# Briefing paper on

# Pathogen Access and Benefit Sharing (PABS)

September 2025

## Introduction

The Pandemic Agreement (PA) was adopted in May 2025 at the 78th World Health Assembly. Under Article 12 of the Agreement, Member States agreed to establish a multilateral system for the sharing of pandemic pathogen materials and sequence information that would provide "safe, transparent, and accountable access and benefit-sharing."[1] The details of this system, the WHO Pathogen Access and Benefit-Sharing System, or PABS system, are to be negotiated in an annex to the PA.

An Intergovernmental Working Group (IGWG) has been established, under WHA Resolution 78.1, to negotiate this annex (the PABS Instrument), and to conduct several preparatory tasks for the Conference of the Parties for the PA, including developing the terms of reference for the Coordinating Financial Mechanism. Member States have set an ambitious timeline for the completion of the IGWG's work: March 2026, with adoption in May 2026 at the 79th World Health Assembly.[2]

This Briefing Paper was prepared by Anna Bezruki in partnership with Pandemic Action Network (PAN). The author and PAN are grateful for comments from Viviana Muñoz-Tellez, Timothée Poisot, Adam Strobeyko, and Gian Luca Burci which helped strengthen the paper. The analysis and views presented do not necessarily represent those of the persons that provided comments.

This paper is intended to provide an outline of what was agreed upon in the Pandemic Agreement regarding the establishment of the PABS system. The paper also seeks to provide answers to some frequently asked questions about the possibilities for the PABS system, and provides a brief overview of some of the other access and benefit-sharing systems in other international agreements. The paper is meant as a helpful contribution to IGWG discussions; there are many issues in this paper that merit a deeper dive as negotiations continue.

For more information, visit www.pandemicactionnetwork.org.

[1] *Agenda Item 16.2 WHO Pandemic Agreement*, WHA 78.1 (World Health Assembly, 2025), https://apps.who.int/gb/ebwha/pdf_files/WHA78/A78_R1-en.pdf.
[2] Intergovernmental Working Group, *Agenda Item 4. Timeline and Deliverables of the Open-Ended Intergovernmental Working Group*, A/IGWG/1/3 Rev.1 (World Health Organization, 2025), https://apps.who.int/gb/IGWG/e/e_igwg1.html.

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## Part 1: PABS in the Pandemic Agreement

Article 12 of the PA addresses the international sharing of pathogen samples and sequence information and the sharing of benefits arising from their sharing and use — that is, pathogen access and benefit-sharing (PABS). It establishes the PABS System, which is defined as a "multilateral system for safe, transparent, and accountable access and benefit-sharing for PABS Materials and Sequence Information." It details features of the PABS system that are to be further elaborated in an annex to the PA, the PABS Instrument.

### Background: Contextualizing PABS

Access and benefit sharing is a well-established concept in international law, dating back several decades to the Convention on Biological Diversity (CBD) (1992) (see Box 1). It recognizes and provides a policy structure for addressing the fact that countries have a sovereign right to their genetic resources, as well as the rights of Indigenous communities over their genetic resources and associated traditional knowledge. As part of the exercise of these rights, they may choose to set terms and conditions on access and use of those resources (including, for example, prior informed consent).

There are now multiple international agreements that include ABS systems, including the Pandemic Influenza Preparedness (PIP) Framework (2011) (see Box 2), the International Treaty on Plant Genetic Resources for Food and Agriculture (2001) (Plant Treaty), and the Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas beyond National Jurisdiction (2023) (BBNJ).

The PABS system will create a new, specialized ABS regime for pathogens of pandemic potential.

### Purpose and Function of PABS system

The PABS system is one of the mechanisms by which the Pandemic Agreement (PA) promises to increase equity and redress one of the primary failures of the Covid-19 pandemic response: inequitable access to medical countermeasures between the Global North and Global South despite longstanding cooperation in disease surveillance and control. Under the PABS System, the "rapid and timely sharing" of pathogen materials and sequence information for pathogens of pandemic potential will be treated on "an equal footing" with the "rapid, timely, fair and equitable sharing of benefits" (Article 12).

On the access side, the agreement aims to reduce barriers and ensure rapid and timely access to samples and sequence data from pathogens of pandemic potential that are critical for supporting outbreak response and producing safe and effective countermeasures.

On the benefits side, it aims to establish clear obligations for the sharing of monetary and non-monetary benefits (such as medical countermeasures and technology transfer), that hold the potential to address longstanding gaps in outbreak governance that have enabled biopiracy and the accumulation of benefits to a select few for decades. Throughout the colonial period, and continuing through the present — despite a growing recognition in international law of a right to sovereignty over genetic resources — pathogen samples have

been taken without the permission of the countries and communities from which they originated and used to create benefits — ranging from medical countermeasures to scientific credit and prestige — that were not shared with the originating communities.[3]

Public funding of surveillance activities and pathogen sharing in outbreaks has enabled substantial profits for industry, but the current system has not guaranteed access to the resultant medical countermeasures. Similarly, for researchers, sharing of pathogen samples and data has primarily benefited those with high capacity in a few countries, research outputs may not be shared widely, and there is insufficient recognition of the contributions of scientists in the Global South.

These benefits are to be shared on the basis of public health need (i.e., access and benefit-sharing are decoupled). Notably, the PA established that, under the PABS System, 20% of real-time production of vaccines, diagnostics, and therapeutics (VTDs) — of which, at least 10% (i.e., half) would be in the form of a donation — would be made available based on public health need in pandemic emergencies (Article 12.6).

Article 12 also outlines how the PABS Instrument is to interact with other relevant international access and benefit-sharing (ABS) agreements, including consistency with the Convention on Biological Diversity (CBD) and its Nagoya Protocol (Article 12.4) (See Box 1), and complementarity with the Pandemic Influenza Preparedness (PIP) Framework (Article 12.5) (See Box 2).

## What remains for the negotiations

The framework sketched in Article 12 will need to be elaborated in the PABS Instrument. Numerous terms remain undefined, including pathogens with pandemic potential (which would be subject to the PABS system), participating manufacturers, and “public health risk and need.” Many structural, operational, and governance questions remain open and will need to be negotiated by the IGWG, including how access to sequence data will be governed (and relationship to existing pathogen sequence databases) and how contracts will be used to define terms of access and benefit-sharing.

There are topics that will likely take up a significant amount of negotiators’ time, due to their technical and legal complexity, political sensitivity, or both. These include, but are not limited to, definition of terms, triggers for benefit-sharing, recipients of benefits, and traceability measures.

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[3] Stefan Elbe, “Who Owns a Deadly Virus? Viral Sovereignty, Global Health Emergencies, and the Matrix of the International,” *International Political Sociology* 16, no. 2 (2022): olab037, https://doi.org/10.1093/ips/olab037; Amy Maxmen, “Why Some Researchers Oppose Unrestricted Sharing of Coronavirus Genome Data,” *Nature* 593, no. 7858 (2021): 176— 77, https://doi.org/10.1038/d41586-021-01194-6; Anthony Rizk et al., *“Everybody Knows This Needs to Be Done, but Nobody Really Wants to Do It”: Governing Pathogen- and Benefit-Sharing (PBS)*, 23, Global Health Centre Working Paper (Global Health Centre, Graduate Institute of International and Development Studies, 2020); Michelle F. Rourke, “Restricting Access to Pathogen Samples and Epidemiological Data: A Not-So-Brief History of ‘Viral Sovereignty’ and the Mark It Left on the World,” *Infectious Diseases in the New Millennium* 82 (May 2020): 167— 91, https://doi.org/10.1007/978-3-030-39819-4_8; Lyn Horn et al., “The Cape Town Statement on Fairness, Equity and Diversity in Research,” *Nature* 615, no. 7954 (2023): 790— 93, https://doi.org/10.1038/d41586-023-00855-y.

### Box 1: Convention on Biological Diversity & Nagoya Protocol

The Convention on Biological Diversity (CBD) (1992) is an international treaty with the following aims: "to conserve biodiversity, promote its sustainable use, and ensure the equitable sharing of benefits arising from the utilization of genetic resources."[4] The CBD recognized that Parties have sovereign rights over their genetic resources.

The CBD has particularly widespread adoption, with 196 States Parties to the CBD (this does not include the United States of America or the Holy See).[5] The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits (Nagoya Protocol) to the CBD was adopted in 2010 and it has 142 Parties.[6] The Nagoya Protocol was added in order to help bring about the aims of the CBD, specifying that use of genetic resources must occur with the prior informed consent of the country of origin (unless the country specifies otherwise) and on mutually agreed terms about use and benefit-sharing.[7]

In 2022, the CBD Conference of Parties (COP) established the Multilateral Mechanism for the Fair and Equitable Sharing of Benefits from the Use of Digital Sequence Information on Genetic Resources to address longstanding questions about how DSI was to be addressed under CBD.[8] In 2024, this was operationalized through COP 16 Decision 16/2;[9] monetary benefit-sharing from the multilateral instrument will operate through the Cali Fund. Certain institutions that use DSI that meets specific criteria[10] will provide payment to the Cali Fund, which will in turn distribute these funds to "developing countries and those with economies in transition, as well

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[4] "Convention on Biological Diversity," adopted 22 May 1992, entered in force 29 December 1993, *Treaty Series*, vol. 1760, no. 30619.(1993): 79-307, https://treaties.un.org/pages/ViewDetails.aspx?src=IND&mtdsg_no=XXVII-8&chapter=27&clang=_en

[5] CBD (Convention on Biological Diversity), "List of Parties," Convention on Biological Diversity, Secretariat of the Convention on Biological Diversity, n.d., https://www.cbd.int/information/parties.shtml.

