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The world preparing for future pandemics and public health emergencies of international concern: Comparison of various multilateral access and benefit-sharing mechanisms and the impact of a new WHO mechanism for pathogens with pandemic potential on Japanese access and benefit-sharing policy

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Abstract: Currently, there is a member-state-led discussion in the Intergovernmental Negotiating Body of the World Health Organization (WHO) to draft and negotiate a convention, agreement, or other international instrument under the Constitution of the WHO to strengthen global pandemic prevention, preparedness, and response (WHO CA+). An access and benefit-sharing (ABS) mechanism for pathogens is likely to be a key element of this instrument, as it may provide legal certainty for rapid pathogen sharing and global access to medical countermeasures against future pandemics and in some cases public health emergencies of international concern, which are expected to be provided to countries in need. A multilateral ABS mechanism may resolve issues arising from the bilateral nature of the current ABS mechanism established under the Nagoya Protocol (which requires recipients to decipher the complex web of ABS legislation, thereby preventing rapid access to pathogens), and may also improve uneven global access to medical countermeasures during pandemics. This study analyzes the ongoing WHO discussion on ABS mechanisms while reviewing other examples of such mechanisms, including those outside the health sector. Additionally, there is a growing global interest in mapping national policies on ABS, as discussions on international policies are ongoing in multiple fora. This study furthermore introduces Japan's ABS policy, which is not widely known, and explores how the new WHO mechanism could affect Japan, namely highlighting the importance and the challenges of participating in such a system for industry and academia in the context of a developed country.

***Keywords*:** Nagoya Protocol (NP), WHO CA+, genetic sequence data (GSD), digital sequence information (DSI), pandemic treaty, pandemic instrument

Introduction

The rapid sharing of pathogens and their genetic sequence data (GSD) is crucial for countries to effectively respond to health emergencies. This has been emphasized on various occasions in the international community, including during the COVID-19 pandemic (*1-5*). Currently, the World Health Organization's (WHO) Intergovernmental Negotiating Body (INB) is drafting and negotiating a convention, agreement, or other international instrument to strengthen pandemic prevention, preparedness, and response (hereafter, the WHO CA+). The access and benefit-sharing (ABS) mechanism for pathogens with pandemic potential is being considered as a key element of this new instrument (*6*). The ongoing WHO negotiation of the ABS mechanism for pathogens with pandemic potential is important; as much as this ABS mechanism can globally facilitate access to medical countermeasures against pandemics, it could also encumber pathogen sharing and complicate the already-complex landscape of ABS legislation.

Although prior studies (*7-13*) have been conducted from the perspective of international organizations, studies comparing different ABS mechanisms developed or under development in various intergovernmental organizations are lacking. This includes work focusing on the pandemic instrument currently being discussed at the WHO. Moreover, there is a growing global interest in mapping national policies on ABS due to the ongoing discussions on ABS mechanisms in multiple international fora (*14*); yet, the literature on Japan's ABS policy is

limited (*15*). Identifying incentives and challenges for industry and academia to participate in the ABS mechanism for pandemics in the context of a developed country is enabled by providing comprehensive information on the Japanese ABS policy in a universal language, as well as exploring how the new ABS mechanism could affect Japan.

Therefore, the present study reviews the debate on ABS within the context of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization of the Convention on Biological Diversity (hereafter, the Nagoya Protocol [NP]), particularly focusing on pathogens, the WHO's Pandemic Influenza Preparedness Framework (PIPF), and other ABS mechanisms discussed in other forums, such as the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) 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 (BBNJ Agreement). These documents are summarized in Table 1. Subsequently, the potential new ABS mechanism for pathogens with pandemic potential that is currently being discussed at the WHO is analyzed in relation to other ABS mechanisms, as well as how the new ABS mechanism could potentially affect Japan's ABS policy. Information regarding the WHO CA+ in this article is based on the latest available information as of March 31, 2025.

