BMJ Public Health

Access and benefit sharing: streamlining legal frameworks for global health equity

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To cite: Berman A, Van Vooren B. Access and benefit sharing: streamlining legal frameworks for global health equity. *BMJ Public Health* 2025;**3**:e002830. doi:10.1136/bmjph-2025-002830

Received 27 February 2025
Accepted 28 February 2025

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In November 2024, the state parties to the Convention on Biological Diversity (CBD) invited pharmaceutical companies utilising publicly available digital sequence information (DSI) from genetic resources to contribute 0.1% of their revenue or 1% of their profit to a global access and benefit-sharing (ABS) fund, known as the Cali Fund. Simultaneously, World Health Organisation (WHO) member states are negotiating a pandemic treaty, which includes a pathogen access and benefit sharing system (PABS). If adopted, PABS will require pharmaceutical companies to provide financial or in-kind contributions when using pathogen genetic sequence data (GSD). Given that both ABS frameworks would apply to the development of the same vaccines, therapeutics, and diagnostics, their overlap could create significant legal complexity and uncertainty, ultimately jeopardising equitable access to medical countermeasures. Therefore, we call on states to create a single, multilateral system that will govern the sharing of pathogen DSI and GSD. This will help ensure that a single ABS system applies to each health product, thereby reducing legal complexity and enhancing regulatory clarity. In turn, this will contribute to advancing global health equity.

ACCESS TO VACCINES IN LOW-INCOME AND MIDDLE-INCOME COUNTRIES

As shown by the COVID-19 and mpox outbreaks, low-income and middle-income countries (LMICs) struggle to get vaccines, therapeutics, and diagnostics during disease outbreaks. To address this issue, there have been international efforts to establish access and benefit-sharing mechanisms that grant countries providing biological or genetic resources the right to receive fair and equitable benefits in return. Notably, the CBD and its 2014 Nagoya Protocol established that states have sovereign rights over their biological and genetic materials and that entities conducting research and development on these materials must share monetary or in-kind benefits with the country of origin. At present, there are 142 countries party to the Nagoya Protocol, and more than 100 national ABS laws have been adopted. Although originally intended to protect biodiversity by attaching a monetary incentive to nature stewardship, many countries have applied the CBD and Nagoya Protocol's ABS principles of ownership and monetisation to pathogens and public health. Under the logic of 'viral sovereignty,' researchers who wish to access pathogen samples and/or sequence data must be authorised by countries and agree to share benefits like financial payments or commitments to provide vaccines or therapeutics developed from those samples.[1]

CHALLENGES IN APPLYING THE NAGOYA PROTOCOL DURING PUBLIC HEALTH EMERGENCIES

Notwithstanding its laudable objectives, the CBD/Nagoya Protocol's ABS mechanism has several shortcomings during public health emergencies. First, ownership and monetisation incentivise not sharing pathogens until a benefit-sharing agreement has been reached. Second, ABS relies on bilateral negotiations between the provider and the user. Slow and cumbersome transactions make them impractical during public health emergencies.

Against this background, and following the COVID-19 pandemic, WHO member states are negotiating a 'Pathogen Access and Sharing System' (PABS) under a pandemic treaty. This system would require parties to rapidly share pathogens of 'pandemic potential'—or the GSD of such pathogens—through a WHO multilateral system. Participating users would sign legally binding contracts with WHO to provide the multilateral mechanism with annual contributions as well as a percentage of the vaccines,

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therapeutics, or diagnostics developed for the pathogen-causing pandemic. If adopted at the 78th World Health Assembly in June 2025, member states will subsequently develop the PABS's operational details.[2]

THE SHIFT FROM PHYSICAL PATHOGEN SAMPLES TO PATHOGEN GSD

Traditionally, ABS involved the exchange of physical pathogen samples to 'trigger' a benefit-sharing agreement. However, in today's technological and health landscape, scientists increasingly share large quantities of pathogen GSD. These data are digital files containing pathogen genetic sequences that can be uploaded to a database, such as GenBank or the Global Initiative on Sharing all Influenza Data (GISAID), or shared via email. New data technologies and the public health imperative for comprehensive epidemiological data and global surveillance require the rapid availability and sharing of such data.