[6] CBD (Convention on Biological Diversity), "Parties to the Nagoya Protocol," Convention on Biological Diversity, Secretariat of the Convention on Biological Diversity, n.d., https://www.cbd.int/abs/nagoya-protocol/signatories/.

[7] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity: Text and Annex, 25 (2010). https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf.

[8] CBD et al., *Guide to the Cali Fund: Sharing the Benefits of Genetic Data from Nature* (Convention on Biological Diversity (CBD), United Nations Environmental Programme (UNEP), United Nations Development Programme (UNDP), 2025), https://www.cbd.int/article/Publication-Guide-to-Cali-Fund; CBD COP 15, *Decision Adopted by the Conference of the Parties to the Convention on Biological Diversity 15/9. Digital Sequence Information on Genetic Resources*, CBD/COP/DEC/15/9 (Conference of the Parties to the Convention on Biological Diversity, 2022).

[9] CBD COP 16, *Decision Adopted by the Conference of the Parties to the Convention on Biological Diversity 16/2. Digital Sequence Information on Genetic Resources*, CBD/COP/DEC/16/2 (Conference of the Parties to the Convention on Biological Diversity, 2024), 16, https://www.cbd.int/doc/decisions/cop-16/cop-16-dec-02-en.pdf.

[10] These criteria include that the DSI "has been made publicly available; is not subject to mutually agreed terms, unless those terms explicitly allow public sharing" and "is not already governed by another international agreement on access and benefit-sharing, unless that agreement opts to use this mechanism." See:

as indigenous peoples and local communities in both developing and, where appropriate, developed countries."[11]

Pathogens, while not explicitly addressed within the texts, are not excluded from them and have over time generally come to be treated as within the scope of CBD and the Nagoya Protocol.[12] There has been substantial debate on this topic. Recent decisions by the CBD COP that have considered the interlinkages between biodiversity and health have also not excluded pathogens or the sharing of health products as a form of benefit-sharing.[13] In 2024, COP 16 adopted the Global Action Plan on Biodiversity and Health under Decision 16.9, to assist with implementation of the Kunming-Montreal Global Biodiversity Framework. Under the Global Action Plan on Biodiversity and Health, one of the actions is:

> Recognize the role of genetic resources, digital sequence information on genetic resources and traditional knowledge associated with genetic resources in the research and development of health products and services, and the importance of the fair and equitable sharing of benefits arising from their utilization in this regard.

Article 12.4 of the PA establishes that "the PABS Instrument shall be consistent with, and not run counter to, the objectives of" the CBD and Nagoya Protocol. This still leaves room for additional consideration and specification of the relationship between the instruments, such as whether the PABS Instrument will be recognized as a Specialized International Instrument (SII) under the Nagoya Protocol.[14] If recognized as an SII, the PABS Instrument would act in place of the Nagoya Protocol, for Parties to the Nagoya Protocol, for the PABS materials in scope of the Instrument. The PABS Instrument has the potential to streamline and standardize the process of compliance with prior informed consent for access under CBD and Nagoya for pathogens of pandemic potential, by moving from case by case, bilateral agreements to a multilateral system.

In addition to outstanding questions about the relationship and interaction between the PABS Instrument and CBD and Nagoya, the IGWG may turn to the CBD, Nagoya, the Cali Fund, Plant Treaty, and BBNJ to think through options for aspects of the structure, operation, and terms of the PABS Instrument. Driven in part by the establishment of the Cali Fund,[15] there may be a push by some Member States in the IGWG to treat sequences differently in terms of benefits-sharing. However, the Cali Fund approach is not the only option for sequence data benefit-sharing (see Question 6 for more on how data engineering can support traceability).

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[11] CBD et al., *Guide to the Cali Fund: Sharing the Benefits of Genetic Data from Nature*.
[12] Abbie-Rose Hampton et al., "'EQUITY' IN THE PANDEMIC TREATY: THE FALSE HOPE OF 'ACCESS AND BENEFIT-SHARING,'" *International and Comparative Law Quarterly* 72, no. 4 (2023): 909— 43, https://doi.org/10.1017/S0020589323000350; Dario Piselli, *International Sharing of Pathogens and Genetic Sequence Data Under a Pandemic Treaty*, Global Health Centre Policy Brief (Global Health Centre, Graduate Institute of International and Development Studies, 2022), https://www.graduateinstitute.ch/library/publications-institute/international-sharing-pathogens-and-genetic-sequence-data-under.
[13] CBD COP 16, *Decision Adopted by the Conference of the Parties to the Convention on Biological Diversity 16/19. Biodiversity and Health*, CBD/COP/DEC/16/19 (Conference of the Parties to the Convention on Biological Diversity, 2024).
[14] Piselli, *International Sharing of Pathogens and Genetic Sequence Data Under a Pandemic Treaty*.
[15] CBD et al., *Guide to the Cali Fund: Sharing the Benefits of Genetic Data from Nature*.

### Box 2: Pandemic Influenza Preparedness (PIP) Framework

The Pandemic Influenza Preparedness (PIP) Framework concerns the sharing of "H5N1 and other influenza viruses with human pandemic potential" and access to benefits, including vaccines.[16] Adopted in 2011 by the World Health Assembly as a nonbinding resolution, it was the first pathogen-specific ABS agreement. It builds on the principles of ABS in the CBD, placing — as the PA does — access and benefit sharing on equal footing.

PIP is a narrow framework that applies to "PIP biological materials" — physical samples of influenza viruses with human pandemic potential, leaving unresolved the question of ABS for genetic sequence data.[17] Samples are shared under PIP via the Global Influenza Surveillance and Response System (GISRS), a network of laboratories around the world coordinated by the WHO (that predates PIP by several decades).[18]

Under PIP, participating laboratories and manufacturers enter into standard, legally binding contracts — Standard Material Transfer Agreements (SMTAs) — which govern their use of the materials and the benefits to be shared. There are two SMTAs available — one for Member States to share materials with WHO via GISRS laboratories (SMTA1) and one for sharing from GISRS to both commercial and noncommercial entities (SMTA2).[19] The SMTA2 contracts contain a menu of benefit-sharing options that entities may select from (checkboxes) that vary based on whether they will be using samples for commercial or non-commercial use.[20]

Article 12.5 specifies that the PABS Instrument "shall contain provisions regarding" the "development and implementation in a manner" that is "complementary to, and not duplicative of, the access and benefit-sharing measures and obligation of the Pandemic Influenza Preparedness Framework." There are open questions for the IGWG regarding this relationship — for example, regarding how pandemic influenza sequences, which are out of scope of PIP, may be addressed within the PABS Instrument.

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[16] WHO, *Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*, WHO Doc A64/8 (World Health Organization, 2011), 68, http://www.who.int/influenza/resources/pip_framework/en/.
[17] Lawrence O. Gostin et al., "Virus Sharing, Genetic Sequencing, and Global Health Security," *Science* 345, no. 6202 (2014): 1295— 96, https://doi.org/10.1126/science.1257622.
[18] WHO (World Health Organization), *Brief History of the Development of the Framework on Sharing Influenza Viruses and Access to Vaccines and Other Benefits* (World Health Organization, 2011), https://www.who.int/influenza/pip/Framework_History_2011.pdf?ua=1.
[19] WHO, *Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*.
[20] For additional perspectives on PIP, see: David P. Fidler and Lawrence O. Gostin, "The WHO Pandemic Influenza Preparedness Framework: A Milestone in Global Governance for Health," *JAMA* 306, no. 2 (2011): 200— 201, https://doi.org/10.1001/jama.2011.960, and Michelle F. Rourke, "Access by Design, Benefits If Convenient: A Closer Look at the Pandemic Influenza Preparedness Framework's Standard Material Transfer Agreements," *The Milbank Quarterly* 97, no. 1 (2019): 91— 112, https://doi.org/10.1111/1468-0009.12364.

## Part 2: Frequently Asked Questions

### Access questions

### 1. What will be shared in the system? What are PABS materials?

**In Brief:** Both physical pathogen samples (e.g., viral isolates and bacterial cultures) and sequence data from pathogens with pandemic potential will be shared in the PABS System.

**PABS Materials and Sequence Information** (PABS materials) are defined in Article 12.1 as "materials and sequence information on pathogens with pandemic potential." PABS materials encompass both physical samples of pathogens of pandemic material and the associated genetic sequence data (i.e., DNA or RNA).

The IGWG has to further refine this definition of PABS materials — to define what, for the purposes of the PABS Instrument, constitutes a pathogen of pandemic potential and how, when, and by whom these determinations will be made and, as needed, amended over time (see Questions 2 and 3).

### 2. What kind of pathogens are going to be shared via the PABS System?

**In Brief:** Those that are determined to have "pandemic potential." Defining this term will be one of the central tasks of the IGWG and will have a significant impact on the future shape and function of the PABS system.

