the Berlin Declaration states that "companies will reserve an allocation of real-time production for distribution to priority populations in lower-income countries, as determined by health authorities during pandemics."

But it is important to note that this can only happen if these same companies and researchers, as well as surveillance networks, have rapid and predictable access to pathogens and their data.

Looking ahead – IFPMA's vision

IFPMA is actively representing the innovative pharmaceutical industry in policy discussions with governments and international health bodies to help ensure pathogens and their information are shared more widely and speedily.

We ask Member States and relevant multilateral partners to help facilitate the fast and unencumbered sharing of pathogens and their data to help deliver on the 100-Day Mission and deliver its full benefits for the sake of global public health.

How you can help

- → Join the conversation on Twitter and raise awareness of the need to #ShareDataOnPathogens.
- → Find out more about the pathogen sharing crisis and how you can help by speaking to IFPMA experts.

About IFPMA

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) represents over 90 innovative pharmaceutical companies and associations around the world. Our industry's almost three million employees discover, develop, and deliver medicines and vaccines that advance global health. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community improve the lives of people everywhere.

For more information, visit ifpma.org.