The ABS mechanism for pathogens

Currently, no international laws require states to share pathogens or GSD. The WHO's International Health Regulations (2005), which apply to all WHO-member states and are "designed to prevent the international spread of disease", do not have a provision that explicitly requires the sharing of pathogen samples and GSD. They only require the sharing of "public health information" regarding events that may constitute a public health emergency of international concern (Article 6) (*16*).

During the COVID-19 pandemic, expert groups stressed the need for clear obligations for access to pathogens and GSD as well as sharing of vaccines, therapeutics, and diagnostics (VTDs) during health emergencies (*9,17*). Rourke *et al.* (2020) appealed the necessity for an adequate legal framework that cultivates mutual trust and equitable scientific collaboration and enables sharing of, and access to, pathogens and GSD for rapid research and development of VTDs. The Independent Panel for Pandemic Preparedness and Response (2021) proposed a framework convention-protocol approach and suggested to consider legal mechanisms for rapid sharing of sequence data and samples and the equitable sharing of VTDs. This issue is not new in the field of public health, as it first garnered widespread attention in 2006 when Indonesia refused to share its influenza A virus (known as H5N1) samples with the WHO for risk assessment through the WHO global influenza surveillance response system (WHO GISRS) — a voluntary network of laboratories and institutions sharing influenza samples (*18*). This barrier to rapid access to influenza virus samples originated from a sense of inequity and the undermining of sovereignty in developing countries. Indonesia argued that while they made information and samples available through the WHO GISRS, they could seldom afford the medical countermeasures that were developed and patented by pharmaceutical companies in industrialized countries (*19*). To resolve this issue, an ABS mechanism for influenza viruses with pandemic potential (IVPP) — the PIPF — was developed in 2011, following the adoption of a resolution by the World Health Assembly — issued in May 2007 — that stressed the need for "the timely sharing of viruses and specimens" through the WHO GISRS and the promotion of "transparent, fair and equitable sharing of the benefits arising from the generation of information, diagnostics, medicines, vaccines and other technologies" (*20,21*). Although limited to IVPP, the PIPF is the first reported ABS mechanism for pathogens.

The implications of the NP — a supplementary agreement to the Convention on Biological Diversity (CBD) — for pathogen sharing have been debated and analyzed by the WHO since 2010, triggered by Indonesia's refusal to share its H5N1 samples (*22,23*). The NP's objective is to implement "the fair and equitable sharing of benefits arising out of the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity", which is among the three objectives of the CBD (*24*). In the CBD, "genetic resources" refer to any material of plant, animal, microbial, or other origin containing functional units of heredity (genetic material) of actual or potential value (Article 2); additionally, it stipulates that states have sovereign rights over their natural resources (Article 15) (*25*). The NP sets out obligations for parties to take measures related to access to genetic resources (*e.g.*, Article 6), fair and equitable benefit-sharing (*e.g.*, Articles 5, 10, and 14), and compliance (*e.g.*, Articles 15 and 18). It requires each party to establish measures to ensure prior informed consent (PIC) before granting/being granted access to genetic resources, which would be agreed upon by the provider and recipient of the resources (Article 6).

As pathogens contribute to neither the protection nor the conservation of biological diversity, but rather the opposite by threatening biological diversity and impacting wildlife, questions have been raised regarding the status of pathogens as genetic resources under the CBD (*18,26*). The ambiguity of the NP has created a patchwork of ABS laws for pathogens (*27*), where certain countries are implementing domestic ABS legislation by

Table 1. Key global agreements on access and benefit sharing (ABS) systems issued by intergovernmental organizations