The challenge for the IGWG will be to balance discernment — not including *all* pathogens or potential pathogens — with flexibility and adaptability over time, as pathogens emerge and change, or as countermeasures are developed. The definition will intersect in complex ways with other aspects of the PABS Instrument. The IGWG may wish to consider how pathogen reclassification (from outside scope to within scope of PABS materials) may produce loopholes to benefit-sharing.[21]

[21] For example, would a vaccine created using a sequence shared before a pathogen was within scope, but accessed and used after it was within scope be subject to benefit-sharing obligation under the PABS Instrument? In addition, see Question 2b.

**Summary Table**

| | What is in the PA | What is left to the IGWG |
|---|---|---|
| **PABS SYSTEM** | Article 12 of the Pandemic Agreement establishes a multilateral system for the sharing of pathogens of pandemic potential and benefits arising from their sharing and use. | To develop and define the framework outlined in Article 12 in terms of scope, structure, governance, and operationalization. |
| **PABS MATERIALS** | PABS materials are defined in Article 12.1 and encompass both physical samples of **pathogens of pandemic material** and the associated information on their genetic sequences (i.e., DNA or RNA). | Define **pathogens of pandemic potential**<br>● Which pathogens?<br>● Which pathogen characteristics (e.g. disease severity, transmissibility, availability of countermeasures)?<br>● From which sources (animals and humans)?<br>● What is the process for (re)assessing pathogens as circumstances change?<br>● How to deal with legacy data? |
| **TRACEABILITY** | Address traceability mechanisms in the PABS Instrument (Article 12.3). | Determine how traceability will be defined, and which mechanisms will be used to achieve it. |
| **BENEFITS** | Benefits will include access to vaccines, therapeutics and diagnostics to combat a pandemic emergency.[22]<br>Range of other benefits to be incorporated into legally binding contracts, including capacity-building and technology transfer (Article 12.8).<br>**Participating manufacturers** "shall make available … rapid access targeting 20%" of real-time production of vaccines, diagnostics, and therapeutics | Define **participating manufacturers** and **affordable prices**<br>Determine access to vaccines, therapeutics, and diagnostics during a public health emergency of international concern (PHEIC).<br>Define a menu of benefit-sharing options to be included in standardized contracts |

[22] See Box 3: Pandemic Emergencies and PHEICs

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|---|---|---|
| | in a pandemic emergency to WHO, with at half of that (10%) in the form of a donation and the rest at **affordable prices** (Article 12.6). | |
| **BENEFIT RECIPIENTS** | Vaccines, therapeutics, and diagnostics (VTDs) secured by the WHO through benefit-sharing arrangements with participating manufacturers will be shared based on **public health risk and need** (Article 12.6). | Define **public health risk and need**.<br>Determine eligibility of non-Parties to receive VTDs procured through the PABS System.<br>Determine how benefits outside of VTDs in pandemic emergencies will be allocated. |
| **ROLE OF WHO** | WHO will administer and coordinate the PABS System (Article 12.2). | Specify the terms of how the PABS system will be administered and coordinated by the WHO and its coordination with other institutions. |
| **TRANSPARENCY & ACCOUNTABILITY** | The PABS system is to be transparent and accountable (Article 12.1). Transparency and accountability of the PABS system also appear in reference to traceability measures and open access to data (Article 12.3). PABS system to be operationalized in a transparent and accountable manner. | Determine how transparency and accountability will be operationalized in the PABS System. |

### a. What are the different ways to define a pathogen of pandemic potential?

**In brief:** There may be several approaches to defining pathogens of pandemic potential. Two approaches that are sometimes discussed are a list-based approach and a pathogen agnostic or all-hazards approach.

Under a list-based approach, a list of all pathogens meeting certain criteria would be included — such a list may include pathogens, such as mpox virus or families of pathogens, such as Poxviridae (of which mpox virus is a part). In contrast, a pathogen agnostic or all-hazards approach would attempt to identify characteristics of pathogens and/or the diseases they cause that are associated with pandemics (such as high morbidity).

While sometimes these approaches — list-based and pathogen agnostic or all-hazards — are described as in contrast to each other, it does not have to be a strict binary. The IGWG may wish to combine elements of each of these approaches to develop a definition of a pathogen of pandemic potential.

Lists can provide clarity on what is or is not within scope of an agreement, but they can quickly become out of date, particularly as pathogens spillover from animals and spread in humans (see more on this in Question 2b). Nevertheless, there are several existing lists of pathogens that may serve as starting points for negotiators in identifying some of the pathogens, or characteristics of pathogens, that they wish to include in the PABS Instrument's definition of a pathogen of pandemic potential. These range from notifiable diseases and public health events under the IHR(2005)[23] and notifiable animal diseases articulated in WOAH's Terrestrial and Aquatic Animal Health Codes[24] to the WHO's R&D Blueprint for Epidemics, to the "List of Human and Animal Pathogens for Export Control,"[25] of the Australia Group (a group of 42 countries plus the EU)[26] as well as lists produced by national governments for various purposes, such as guiding R&D[27] and regulating possession and use.[28]

Both the IHR(2005) and the WHO Blueprint combine elements of a list approach and an all-hazards approach — leaving space for emerging or reemerging diseases to be recognized and included. The Blueprint incorporates the concept of a Pathogen X — that an

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[23] World Health Assembly, *International Health Regulations, 3rd Edition* (World Health Organization, 2005), https://apps.who.int/iris/bitstream/handle/10665/246107/9789241580496-eng.pdf?sequence=1.
[24] "Animal Diseases," *WOAH - World Organisation for Animal Health*, n.d., accessed August 6, 2025, https://www.woah.org/en/what-we-do/animal-health-and-welfare/animal-diseases/.
[25] The Australia Group, *List of Human and Animal Pathogens and Toxins for Export Control* (The Australia Group, 2023), https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/human_animal_pathogens.html.
[26] Australia Group, "Participants — The Australia Group," 2023, https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/participants.html.
[27] UKHSA, *Priority Pathogen Families Research and Development Tool* (United Kingdom Health Security Agency, 2025), https://www.gov.uk/government/publications/priority-pathogen-families-research-and-development-tool.
[28] Federal Select Agent Program, "Select Agents and Toxins List," United States Federal Select Agent Program, January 14, 2025, https://www.selectagents.gov/sat/list.htm.

unknown or uncharacterized pathogen may cause a PHEIC.[29] Annex 2 of the IHR(2005) contains a decision instrument to be used to assess whether an event should be notified as a potential PHEIC, which includes consideration of whether the public health impact is serious, the event is unusual or unexpected, and if it comes with a significant risk of international spread. However, both the Blueprint and the IHR(2005) list some specific pathogens that, in the former, are understood as warranting further R&D and in the latter, notification to the WHO.

There are likely multiple pathogens that appear on many of these lists — including, for example, Nipah virus — that the IGWG will want to be within scope of their definition of pathogens of pandemic potential. In addition, the IGWG may consider building on the approach in the WHO R&D Blueprint by looking at pathogen and disease characteristics and pathogen/host dynamics, such as transmissibility, disease severity, and availability of targeted countermeasures in reaching this definition. There are a number of bodies that could potentially be modified to provide the necessary scientific synthesis, such as (but not limited to) the existing TAG system or the WHO Berlin Hub, or the IGWG may wish to consider creating a new body for this purpose.

### b. Would animal pathogens be included or only those that have infected humans?

**In Brief:** Article 12 of the PA does not address this explicitly and it is one of the open questions for the IGWG.

Animal pathogens may be included in scope because **pathogens of pandemic potential** are not defined in the PA (see Question 2) and their inclusion would align with the broader

[29] The WHO's R&D Blueprint for Epidemics has, since 2015, identified priority pathogens for R&D, by identifying pathogens that due to features of their transmission, the availability and accessibility of medical countermeasures, and virulence have potential to cause a PHEIC. From its inception, it has included a Novel Agent, Disease X (and now Pathogen X) category — recognizing that some pathogens that are currently unknown or not characterized as a potential PHEIC may become a PHEIC in the future. In 2024, the prioritization process was further revised and updated, and now also includes priority pathogen families, and steps to further attempt to identify pathogens that might become capable of causing a PHEIC in the future (e.g., Pathogen X). See: WHO, *Pathogens Prioritization: A Scientific Framework for Epidemic and Pandemic Research Preparedness* (World Health Organization (WHO), 2024), https://www.who.int/teams/blueprint/who-r-and-d-blueprint-for-epidemics, WHO (World Health Organization), *An R&D Blueprint for Action to Prevent Epidemics - Accelerating R&D and Saving Lives Update 2017* (World Health Organization, 2017), http://www.who.int/blueprint/about/brochure-2017.pdf?ua=1, WHO (World Health Organization), *An R&D Blueprint for Action to Prevent Epidemics: Plan of Action May 2016* (World Health Organization, 2016).

aims of the PA.[30] Excluding animal pathogens entirely from the definition of pathogens of pandemic potential would effectively exclude many pathogens of pandemic potential.

