Spark Street Advisors
Data Driven Strategies

Briefing note on the WHO Pathogen Access and Benefit Sharing System (PABS)

21 March 2024

What do the terms "access" and "benefit sharing" mean?

As currently proposed, "access" means the rapid and open sharing of biological materials and genetic sequence data (GSD) of pathogens of pandemic potential through a coordinated laboratory network and recognized databases. 'Benefit sharing' involves the timely and equitable availability of pandemic products (e.g., drugs, vaccines, or diagnostics) and monetary contributions from companies producing pandemic products. This could be done, for example, by allocating a percentage of production to developing countries, or financial contributions toward capacity-building, and complemented by other types of in-kind and voluntary contributions such as technology transfer.

Why is this important?

The COVID-19 pandemic highlighted the imbalances in equity between countries during global public health emergencies. As an example, South African researchers shared genomic sequence data for the Omicron variant, but the vaccines developed by pharmaceutical companies in high-income countries using these sequences were largely inaccessible to the majority of Africans. The country was also penalized for sharing (e.g., travel bans).

The rapid sharing of pathogens and their sequence data is also critical for pandemic preparedness and response, but due to developments in international law in recent years, pathogen sharing has been impeded.

What exactly is being proposed?

The current draft includes a Pathogen Access and Benefit Sharing (PABS) mechanism that operates in two parts: (1) Parties have an obligation to share the biological materials and genetic sequence data of pathogens with pandemic potential, (2) the benefits from the use of those materials and data, such as vaccines, medicines, know-how transfer, capacity building, and financial compensation, would be equitably shared on public health risks, needs, and demand basis. Parties would share PABS biological materials with laboratories that are part of an established WHO-coordinated laboratory network, and databases recognized as part of the PABS system, which are publicly accessible and agree with the WHO PABS terms and conditions. The system is open to all users, and all of them are expected to contribute in different ways, with the difference being that manufacturers are expected to sign binding contracts committing to the aforementioned benefits.

Is there a precedent for this type of system?

Yes. A similar system was used under the 2011 Pandemic Influenza Preparedness (PIP) Framework, by which vaccine manufacturers are expected to commit or reserve at least 10% of production for the WHO at affordable prices when they use influenza materials shared through the Global Influenza Surveillance and Response System.

Also, the draft treaty references the Nagoya Protocol of the Convention on Biodiversity (CBD), a binding agreement from 2010 that creates legal obligations for users of genetic resources, including pathogens.

What is at the core of the debate?

There are a number of questions under discussion. How are benefits to be shared? How much guarantee can the system give that enough benefits will be shared and that users will not engage in free riding? What would be the monetary contributions expected from pandemic product manufacturers who are part of the PABS system? How much product would manufacturers benefitting from the system be required to make available, and at what point, and how would WHO pay for these?

The language in the current draft of the Accord proposes non-exclusive licensing and time- and scope-limited intellectual property (IP) waivers, particularly for manufacturers benefiting from public funding. While rights may not be sought on shared biological materials or GSD (similar to PIP), the PABS system does not restrict seeking IP rights on products developed using biological materials or GSD. While the text proposes that parties agree that IP rights may not be sought on pathogens or their GSD used during public health emergencies of international concern or pandemics, it is unclear when "during" begins and ends for pandemics.

How does this relate to the recent World Trade Organization (WTO) discussions?

When more than 100 developing countries applied to the WTO for a waiver of IP during the COVID-19 pandemic, high-income countries blocked and delayed the proposal, arguing that they wanted manufacturers to have their IP protected. Instead, the WTO Members agreed to a Decision on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and COVID-19 that reiterates the rights countries have to apply IP flexibly, but the agreement only refers to vaccines. A decision to include therapeutics and diagnostics was supposed to be taken later but that did not happen. Some high-income countries are also making the argument that issues related to IP should be the exclusive roam of the WTO and World Intellectual Property Organization (WIPO) and not be considered within the remit of WHO.

What is at the core of the debate?

This article is one where the rubber hits the road on equity. While there is a lot of "devil in the detail," the bottom line is that low- and middle-income countries are concerned that when they share PABS material and data, they will not receive monetary compensation, access to timely or affordable pandemic products, or access to know-how or tech transfer required to produce their own countermeasures. They want to ensure a system where access and benefits sharing are on "equal footing": providing rapid, systematic timely access to biological materials of pathogens with pandemic potential and GSD, and equitable, fair, and rapid sharing of monetary and non-monetary benefits.

High-income country pharmaceutical companies (and their respective Member States) want "unconditional access to materials purporting that the system as currently proposed would slow their ability to produce products. They promise in exchange certain concessions e.g., concessional pricing, and allocation of products to developing countries. How they would be held accountable for these commitments is not clear.