Year	Organization	Key features / Summary (*Ref.*)
1. The Convention on Biological Diversity (CBD) (*24*)		
1992	CBD Secretariat (UNEP*)	- Three objectives: "the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the utilisation of genetic resources" - Entered into force on December 29th, 1993. *United Nations Environment Program
2. Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) (*48*)		
2001	FAO	- Objective: "conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security" - Establishes a multilateral ABS mechanism for plant genetic resources (no DSI). Recipients gain access from a common pool without bilateral negotiations with providers - Recipients deposit a portion of the profits into a fund if new varieties of plants are developed and commercialized to support agricultural projects in developing countries
3. WHA60.28 Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits (*21*)		
2007	WHO	- A resolution adopted by the Sixtieth World Health Assembly - Stressed the need for "the timely sharing of viruses and specimens" through the WHO GISRS and the promotion of "transparent, fair and equitable sharing of the benefits arising from the generation of information, diagnostics, medicines, vaccines and other technologies"
4. the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization of the Convention on Biological Diversity (the Nagoya Protocol) (*24*)		
2010	The CBD Secretariat (UNEP)	- A supplementary agreement to the CBD, which was opened for signature in 1992 - Objective: to implement "the fair and equitable sharing of benefits arising out of the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity" - Sets out obligations for parties to take measures related to access to genetic resources, fair and equitable benefit-sharing, and compliance - Requires each party to establish measures to ensure prior informed consent before granting/being granted access to genetic resources, which would be agreed upon by the provider and recipient of the resources
5. Pandemic Influenza Preparedness Framework (PIPF) (*20*)		
2011	WHO	- Objective: to improve "pandemic influenza preparedness and response, and strengthen the protection against pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system ('WHO GISRS'), with the objective of a fair, transparent, equitable, efficient, effective system for, on an equal footing: *i*) the sharing of H5N1 and other influenza viruses with human pandemic potential; and *ii*) access to vaccines and sharing of other benefits" - Manufacturers are required to sign a Standard Material Transfer Agreement with the WHO to receive influenza samples, which includes commitments to set aside specific quantities of vaccines, antivirals, or diagnostic kits for donation or purchase in the event that influenza pandemic emerges and to provide an annual partnership contribution, which would be allocated to pandemic influenza preparedness capacity-building, response activities, and the implementation of the PIPF
6. United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas beyond National Jurisdiction (BBNJ Agreement) (*54*)		
2023	United Nations	- Objective: "to ensure the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction, for the present and in the long term, through effective implementation of the relevant provisions of the Convention and further international cooperation and coordination" - Establishes a multilateral ABS mechanism for marine genetic resources in areas beyond national jurisdiction and their DSI - Establishes a financial mechanism where developed parties are required to make annual contributions to the fund

extending the NP to pathogens and GSD (*14*). For this reason, the NP has been criticized for hindering rapid access to pathogens, thereby impeding scientific research, particularly in the health emergency context (*28,29*). There have been reports regarding delays in sharing samples of seasonal and pandemic influenza, SARS-CoV-2, Zika, mpox, Japanese encephalitis, foot and mouth disease, African swine fever, and bacterial isolates that are important for assessing antimicrobial resistance (*12,30*). The current practice entails pathogens to be handled according to the laws of national jurisdiction (*23*) and, as no established multilateral ABS mechanisms currently exist for pathogens (except for the PIPF), recipients — including researchers and manufacturers — are required to bilaterally obtain PIC from the provider when accessing pathogens depending on the country of origin's ABS legislation. Japan is a party to the NP, but the PIC is not required to obtain access to genetic resources within its national jurisdiction (*31,32*).

Features of the NP relevant to the pandemic instrument currently under discussion