Many pathogens can infect both humans and animals. The complex and dynamic nature of pathogen-host and animal-human interactions (including spillovers of pathogens from animals to humans, spillbacks of pathogens from humans to animals, and continual pathogen evolution) mean there is no conclusive, non-arbitrary, or permanent division between animal and human pathogens. Almost all new infectious diseases in humans originate in animals.[31] There are tens of thousands of pathogens that exist in animals that have not been seen in humans but that might pose a human health risk.[32] Only a small proportion of infectious diseases in humans are the result of ongoing animal to human transmission — but such 'spillovers' can be the source of important outbreaks, particularly if ongoing human-to-human transmission is then sustained. One reason that animal pathogens are particularly important as a source of pandemic risk is that species or lineages of pathogens that have primarily circulated in animals prior to a spillover event encounter an immunologically naive human population.

All of these scientific complexities raise questions about whether, where, and how to draw legal lines. In particular, because there is an increasing amount of countermeasure development that works from pathogen samples taken from animals,[33] it is worth considering not just the question of whether samples from animals are in scope, but whether medical countermeasures developed in part or in full before a PHEIC or pandemic emergency using those samples are in scope.

There are pathogens that are circulating among animals that have not yet caused (or been recognized to have caused) disease in humans today that will, in the future, spill over and spread among humans to the point of becoming a large-scale outbreak. It may be possible to identify some of these pathogens prospectively — before they have infected multiple

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[30] For some perspectives on the inclusion of animal pathogens, see: Colin J. Carlson et al., "Prioritizing Prevention in the Pandemic Treaty," *Think Global Health*, January 21, 2025, https://www.thinkglobalhealth.org/article/prioritizing-prevention-pandemic-treaty, Michelle Rourke, "One Health and Pathogen Sharing: What's Missing in the Pandemic Treaty's Proposed Pathogen Access and Benefit-Sharing (PABS) System?," SSRN Scholarly Paper 4965622 (Social Science Research Network, September 24, 2024), https://doi.org/10.2139/ssrn.4965622, Adam Strobeyko, "The Devil Is in the Annex: Pathogen Access and Benefit Sharing," *Governing Pandemics Snapshot*, June 2025, https://www.governingpandemics.org/gp-snapshot, and Alexandra L. Phelan and Colin J. Carlson, "A Treaty to Break the Pandemic Cycle," *Science*, July 14, 2022, eabq5917, https://doi.org/10.1126/science.abq5917.

[31] Colin J. Carlson et al., "Pathogens and Planetary Change," *Nature Reviews Biodiversity* 1, no. 1 (2025): 32— 49, https://doi.org/10.1038/s44358-024-00005-w; Kate E. Jones et al., "Global Trends in Emerging Infectious Diseases," *Nature* 451, no. 7181 (2008): 7181, https://doi.org/10.1038/nature06536.

[32] Colin J. Carlson et al., "Global Estimates of Mammalian Viral Diversity Accounting for Host Sharing," *Nature Ecology & Evolution* 3, no. 7 (2019): 1070— 75, https://doi.org/10.1038/s41559-019-0910-6.

[33] For example, several of H5N1 pandemic vaccines approved for use by the EMA are derived from avian samples, and there is research using coronaviruses isolated from bats to try to develop a broad spectrum coronavirus vaccine as well as to compare cross-reactivity of different SARS-CoV-2 spike sequences to sarbecoviruses derived from bats and pangolins. See: FDA, *FDA Briefing Document Vaccines and Related Biological Products Advisory Committee Meeting October 10, 2024*; Thimmiraju et al., "A Trivalent Protein-Based Pan-Betacoronavirus Vaccine Elicits Cross-Neutralizing Antibodies against a Panel of Coronavirus Pseudoviruses"; Renner et al., "Reduced Cross-Protective Potential of Omicron Compared to Ancestral SARS-CoV-2 Spike Vaccines against Potentially Zoonotic Coronaviruses."

people. This is scientifically quite challenging, but it is also an area of active research and there have been substantive strides in this area that are anticipated to increase with the advance of artificial intelligence models.[34] One question for the IGWG is whether an existing or new scientific advisory body may evaluate, synthesize, and translate these findings on an ongoing basis into the PABS material definition.

Given the complexities involved, even with prospective identification efforts, some pathogens will likely only be recognized as pathogens of pandemic when they cause an epidemic or pandemic. But they may not have been fully unknown to science prior to this — it is possible that they will have previously been sampled from animals, with test tubes sitting in freezers in laboratories or sequenced and shared in international databases. An open question for the IGWG is how to handle those materials collected and potentially shared prior to recognition as a pathogen of pandemic potential. There may be scope for the IGWG to consider whether or how to address some form of retrospectivity in the Instrument.

In addition, outside of consideration of how pathogens may spillover and sustain spread in humans, several known pathogens that are likely to fit within the category of "pathogens of pandemic potential" — such as mpox virus and MERS-CoV — have animal reservoirs. The continual evolution of new lineages in animals leads to the possibility that new lineages will emerge in humans with greater pandemic potential than previous human outbreaks — and which may escape current medical countermeasures. As such, samples from these animal reservoirs have clear scientific and public health applications. If these were not included within the definition of PABS materials, sharing for these pathogens would occur as it does now, under ad hoc, bilateral agreements, with uncertainty regarding timely access and equitable benefit-sharing. In addition, their exclusion has the potential to result in a loophole by which manufacturers of vaccines, therapeutics, and diagnostics could develop countermeasures that would not be subject to benefits-sharing obligations. For example, a company could develop a MERS vaccine for humans using sequences derived from viral samples isolated from camels. This may undermine the potential of the PABS system to increase access to countermeasures for pathogens of pandemic potential. At the same time, the broader the scope of PABS materials is, the potentially greater the implementation challenges.

## 3. Will sequence data and physical samples be subject to different benefit-sharing obligations?

**In Brief**: The text of Article 12 does not include a clear differentiation in benefits-sharing obligations between sequence data or physical samples, and it will be up to the IGWG to determine if they wish to do so.

Both sequence data (e.g., DNA and RNA sequences) and physical samples of pathogens of pandemic potential are included under the definition of PABS materials and are within scope

[34] Zoë L. Grange et al., "Ranking the Risk of Animal-to-Human Spillover for Newly Discovered Viruses," *Proceedings of the National Academy of Sciences* 118, no. 15 (2021): e2002324118, https://doi.org/10.1073/pnas.2002324118; Colin J. Carlson et al., "The Future of Zoonotic Risk Prediction," *Philosophical Transactions of the Royal Society B: Biological Sciences* 376, no. 1837 (2021): 20200358, https://doi.org/10.1098/rstb.2020.0358; Nardus Mollentze and Daniel G Streicker, "Predicting Zoonotic Potential of Viruses: Where Are We?," *Current Opinion in Virology* 61 (August 2023): 101346, https://doi.org/10.1016/j.coviro.2023.101346.

of the PABS System under Article 12 of the Pandemic Agreement. DNA and RNA sequence data are also sometimes referred to in these discussions as digital sequence information, since it is dematerialized data that is stored and transmitted digitally.[35]

It will be up to the WHO Member States, as part of the IGWG, to decide on the rules governing physical samples and sequence data. The IGWG may choose to introduce some degree of variation in the rules and processes governing the sharing of sequence data and physical samples and how benefits-sharing obligations are recognized and enforced, by dint of the material differences between them (i.e., the fact that sequence information can be transmitted digitally).

## Benefits questions

### 4. What are the benefits to be provided by the PABS system?

**In Brief:** The benefits provided under the PABS Instrument may include monetary or non-monetary benefits. Several forms of non-monetary benefits, including access to medical countermeasures and technology transfer, are outlined in the PA and will be further specified within the PABS Instrument. There is scope for additional benefits to be negotiated in the PABS Instrument that are not explicitly detailed in Article 12.

The PA identifies three broad groups of benefits that the PABS Instrument will include: (1) access to medical countermeasures in a pandemic emergency[36], (2) access to benefits, including medical countermeasures in a PHEIC, and (3) other options for benefits-sharing.

First, in the event of a pandemic emergency,[37] **participating manufacturers** "shall make available … rapid access targeting 20%" of their real-time production of vaccines, therapeutics, and diagnostics in a pandemic emergency to WHO, with at least half (10%) in the form of a donation and the rest at **affordable prices**, in accordance with legally binding contracts with WHO (Article 12.6). The IGWG will need to define several terms, including **participating manufacturers** and **affordable prices**.

Under Article 12.6(a), in the event of a pandemic emergency (as determined under the IHR(2005)), "each participating manufacturer shall make available to the World Health Organization, pursuant to legally binding contracts signed with the World Health Organization, rapid access targeting 20% of their real time production of safe, quality and effective vaccines, therapeutics, and diagnostics for the pathogen causing the pandemic emergency, provided that a minimum threshold of 10% of their real time production is made available to the World Health Organization as a donation, and the remaining percentage, with flexibility based on the nature and capacity of each participating manufacturer, is reserved at affordable prices to the World Health Organization."

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[35] These terms are being used in this piece informally and in keeping with general usage. However, formal definitions vary. For one example of how the definition debate has unfolded in the CBD, see: Wael Haussen et al., *Digital Sequence Information on Genetic Resources: Concept, Scope and Current Use* (Convention on Biological Diversity (CBD) Secretariat, n.d.).
[36] See Box 3: Pandemic Emergencies and Public Health Emergencies of International Concern
[37] As defined in the 2024 revision to the IHR(2005). See: *Strengthening Preparedness for and Response to Public Health Emergencies through Targeted Amendments to the International Health Regulations (2005)*, WHA77.17 (World Health Assembly, 2024).