The PABS being negotiated at the WHO applies both to physical samples and GSD of pathogens with pandemic potential. In parallel, in December 2022, CBD parties established a multilateral mechanism for benefit sharing from DSI on genetic resources. From November 2024, large companies making commercial use of publicly available DSI on genetic resources are invited to pay 0.1% of their revenue or 1% of their profits to a global biodiversity fund, also referred to as the Cali Fund. The term DSI has not been defined yet but is expected to cover DSI of all genetic resources, including pathogen GSD.[3]

DEVELOPMENT OF VACCINES: THE STACKING OF NATIONAL AND INTERNATIONAL LEGAL OBLIGATIONS

A case study on a SARS-CoV-2 messenger RNA (mRNA) vaccine[4] shows that developing a vaccine can require over 250 pathogen genetic sequences. Some of these sequences are of *pandemic* pathogens, while others are of *other* pathogens. Consequently, vaccine developers will have to contend with three sets of ABS mechanisms: (1) the Nagoya Protocol to the CBD and its more than 100 national ABS laws, of which at least 39 apply to DSI; (2) the Cali Fund for benefit sharing from DSI; and (3) the PABS under the WHO pandemic treaty (if adopted).

This means that *for every single sequence*, a research entity must determine whether it is governed by 100+ national ABS laws and/or by the Cali Fund and/or by the PABS, or by some or all of them. Such an investigation is very complicated, time-consuming and costly. Furthermore, some jurisdictions, like Switzerland, the UK, and the European Union, sanction non-compliance with administrative or criminal fines.

THE UNDESIRED SECONDARY EFFECTS OF LEGAL UNCERTAINTY AND COMPLEXITY

Vaccine developers face an almost insurmountable legal spaghetti bowl. Such legal complexity can have (and already has been having) unintended and undesirable consequences for global health equity. First, concerned about the immense amount of red tape and the consequent expected delays, researchers refrain from obtaining pathogen data or samples from 'ABS-burdened jurisdictions'. Second, researchers wait for 'the returning traveler' bringing the pathogen to a non-ABS jurisdiction, thus gaining access to samples free from legal complexities. However, this has led to tangible public health impacts, such as suboptimal vaccine composition (e.g., for rapid growth in eggs), medical countermeasures not being tailored to or tested for efficacy against new variants, and a lack of regional representativeness in multivariant vaccines.

In short, well-intentioned but poorly designed ABS frameworks create a lose-lose situation for global health equity.

RECOMMENDATIONS

ABS can support global health equity by allocating a fair portion of vaccines to LMICs. However, for these mechanisms to succeed, the legal framework underpinning them must be designed to avoid excessive complexity and inconsistency. We are concerned that the CBD fund for DSI and PABS will create further fragmentation and conflicting and overlapping requirements, to the detriment of global health equity.

A legally unambiguous ABS without conflicts and inconsistencies will benefit global public health the most. As such, we provide a few recommendations:

- Rather than rushing negotiations on a PABS or Cali Fund for DSI for political reasons, countries should negotiate a *truly* unified, centralised, multilateral system that will simplify ABS and govern the sharing of GSD and pathogen DSI. There is a near-complete overlap between CBD and WHO member states, so this could be done.
- Parties should seek to create one system such that countries do not have coexisting bilateral or multilateral sources for ABS obligations that apply to the same vaccine development activity.
- States should not seek constructive ambiguity, as is so often the case in international negotiations, but should develop a comprehensive ABS system for pathogen sequences that promotes legal certainty and removes complexity.

As the world grapples with the lessons learned from the COVID-19 pandemic, ABS frameworks must be refined to facilitate, rather than hinder, global health equity. If critical details are not addressed, the entire system risks failure—not due to a lack of good intentions, but because of an overly complex and impractical legal landscape. The future of rapid and equitable responses to global health emergencies depends on getting these legal details right.

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Contributors Both AB and BVV meet all four criteria for authorship. AB prepared the initial draft, and BVV revised the draft and made substantial contributions. Both

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authors accept full responsibility for the finished work and/or the conduct of the study, had access to the data and controlled the decision to publish.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests BVV frequently advises the innovative biopharmaceutical on ABS under the CBD and WHO pandemic accord. This contribution was written in his own name.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication Not required.

Provenance and peer review Commissioned; internally peer reviewed.

Data availability statement No data are available.

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