Two articles of the NP are relevant to the WHO CA+. Article 4.4 of the NP stipulates that the protocol does not apply to genetic resources covered by other international ABS instrument(s) (hereafter, specialized international instrument [SII]) as long as they are "consistent with, and does not run counter to the objectives" of the CBD and the NP (*24*). Consequently, some parties of the NP, including the EU and Japan, have designated the PIPF as an SII (*33,34*). Due to the differences among the parties with respect to the interpretation and the implementation of this article, an attempt to develop an internationally agreed upon criteria for a SII has been initiated. The NP Subsidiary Body on Implementation has noted a list of "indicative criteria" in March 2022, which remains to be discussed in the CBD (*35*). Article 8 (b) provides special considerations for health emergencies when developing and implementing ABS legislation in each party. It also touches upon the need for expeditious access to genetic resources and fair and equitable sharing of benefits arising out of the use of genetic resources, including access to affordable treatments, especially in developing countries (*24*). Nevertheless, the implementation of these special considerations is unclear and left to domestic jurisdictions. The WHO CA+ may establish an ABS mechanism for pathogens with pandemic potential that may also be designated as an SII, therefore allowing recipients in NP parties to avoid the complex PIC process and mutually agreed terms (MATs) from the provider country.

ABS mechanism for data

Since the adoption of the CBD and NP, science and technology have advanced substantially. A significant increase in the value of data, including GSD, for product development has been observed, particularly in the biological and agricultural sectors. This has fostered a discussion on the need to consider an ABS mechanism for "digital sequence information" (DSI) in the CBD and the NP. As mentioned previously, "genetic resources" are defined as any material containing functional units of heredity (Article 2) in the CBD. Whether this term includes information such as GSD is unclear. However, provider countries of genetic resources have voiced concerns that recipients and users avoid or circumvent the ABS of genetic resources under the CBD and NP by utilizing DSI, and the benefits that would otherwise arise from the use of genetic resources are being compromised. In the CBD, a difference exists in the interpretation of genetic resources between developing and developed countries, where the former claim the inclusion of DSI while the latter claim exclusion, as information is not considered material (*36,37*). However, a decision was made in the fifteenth meeting of the Conference of the Parties (COP) to the CBD to establish "a multilateral mechanism for benefit-sharing from the use of digital sequence information on genetic resources, including a global fund", "recognizing the different understandings of the concept and scope of DSI on genetic resources, and the range of views regarding the need to define such concept and scope". An ad hoc open-ended working group was established to make recommendations on such a multilateral mechanism to the COP at its sixteenth meeting (*38*). The sixteenth COP held from October to November 2024 decided that parties would encourage DSI users including those from the pharmaceutical industry to contribute a portion of their profits to the global fund (the Cali Fund), supporting the objectives of the CBD (*39*).

As of March 31, 2025, no agreement has been reached on the definition of DSI. Workstreams under the CBD discussed the definition for two years before the COP's fifteenth meeting. The list developed by the Ad Hoc Technical Expert Group on DSI of genetic resources contained definitions ranging from nucleic acid sequence reads and associated data to macromolecules and cellular metabolites (*40*). This was eventually narrowed down to four different groups, the narrowest being DNA and RNA (*38*). The COP agreed with the decision regarding the continuing use of the term DSI for further discussions (*41*).

Existing ABS mechanisms and their implications for ABS for pathogens with pandemic potential

The PIPF

The PIPF was adopted at the World Health Assembly of the WHO in May 2011, to improve "pandemic influenza preparedness and response, and strengthen the protection against pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system ('WHO GISRS'), with the objective of a fair, transparent, equitable, efficient, effective system for, on an equal footing: i) the sharing of H5N1 and other influenza viruses with human pandemic potential; and *ii*) access to vaccines and sharing of other benefits" (*20*). The PIPF is a non-binding instrument on ABS. Since the early 1950s, WHO-member states, through their national influenza centers, have voluntarily shared representative influenza viruses detected through national surveillance with the WHO Collaborating Centres in the WHO GISRS. Twice a year, in February and September, scientists from the Collaborating Centres attend a meeting organized by the WHO to review global flu data and make recommendations on specific vaccine viruses that would compose seasonal flu vaccines (*42*). Since the PIPF's adoption, influenza laboratories that have been designated or recognized by the WHO and have accepted to work under agreed WHO terms of reference are required to sign a standard material transfer agreement (SMTA) within the WHO GISRS, while manufacturers are required to sign an SMTA outside the WHO GISRS with the WHO to receive influenza samples from the