Second, contracts between participating manufacturers and WHO will also include benefits-sharing provisions, including "options regarding access to" vaccines, therapeutics, and diagnostics, for during a PHEIC (Article 12.7) (for more on these contracts, see Question 9). In addition, under Article 12.8, the IGWG is instructed to develop options for a range of other non-monetary benefits to be included in legally binding contracts in the PABS system, including capacity building and technical assistance, R&D cooperation, granting of non-exclusive licenses to manufacturers in developing countries, as well as other types of technology transfer "as mutually agreed," where this is defined under Footnote 8 of the PA as "willingly undertaken and on mutually agreed terms, without prejudice to the rights and obligations of the Parties under other international agreements." It will be up to the IGWG to further develop these options.

## 5. What triggers benefit sharing obligations under PABS?

**In Brief**: It will be up to the IGWG to specify the trigger(s) for benefits-sharing obligations.

Article 12.5 notes that the PABS Instrument will contain provisions regarding the sharing of benefits "arising from the sharing and/or utilization of PABS Materials and Sequence Information for public health purposes." Participating manufacturers will enter into legally binding contracts that specify benefit-sharing obligations.

Utilization is not defined in the PA. Use or utilization is often a trigger in ABS systems, though the precise definitions and interpretations vary. Notably, *use* and *utilization* may be quite broadly defined and do not necessarily have to be limited to the creation of vaccines, therapeutics, and diagnostics.[38] Access alone is not typically sufficient in other ABS systems to be a benefit-sharing trigger, though negotiators of the PABS Instrument may determine that access should be a trigger here. The trigger for benefit-sharing is tied to questions about the structure of the system, including traceability (see Question 6). For example, if one trigger for benefit-sharing is market release of a product that utilized PABS materials, then this raises questions for how a system should be structured to enable, encourage, and assess compliance with that trigger and which traceability approaches may support that. There are temporal considerations for the triggers as well regarding how to address usage of PABS materials sampled and shared and medical countermeasures developed before entry into force (also see Question 2).

In addition, the definition of use or utilization that the PABS Instrument adopts has the potential to influence whether the PABS Instrument is treated as an SII of Nagoya, within which "utilization of genetic resources" is defined as "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention" [on Biological Diversity] (see Box 2. PIP Framework).[39]

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[38] Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, entry into force 9 June 2014, *OJ L* 150, 20.5.2014, pp. 59— 71, (European Union); Law No. 13.123 Access and Benefits Sharing of Genetic Resources and Associated Traditional Knowledge of 20 May 2015, entry into force 17 November 2015, (English translation) (Brazil).

[39] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity: Text and Annex.

In terms of what triggers the sharing of benefits, this is partially specified in Article 12 and partially left open for the IGWG. Under Article 12.6, the sharing of 20% of real-time production of VTDs by participating manufacturers will occur in the event of a declaration of a pandemic emergency. Similarly, under Article 12.7, some benefit-sharing provisions (to be determined by the IGWG) will be applicable in the event of a PHEIC. For the additional benefit-sharing provisions to be developed by the IGWG, including those outlined in Article 12.8, it will be up to the IGWG to determine the trigger for the sharing of benefits or to leave that partially open to specification within contracts.

## Structural questions

### 6. How might traceability measures appear in the PABS Instrument?

**In Brief**: Article 12.3 establishes that the PABS System "shall address traceability measures and open access to data." Neither *traceability measures* nor *open access to data* are defined within the Pandemic Agreement, and it will be up to the IGWG to determine how this will be addressed in the PABS Instrument.

If benefit-sharing is triggered by use of PABS materials, then this raises the question of how users will be identified, and whether distinctions will be made among the users or the types of use (such as between commercial and non-commercial uses). Put another way, how do we know who owes benefits? Traceability measures may form part of the answer to this question.

Broadly speaking, traceability measures are ways of tracing products back to their source materials.[40] They provide one way of identifying users of PABS materials and determining and enforcing benefit-sharing obligations. Traceability is relatively straightforward for physical samples but is a bit more complicated for digital sequence information.

Traceability does not have a single, agreed upon definition, and while distinctions are sometimes made between "track and trace" and "traceability," the two terms are often used inconsistently and, at times, interchangeably:[41]

- A "track and trace" mechanism may be generally understood as following along with the sample as it moves through the system and how it is used over time. An example of a system using a track and trace approach is the Influenza Virus Tracing Mechanism (IVTM) for samples shared to GISRS, under the PIP Framework.[42]

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[40] Rizk et al., *"Everybody Knows This Needs to Be Done, but Nobody Really Wants to Do It": Governing Pathogen- and Benefit-Sharing (PBS)*; Fran Humphries et al., "Traceability Approaches for Marine Genetic Resources Under the Proposed Ocean (BBNJ) Treaty," *Frontiers in Marine Science* 8 (April 2021): 661313, https://doi.org/10.3389/fmars.2021.661313.

[41] Humphries et al., "Traceability Approaches for Marine Genetic Resources Under the Proposed Ocean (BBNJ) Treaty"; Mark Eccleston-Turner et al., "Fate Unknown: The Pandemic Agreement's Pathogen Access and Benefit Sharing," *Think Global Health*, May 20, 2025, https://www.thinkglobalhealth.org/article/fate-unknown-pandemic-agreements-pathogen-access-and-benefit-sharing; Scarlett Sett et al., "Harmonize Rules for Digital Sequence Information Benefit-Sharing across UN Frameworks," *Nature Communications* 15, no. 1 (2024): 8745, https://doi.org/10.1038/s41467-024-52994-z; Nirmalya Syam, *The WHO CA+ Discussions on Pathogen Access and Benefit Sharing: State of Play*, Policy Brief 123 (South Centre, 2023).

[42] WHO (World Health Organization), "IVTM 2.0," June 2020, https://extranet.who.int/ivtm2.

- Sometimes, “track and trace” is posited as a subset of, or one way to achieve, traceability.[43]
- Other times, it may appear as a separate, contrasting activity from traceability — where “track and trace” follows along at each step of a process, and “traceability” is backward-looking. This is sometimes articulated as the difference between real-time tracking and forensic or retrospective tracing.
- Forensic or retrospective tracing may work at specific points in time, “triggered by an event.”[44] These may function by looking at a product and working backward to the sample(s) or sequence(s) that were used in its creation and/or testing.

Some observers have expressed concerns that attempting to trace one or more sequences used in a commercial product back to its source would be associated with significant enforcement challenges and neither technically feasible nor desirable.[45] This is often posited as a bad actors problem — there may be bad actors who seek to obfuscate the source of the materials used in their commercial product(s) and thereby skirt benefit-sharing obligations — and as involving significant technical barriers for sequence databases. The concern about bad actors is likely well-founded: a system that expects end users to report their usage of PABS materials likely will experience some number of bad actors who attempt to skirt or undermine these rules.

However, this is fundamentally a compliance issue — and there are numerous measures that databases, scientific journals, academic institutions and funding agencies, and national governments can take to facilitate compliance.[46] Some of these could potentially form components of the PABS system, or may be part of an enabling environment that encourages participation in the PABS system by enabling clear evidence of use at various checkpoints and stages.

**Databases:** There are several ways that traceability and compliance can be supported and facilitated by sequence databases that are not only technically feasible, but which already exist in scientific databases in some form. This could, but does not necessarily need to involve, the creation of new unique identifiers that are attached to every sample and sequence and which can be used to mark status as PABS materials.[47] Unique accession

[43] Humphries et al., “Traceability Approaches for Marine Genetic Resources Under the Proposed Ocean (BBNJ) Treaty.”
[44] Humphries et al., “Traceability Approaches for Marine Genetic Resources Under the Proposed Ocean (BBNJ) Treaty.”
[45] Fran Humphries et al., “Traceability Approaches for Marine Genetic Resources Under the Proposed Ocean (BBNJ) Treaty,” *Frontiers in Marine Science* 8 (April 2021): 661313, https://doi.org/10.3389/fmars.2021.661313; Bart Van Vooren, *Written Submission for INB Related Interactive Dialogues Topic 1. Article 12 (Pathogen Access and Benefit-Sharing System)* (2024); Stephanie Switzer et al., *Written Submission for INB Interactive Dialogue on “Article 12 (Pathogen Access and Benefit-Sharing System)”, 3 September 2024* (2024); Scarlett Sett et al., “Harmonize Rules for Digital Sequence Information Benefit-Sharing across UN Frameworks,” *Nature Communications* 15, no. 1 (2024): 8745, https://doi.org/10.1038/s41467-024-52994-z; Amber Hartman Scholz, *Written Submission for INB Related Interactive Dialogues Topic 1. Article 12 (Pathogen Access and Benefit-Sharing System)* (2024).
[46] For a more detailed discussion of this, see: Colin J. Carlson et al., “The LISTEN Principles for Genetic Sequence Data Governance and Database Engineering,” *Nature Genetics*, Nature Publishing Group, July 28, 2025, 1— 7, https://doi.org/10.1038/s41588-025-02270-7.
[47] Stephanie Switzer et al., “Negotiating Pathogen Access and Benefit-Sharing (PABS): Recommendations and Priority Issues,” preprint, August 7, 2025, https://doi.org/10.31235/osf.io/9r3g7_v1.