WHO GISRS. The latter SMTA includes commitments to set aside specific quantities of vaccines, antivirals, or diagnostic kits for donation or purchase in case an influenza pandemic emerges, as well as to provide an annual partnership contribution (PC), which would be allocated to pandemic influenza preparedness capacity-building, response activities at the time of a pandemic, and the Pandemic Influenza Preparedness Secretariat for the implementation of the PIPF (*43*). The sum of the annual PC equals 50% of the running cost of the WHO GISRS, which was estimated to be 56.5 million USD in 2010, setting the annual PC to 28 million USD. The amount contributed by each manufacturer is calculated using a weighted formula that considers the contributor's average annual influenza product sales for four years (*44-46*). Noteworthily, if required under the NP, then PIC and MATs from the provider country must be obtained for manufacturers to receive influenza virus samples other than H5N1 and influenza viruses of pandemic potential from the WHO GISRS (*47*). Additionally, the term GSD is used instead of DSI in the PIPF (to the best of the authors' knowledge, DSI has never been used in WHO's previous technical documents before the WHO CA+), and laboratories are expected to share "GSD and analyses arising from that data, relating to H5N1 and other influenza viruses with human pandemic potential", "in a rapid, timely and systematic manner with the originating laboratory and among WHO GISRS laboratories" (*20*). An ABS mechanism within the different drafts of the WHO CA+ is clearly informed by the PIPF model. However, because the WHO CA+ targets pathogens with pandemic potential, their countermeasures and the manufacturers of these countermeasures cannot be identified. Unlike influenza viruses of pandemic potential, adapting the PIPF model — including the determination of the PC — poses many challenges. The details of these challenges will be covered in detail in later sections.

The ITPGR

The ITPGR was adopted in 2001 by the thirty-first Food Agricultural Organization Conference with the objective of "conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security" (*48*). Japan became a member of the treaty in October 2013 after the approval of the 183rd Ordinary Session of the Diet (*49*). The treaty facilitates access to plant genetic resources for food and agriculture for research and breeding, particularly to those important from the perspective of food security listed in Annex I as a "list of crops covered under the Multilateral System". The treaty furthermore establishes a Multilateral System of Access and Benefit-sharing to ensure that benefits accrued from these plant genetic resources are shared fairly and equitably. This multilateral system enables access to plant genetic resources provided by Contracting Parties from a common pool by signing an SMTA, which allows recipients to avoid bilateral negotiations on the terms and conditions for every access. Recipients are expected to deposit a portion of the profits into a Benefit-sharing Fund if new varieties are developed and commercialized (*50*). This fund supports agricultural projects in developing countries contributing to the conservation and sustainable use of plant genetic resources in food and agriculture (*51*). Japan recognizes the ITPGR as an SII under Article 4, Paragraph 4 of the NP (*49,52*).

The establishment of a pool of plant genetic resources available for access and a fund for capacity-building, observed in the ITPGR, is a potential ABS model that the pandemic instrument could apply. However, there are three challenges: *i*) difficulties in characterizing and identifying pathogens that would fall under the scope of the multilateral ABS system, *ii*) processing SMTAs for each access, and *iii*) handling of GSD in the multilateral system. A possibility exists that the ABS mechanism in the WHO CA+ could be applied to a list of pathogens that fulfill certain criteria similar to the ITPGR's approach; however, the scope of the pathogens is still under debate. Would the list encompass only pathogens with pandemic potential, or would it be significantly broader? How would the WHO and member states develop criteria for pathogens with pandemic potential which include unknown pathogens that may cause future pandemics? The list of priority pathogens with pandemic potential that the WHO is currently developing as part of its regular normative work (*53*) may help inform the INB's work. Secondly, although a bilateral negotiation on access and benefits between a provider and a recipient is not required in the ITPGR, an SMTA still needs to be concluded for every access. A simpler procedure for access may be needed in the pandemic instrument to incentivize the industry's participation. Lastly, because the ITPGR was developed more than 20 years ago, DSI is not currently within the scope of the Multilateral System of Access and Benefit-sharing.