numbers are already used for sequences in online databases, including in the INSDC databases (including GenBank) and GISAID. In addition, other online identifier systems, such as Digital Object Identifiers (DOIs) exist and could be expanded for use here. Such identifiers could be used to assist end users in tracking and reporting their use of PABS materials.[48] In addition, traceability could be reinforced or supported by databases through evidence of access to sequence data.[49] Sequences databases run by or compliant with a PABS system could be, as outlined in the LISTEN framework, "supervised" — ensuring that all access is "logged, time-stamped, and attributed to an identified user, and attached to a full account of which data were queried and whether they were downloaded."[50] Several scientific databases already have features that go beyond these minimum expectations. Notably, GenBank tracks users without logins in case of criminal usage,[51] and GISAID requires logins and tracks data use in publications.[52]

**Scientific journals**. Journals could, as a condition of publication, require authors to report information on the origins of all genetic sequence data used in their research (which may include accession number, database in which it was accessed, DOI, associated license, and/or other signifiers of PABS material status).[53] Many journals already require reporting of accession numbers.[54]

**Research institutions and funders**. Academic institutions could choose not to support research that is not sufficiently traceable — through additional expectations as part of internal ethics review processes or as part of receiving internal funding awards. Similarly, funders of academic research could make grant funding contingent on incorporation of adequate levels of traceability, in alignment with the aims of the PABS system.

**National governments**. Traceability measures to support compliance include national governments requiring information at given checkpoints, such as disclosure of the origin of sequences and samples in submissions for patent registrations or market approval.[55] Similar measures exist in implementing legislation for CBD and Nagoya, including for the EU.

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[48] Adam Strobeyko, "When Science Meets Sovereignty: Regulating Infrastructures for Pathogen Genetic Sequence Data," SSRN Scholarly Paper 5315993 (Social Science Research Network, May 29, 2025), https://doi.org/10.2139/ssrn.5315993; Colin J. Carlson et al., "The LISTEN Principles for Genetic Sequence Data Governance and Database Engineering," *Nature Genetics*, Nature Publishing Group, July 28, 2025, 1— 7, https://doi.org/10.1038/s41588-025-02270-7.
[49] Carlson et al., "The LISTEN Principles for Genetic Sequence Data Governance and Database Engineering."
[50] Carlson et al., "The LISTEN Principles for Genetic Sequence Data Governance and Database Engineering."
[51] NCBI, "NCBI Website and Data Usage Policy and Disclaimers," National Center for Biotechnology Information (NCBI), n.d., https://www.ncbi.nlm.nih.gov/home/about/policies/.
[52] GISAID, "GISAID EpiFlu™ Database Access Agreement," 2012, https://www.re3data.org/repository/r3d100010126.
[53] Carlson et al., "The LISTEN Principles for Genetic Sequence Data Governance and Database Engineering."
[54] For two examples, see: Nature, "Reporting Standards and Availability of Data, Materials, Code and Protocols," https://www.nature.com/nature-portfolio/editorial-policies/reporting-standards; Science Journals, "Science Journals: Editorial Policies," accessed August 22, 2025, https://www.science.org/content/page/science-journals-editorial-policies.
[55] Carlson et al., "The LISTEN Principles for Genetic Sequence Data Governance and Database Engineering"; Humphries et al., "Traceability Approaches for Marine Genetic Resources Under the Proposed Ocean (BBNJ) Treaty."

## 7. Would PABS be an open or closed system or a mix?

**In Brief**: It will be up to the IGWG to determine the structural features of the PABS system that may enable more restrictive or more open sharing and access.

People use “open” and “closed” in different, sometimes contradictory ways in ABS discussions[56] — and there are many potential configurations of a PABS system that do not fit neatly into a binary of open and closed. Given this, and the fact that usage of open/closed may also reflect positionality on what a PABS Instrument should be, for the purposes of this discussion, it is perhaps more useful to consider some systems that are relatively more or less restrictive in terms of access to materials.

For example, GISRS, under the PIP Framework, has features of being a relatively more restrictive system than other approaches such as the Cali Fund, as set out below. Under PIP, manufacturers prospectively sign contracts to gain access to samples. A similar system could be modified for the PABS system, and extended to sequence data. Under such a scenario, sequence databases could make modifications to become PABS-compliant and/or a new PABS-compliant database could be created under WHO auspices. An alternative example that has some less restrictive elements is the Cali Fund. Commercial actors access and use publicly accessible DSI, and voluntarily pay fixed percentages of their annual revenue or profit.

Importantly, the open versus closed framing may be used to suggest that there is an inherent tension between any conditions on access and open access or open science principles. This is not the case. Open science is not only about securing access to scientific products (such as, in this case, sequence data), but is also about making the benefits of scientific advances available and reducing barriers to participating in scientific endeavors. Conditions on data access and use, such as user authentication and data licenses, align with the broader principles of open science, are permissible under the FAIR framework that guides scientific data sharing,[57] and are used by platforms that are recognized as part of an open science

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[56] Adam Strobeyko, “The Devil Is in the Annex: Pathogen Access and Benefit Sharing,” *Governing Pandemics Snapshot*, June 2025, https://www.governingpandemics.org/gp-snapshot; Nithin Ramakrishnan and Chetali Rao, *“Open” Databases Undermine Access and Benefit Sharing*, TWN Briefing Note (Third World Network, 2023), https://twn.my/title2/biotk/2023/btk230301.htm; Colin J. Carlson et al., “The LISTEN Principles for Genetic Sequence Data Governance and Database Engineering,” *Nature Genetics*, Nature Publishing Group, July 28, 2025, 1–7, https://doi.org/10.1038/s41588-025-02270-7; Amber Hartman Scholz et al., “Multilateral Benefit-Sharing from Digital Sequence Information Will Support Both Science and Biodiversity Conservation,” *Nature Communications* 13, no. 1 (2022): 1, https://doi.org/10.1038/s41467-022-28594-0; Manuel Ruiz Muller et al., *“Common Ground, Cause and Sense for Users, Providers and Agents: Bounded Openness over Genetic Resources” In Response to Invitation to Submit Views and Other Information on ‘Digital Sequence Information’ (NCP GB8-016 MYPoW/DSI) for the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture* (2018).

[57] Mark D. Wilkinson et al., “The FAIR Guiding Principles for Scientific Data Management and Stewardship,” *Scientific Data* 3, no. 1 (2016): 1— 9, https://doi.org/10.1038/sdata.2016.18.

ecosystem.[58] As such, there is space for the IGWG to consider various ways to fulfill the expectation under Article 12.3 that the PABS System address "open access to data."

However, there is an important open science consideration when it comes to data *sharing* (what researchers provide) rather than access. At a national level, if a government compelled scientists to share sequences only on specific platforms (or forbade sharing on other platforms), this would pose a substantial risk to open science and potentially undermine the PABS Instrument.

Importantly, the PABS system — whether it is more or less restrictive — will be enacted in a world in which some countries will permit sharing of pathogens of pandemic potential without an expectation of benefit-sharing. This will be the case both for non-parties to the PA, such as the United States of America, as well as potentially parties to the PA with national legislation that permits this. As such, there will be the possibility for people seeking samples and sequences to go outside the PABS system to get them. Similarly, some State Parties may also seek out bilateral arrangements that have more attractive terms than are available through the PABS system. The question for negotiators is how to facilitate benefits-sharing within the PABS system in light of this.

## 8. A 'subscription model' has been used in existing ABS instruments. What would a subscription model look like for the PABS system?

**In Brief**: Under a subscription model, users of eligible PABS materials would pay an annual fee.

The subscription model stands in contrast to alternate benefit-sharing triggers, such as bringing a product to market. Notably, the subscription model is often discussed — and has been implemented under PIP as — *one* component of financing for an ABS system, and observers have noted that it is often not anticipated to be sufficient to be a sole funding source.[59]

A "subscription model" has been incorporated as one of the financing mechanisms in existing ABS instruments, including in the PIP Framework. In PIP, there is the GISRS Partnership Contribution, which may be considered a type of subscription model.[60] Under the Partnership Contribution, commercial actors that use GISRS material provide monetary contributions of 28 million USD, which corresponds to 50% of GISRS operating costs. These costs are calculated based on the result of a survey completed by the users.[61] The PIP

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[58] Carlson et al., "The LISTEN Principles for Genetic Sequence Data Governance and Database Engineering."
[59] Adam Strobeyko, *International Sharing of Pathogens, GSD and Benefits*, Workshop Series Report (Graduate Institute of International and Development Studies, 2022), https://www.graduateinstitute.ch/library/publications-institute/international-sharing-pathogens-gsd-and-benefits.
[60] Florian Rabitz, *Managing Genetic Resources: International Regimes, Problem Structures, National Implementation*, Earth System Governance Working Paper No. 27 (Lund: Earth System Governance Project, 2017), https://www.earthsystemgovernance.org/publication/managing-genetic-resources-international-regimes-problem-structures-national-implementation/.
[61] WHO, "Partnership Contribution," World Health Organization, accessed August 8, 2025, https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/partnership-contribution.

Partnership Contribution is primarily used to help finance influenza preparedness and response activities around the world (the remaining 10% is used to fund the PIP Secretariat).[62]

## 9. How might Standard Material Transfer Agreements be used in a PABS System?

**In Brief:** Under the PABS system, standardized contracts — Standard Material Transfer Agreements (SMTAs) — may be used to establish terms and conditions for the sharing and use of PABS materials in order to streamline the contract process. Depending on how the SMTAs are crafted, they could be used for traceability — putting the onus on end users to report.

Article 12 of the PA does not mention Standard Material Transfer Agreements (SMTAs) as such, but there are repeated references to legally binding contracts between WHO and participating manufacturers in the PABS system, and to the creation of a range of benefit-sharing options to be included in contracts with WHO. This suggests that the PABS system will likely use standard contracts, such as the SMTAs used under the PIP Framework.

The PIP Framework includes standard contracts to facilitate the sharing of influenza samples of pandemic potential (see Box 2). There are two standard contracts used — Standard Material Transfer Agreements (SMTAs) — one for the sharing of samples between Member States and WHO via a global network of laboratories known as GISRS (SMTA1), and one for sharing from GISRS to both commercial and noncommercial entities (SMTA2).[63] The SMTA2 contracts contain a menu of benefit-sharing options. These options vary depending on whether the samples will be used for commercial or non-commercial use. The standardization of these agreements streamlines the process of entering into a sample sharing arrangement.

Similarly, under a PABS system, a set of standardized contracts could be prepared for different entities — commercial and non-commercial — and perhaps also differentiating between different types or sizes of commercial entities, and with a range of pre-approved options for benefit-sharing.

Some researchers have argued that term sheets associated with SMTAs should be made publicly available for transparency and accountability purposes.[64] However, transparency interests may be weighed against incentives for the participation of commercial actors. Confidential term sheets are standard practice in the commercial sector, and the protection of what is perceived to be sensitive information may be an important factor for companies in determining their participation in the PABS system.

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[62] WHO, *Pandemic Influenza Preparedness Framework Partnership Contribution High-Level Implementation Plan III 2024-2030* (World Health Organization (WHO), 2023).
[63] World Health Organization, *Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*, 2nd ed (World Health Organization, 2021), https://apps.who.int/iris/handle/10665/341850.
[64] Eccleston-Turner et al., “Fate Unknown”; Switzer et al., “Negotiating Pathogen Access and Benefit-Sharing (PABS).”

### 10. What would be the procedure to collect and share PABS materials?

**In Brief:** While collection and sharing of PABS materials may be specified to some extent in the PABS Instrument, this procedure will likely look different across States Parties, given other applicable international, national, and subnational laws.

Article 12 does not specify the procedure by which samples will be collected and shared. The PABS Instrument may provide greater detail on the mechanism by which sharing can occur. However, regardless of whether the PABS Instrument further specifies the sharing mechanism, the procedure for collecting and sharing of pathogen samples and genetic sequences will continue to be governed by other relevant international, national, and subnational laws, as well as institutional rules and processes (as well as the preferences of individual researchers). As such, the precise steps between collection and sharing will likely be fairly heterogenous across Parties.

Importantly, the Pandemic Agreement, under Article 22, does not give the World Health Organization any authority to prescribe or alter national laws or policies or to require Parties to “take specific actions.”

## Membership & Governance questions

### 11. Who will be receiving the “benefits” associated with the PABS system?

**In Brief**: Vaccines, therapeutics and diagnostics developed by participating manufacturers in the PABS system will be distributed “on the basis of public health risk and need, with particular attention to the needs of developing countries” according to Article 12.6(b) of the Pandemic Agreement.

Public health risk and need is not defined in the PA, and remains open for the IGWG to determine. Under Article 12, the provision of VTDs in a pandemic emergency are not limited to Parties. It is based on “particular attention to the needs of developing countries” not to “developing country Parties.”

As the IGWG develops the PABS Instrument, they may seek to restrict this definition further to apply only to Parties to the agreement. However, given that a central aim of the PA is to augment the collective capacity to respond to and contain a pandemic threat, limiting VTDs to Parties may undermine the purpose of the agreement itself and hinder an effective response WHO Member States may not want to inadvertently limit their ability to render assistance to other countries in need, particularly given that countries may face delays or hurdles in the ratification process, which can be quite costly and time-consuming.

Outside of the 20% VTDs in pandemic emergencies, additional benefits, such as technology transfer arrangements, are also going to be part of contracts with WHO — and it is also up to the IGWG to decide on the criteria for recipients.

## 12. What is the role of the WHO and will other institutional actors be responsible for the functioning of the system?

**In Brief:** The WHO is tasked, under Article 12.2, to coordinate and operate the PABS system and to collaborate with "relevant international organizations and relevant stakeholders" to do so.

Member States have tasked WHO with administering and coordinating the PABS System, with specific terms of this engagement to be detailed in the PABS Instrument. In addition, under Article 12.2, "For the purposes of the coordination and operation of the PABS System, the World Health Organization shall collaborate with relevant international organizations and relevant stakeholders"

There remains substantial space for negotiators to consider the precise role that WHO and other institutional actors will play in this process (e.g., whether WHO should set up and maintain its own genetic sequence database or how it will coordinate with existing genetic sequence databases), and what governance measures could be instituted to ensure transparency and accountability for all actors in the PABS system.

## 13. Is it the same contact points (at international and national levels) for both PABS as for IHR?

**In Brief:** This is not clearly defined within the PA, nor will this necessarily be addressed explicitly within the PABS Instrument

At the WHO-level, it is not clear how or to what extent the personnel of the IHR Secretariat may overlap with that of a PA Secretariat. At the national level, under the IHR (2005), States Parties are obligated to create a National Focal Point (NFP) — a national country or office — that can act as a contact point between States Parties and the IHR Secretariat.[65] NFPs are not referenced in the PA. It is possible that the PABS Instrument may include expectations for the creation of a similar national body among States Parties or that some Member States may seek to use the personnel and capacities of their NFPs to coordinate some aspects of PABS implementation. In addition, the 2024 revisions to the IHR(2005), which will enter into force in September 2026, include the creation of a new National IHR Authority.[66]

## 14. How might transparency and accountability appear in the PABS system?

**In Brief:** Transparency and accountability are referenced several times as components of the PABS system in Article 12. It will be up to the IGWG to determine how to operationalize these principles in the PABS system.

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[65] World Health Assembly, *International Health Regulations, 3rd Edition*; World Health Organization, "National Focal Points," World Health Organization, accessed August 1, 2025, https://www.who.int/teams/ihr/national-focal-points..

[66] *Strengthening Preparedness for and Response to Public Health Emergencies through Targeted Amendments to the International Health Regulations (2005)*; Chloe Searchinger, "The New Amendments to the International Health Regulations," *Think Global Health*, June 4, 2024, https://www.thinkglobalhealth.org/article/new-amendments-international-health-regulations.

Transparency and accountability appear repeatedly within Article 12 as essential features of a PABS system. Article 12.1 establishes PABS as a "multilateral system for safe, transparent, and accountable access and benefit-sharing for PABS Materials and Sequence Information." Transparency and accountability appear again in Article 12.3, in which "the development of a safe, accountable and transparent PABS System shall address traceability measures and open access to data" (See Question 6 for more on traceability). Finally, Article 12.9 specifies that Article 12 is "without prejudice to consideration of other elements for the effective operationalization of the PABS System in a fair, transparent, accountable and equitable manner." Accountability and transparency also appear throughout the rest of the PA as guiding principles to be operationalized through the text's provisions (see, for example, Article 3.5, Article 10.2, Article 13.2, and Article 18.2).

One of the considerations for the IGWG is how transparency and accountability should be incorporated into the operationalization of the PABS system. There are numerous ways that transparency and accountability could be built into the system, including within provisions of the legally binding contracts with WHO or through reporting obligations to the COP.[67]

### Implementation questions

### 15. What is the incentive for the industry to join PABS rather than bilateral agreements?

**In Brief:** The incentive for industry to join PABS is that participating in PABS will provide predictable, rapid access to a diverse array of pathogens of pandemic potential (both in terms of potential future threats and in terms of taxonomic diversity).

The PABS system offers standardization and predictability — in the terms and conditions of access and reduced transaction costs (i.e., in legal fees and time). Conducting ad hoc, bilateral negotiations is comparatively labor-intensive and carries unpredictable results.

It has been suggested that companies may choose to stay out of the PABS system, planning in an outbreak to access materials once the disease has spread to countries that are not party to the system. Such a choice, given the inherent human toll involved, would be — as others have pointed out — unethical and unjust.[68] In addition, such avoidance of the PABS system would likely put companies at a competitive disadvantage — since those who joined PABS system would likely have faster access to samples and sequences, and to have access to a border array of samples and sequences. This is particularly true in the case of pathogen sequence data, where utility tends to arise from having access to as many sequences as possible. Not joining PABS would mean leaving a significant proportion of sequences outside of a company's reach and potentially in the hands of competitors. (Of course, the relative advantages may vary somewhat on a case-by-case basis, including based on where a disease arises and that country's Party status.)

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[67] Guilherme F Faviero et al., "An Effective Pandemic Treaty Requires Accountability," *The Lancet. Public Health* 7, no. 9 (2022): e730— 31, https://doi.org/10.1016/S2468-2667(22)00192-X.
[68] Johns Hopkins Center for Health Security, *WRITTEN COMMENT RE: IMPLICATIONS OF ACCESS AND BENEFIT SHARING (ABS)*, Written Comment to INB (Center for Health Security, Johns Hopkins University, 2024).

Notably, pursuing bilateral agreements would not, in many cases, provide an opportunity to avoid benefits sharing entirely. In addition to still being subject to any national implementing legislation regarding the PA for countries that become State Parties, most countries in the world are also party to other national and international law that concerns access and benefit sharing (namely the Convention on Biological Diversity and its Nagoya Protocol). Given the uncertainties and costs associated with pursuing such bilateral arrangements, companies may prefer negotiating within the contexts of the PABS system.

### **Box 3**. **Pandemic Emergencies and Public Health Emergencies of International Concern**

The terms “pandemic emergency” and “public health emergency of international concern” or “PHEIC” appear within Article 12, and elsewhere in the Pandemic Agreement. Their precise definitions in the Pandemic Agreement and the IHR(2005), are replicated below.

***Public Health Emergency of International Concern (PHEIC)***

A public health emergency of international concern is defined in the 2024 revisions to the IHR (2005) under Article 1 as:

> an extraordinary event which is determined:
>
> > (i) to constitute a public health risk to other States through the international spread of
> > disease; and
> > (ii) to potentially require a coordinated international response;

This definition is replicated in the Pandemic Agreement, in Article 1g, with the addition of reference to Footnote 2, which reads: “Pursuant to the International Health Regulations (2005). The Conference of the Parties shall consider any further amendments to the International Health Regulations (2005) modifying this term, with the aim to ensure consistency in the use of terms between the International Health Regulations and the WHO Pandemic Agreement.”

Within Annex 2 to the IHR(2005), there is a decision instrument for State Parties to use to assess whether events in their territory may constitute a PHEIC and for which WHO should be notified. Under Article 12 of the IHR(2005), the WHO Director-General is responsible for the declaration, as appropriate, of a PHEIC.

***Pandemic Emergency***

A pandemic emergency is a type of PHEIC. A pandemic emergency is defined in the revisions to the International Health Regulations (2005) that were adopted in 2024 and which enter in force on September 19, 2025.

a public health emergency of international concern, that is caused by a communicable disease and:

(i) has, or is at high risk of having, wide geographical spread to and within multiple States; and

(ii) is exceeding, or is at high risk of exceeding, the capacity of health systems to respond in those States; and

(iii) is causing, or is at high risk of causing, substantial social and/or economic disruption, including disruption to international traffic and trade; and

(iv) requires rapid, equitable and enhanced coordinated international action, with whole-of-government and whole-of-society approaches;[2]

This definition is replicated in Article 1c of the Pandemic Agreement, with the addition of Footnote 2, which notes that: “Pursuant to the International Health Regulations (2005). The Conference of the Parties shall consider any further amendments to the International Health Regulations (2005) modifying this term, with the aim to ensure consistency in the use of terms between the International Health Regulations and the WHO Pandemic Agreement.”

If the WHO Director-General determines that an event meets the qualifying criteria for a PHEIC, the event will further be assessed for whether it meets the criteria for a pandemic emergency, under the 2024 revisions of Article 12 of the IHR(2005).

## Appendix 1. Article 12 of the Pandemic Agreement

*Article 12 of the Pandemic Agreement has been reproduced in full below, for your convenience.*

1. Recognizing the sovereign right of States over their biological resources and the importance of collective action to mitigate public health risks, and underscoring the importance of promoting the rapid and timely sharing of "materials and sequence information on pathogens with pandemic potential" (hereinafter "PABS Materials and Sequence Information") and, on an equal footing, the rapid, timely, fair and equitable sharing of benefits arising from the sharing and/or utilization of PABS Materials and Sequence Information for public health purposes, the Parties hereby establish a multilateral system for safe, transparent, and accountable access and benefit-sharing for PABS Materials and Sequence Information, the "WHO Pathogen Access and Benefit-Sharing System" (hereinafter the "PABS System"), to be developed pursuant to paragraph 2 of this Article.

2. The provisions governing the PABS System, including definitions of pathogens with pandemic potential and PABS Materials and Sequence Information, modalities, legal nature, terms and conditions, and operational dimensions, shall be developed and agreed in an instrument in accordance with Chapter III (hereinafter the "PABS Instrument") as an annex. The PABS Instrument shall also define the terms for the administration and coordination of the PABS System by the World Health Organization. For the purposes of the coordination and operation of the PABS System, the World Health Organization shall collaborate with relevant international
organizations14 and relevant stakeholders. All elements of the PABS System shall come into operation simultaneously in accordance with the terms of the PABS Instrument.

3. Taking into account the differences in the use of PABS Materials and Sequence Information, the development of a safe, accountable and transparent PABS System shall address traceability measures and open access to data.

4. Having regard to Article 4.4 of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their utilization to the Convention on Biological Diversity (hereinafter the "Nagoya Protocol"), the PABS Instrument shall be consistent with, and not run counter to, the objectives of the Convention on Biological Diversity and the Nagoya Protocol, recognising that nothing in this paragraph creates obligations under these instruments for non-Parties thereto.

5. The PABS Instrument referred to in paragraph 2 of this Article, shall contain provisions regarding, inter alia, the following:

(a) the rapid and timely sharing of PABS Materials and Sequence Information and, on an equal footing, the rapid, timely, fair and equitable sharing of benefits, both monetary and non-monetary, including annual monetary contributions, vaccines, therapeutics and diagnostics arising from the sharing and/or utilization of PABS Materials and Sequence Information for public health purposes;

(b) modalities, terms and conditions on access and benefit sharing that provide legal certainty;

(c) implementation in a manner to strengthen, facilitate and accelerate research and innovation, as well as the fair and equitable sharing and distribution of benefits;
(d) development and implementation in a manner:
(i) complementary to, and not duplicative of, the access and benefit sharing measures and obligations of the Pandemic Influenza Preparedness Framework and other relevant international access and benefit sharing instruments, where applicable; and
(ii) to ensure that each Party reviews and, as it deems appropriate, aligns its national and/or regional access and benefit sharing measures applicable to PABS Materials and Sequence Information within the scope of the PABS Instrument, so that measures that are contrary to, or inconsistent with, or duplicative of, the PABS Instrument will not be applied upon entry into operation of all elements of the PABS System.
(e) implementation consistent with applicable international law and with applicable national and/or domestic law, regulations and standards related to risk assessment, biosafety, biosecurity and export control of pathogens, and data protection; and
(f) implementation in a manner to facilitate the manufacture and export of vaccines, therapeutics and diagnostics for pathogens covered by the PABS Instrument.

6. The PABS System, as set out in the Annex referred to in paragraph 2 of this Article, shall provide, inter alia, that in the event of a pandemic emergency, as determined in accordance with Article 12 of the International Health Regulations (2005):
(a) each participating manufacturer15 shall make available to the World Health Organization, pursuant to legally binding contracts signed with the World Health Organization, rapid access targeting 20% of their real time production of safe, quality and effective vaccines, therapeutics, and diagnostics for the pathogen causing the pandemic emergency, provided that a minimum threshold of 10% of their real time production is made available to the World Health Organization as a donation, and the remaining percentage, with flexibility based on the nature and capacity of each participating manufacturer, is reserved at affordable prices to the World Health Organization; and
(b) the distribution of these vaccines, therapeutics, and diagnostics shall be on the basis of public health risk and need, with particular attention to the needs of developing countries, and the Global Supply Chain and Logistics Network referred to in Article 13 may be used to this end.

7. The PABS Instrument shall also include benefit sharing provisions, in the event of a public health emergency of international concern as determined in accordance with Article 12 of the International Health Regulations (2005), including options regarding access to safe, quality and effective vaccines, therapeutics, and diagnostics for the pathogen causing the public health emergency of international concern, pursuant to legally binding contracts signed by participating manufacturers with the World Health Organization.

8. The PABS Instrument shall also include additional benefit sharing provisions to be set out in legally binding contracts signed with the World Health Organization, including options for:
(a) Capacity-building and technical assistance;
(b) research and development cooperation;

(c) facilitating rapid access to available vaccines, therapeutics and diagnostics with a view to responding to public health risks and events in the context of Article 13.3 of the International Health Regulations (2005);
(d) the granting of non-exclusive licences to manufacturers in developing countries, for the effective production and delivery of vaccines, therapeutics and diagnostics; and
(e) other forms of transfer of technology as mutually agreed,16 including transfer of relevant knowledge, skills and technical expertise.

9. This Article is without prejudice to consideration of other elements for the effective operationalization of the PABS System in a fair, transparent, accountable and equitable manner.

Footnote 14: In the context of collaboration with the World Health Organization, “relevant international organizations” is understood in accordance with the Constitution of the World Health Organization.
Footnote 15: The term “participating manufacturer” to be defined in the PABS instrument.
Footnote 16: See footnote 8.
Footnote 8: For the purposes of the WHO Pandemic Agreement, “as mutually agreed” means willingly undertaken and on mutually agreed terms, without prejudice to the rights and obligations of the Parties under other international agreements.