The BBNJ agreement

The BBNJ agreement was agreed upon by the Intergovernmental Conference in June 2023 "to ensure the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction, for the present and in the long term, through effective implementation of the relevant provisions of the Convention and further international cooperation and coordination" (*54*). The first organizational meeting was convened in April 2018; the agreement was adopted by consensus after five sessions, with two resumed fifth sessions and the fourth meeting postponed from 2019 until 2022 (*55*).

The BBNJ agreement includes two features relevant to the WHO CA+. First, it includes the principle of fair and equitable sharing of benefits as one of the general principles and approaches of the agreement. Second, it establishes a multilateral ABS mechanism for marine genetic resources in areas beyond national jurisdiction and their DSI (*54*). Notably, although the BBNJ agreement uses the term "equity", it is not defined. Meanwhile, the same term is used in the drafts of the WHO CA+, and WHO member states are actively debating its definition.

In the ABS mechanism of the BBNJ agreement, a clearing-house mechanism was established whereby parties are required to provide information regarding the collection of marine genetic resources six months or as early as possible before the collection. Subsequently, the clearinghouse mechanism automatically generates a BBNJ-standardized batch identifier. Parties are expected to report the following information with their BBNJ standardized batch identifier: the repository or database where DSI on marine genetic resources is deposited, and the location where all the collected marine genetic resources are deposited. A report with details regarding the geographical area from which the marine genetic resources were collected is also required for submission to the clearinghouse mechanism. Non-monetary benefits include access to sample collections, marine technology transfer, and capacity building; monetary benefits from the utilization of marine genetic resources in areas beyond national jurisdiction and their DSI, including commercialization, are expected to be shared fairly and equitably through a financial mechanism established in the BBNJ agreement. Until new modalities for monetary benefit-sharing are adopted, developed parties are required to make annual contributions to the fund, which comprise 50% of the party's assessed contribution to the budget adopted by the COP (*54*). No SMTA has been developed in the BBNJ agreement, while modalities for capacity building and the transfer of marine technology are provided in articles 42 and 43 of the agreement. The ABS mechanism under the BBNJ agreement is different from that under ITPGR, as it has no list of genetic resources covered because the scope of marine genetic resources of areas beyond national jurisdiction to be targeted and collected is unlimited. This is another model that the pandemic instrument could apply, as developing a list of pathogens that would fall under the scope of the instrument could be difficult.

This section provides an overview of the existing ABS mechanisms agreed in several international fora, namely the PIPF, the ITPGR, and the BBNJ agreement. The key elements of the ITPGR and the BBNJ agreement and their implications for an ABS mechanism for pathogens with pandemic potential are summarized in Table 2. The elements of the PIPF are presented separately in Table 3, along with details on the challenges of incorporating the PIPF elements into an ABS mechanism for pathogens in the pandemic instrument. These challenges are detailed in later sections.

Negotiation of the WHO CA+

Pandemic-related ABS mechanism discussed in WHO CA+

In a special session held in December 2021, the World Health Assembly (WHA) adopted a decision to establish the INB to draft and negotiate the WHO CA+ (*56*). The first meeting was held in February 2022, and two co-chairs — one from the Netherlands and one from South Africa — and four vice-chairs — from Brazil, Egypt, Thailand, and Japan — were elected to comprise the INB bureau (*57*). At the second meeting, held in July 2022, the INB agreed that the new instrument should be legally binding (*58*). The INB has been discussing several texts during its negotiating process: the conceptual zero draft developed in November 2022 (*59*), the zero draft developed in February 2023 (*60*), the bureau's text developed in April 2023 (*61*), and the negotiating text developed in October 2023 (*6*), while an ABS mechanism for pathogens with pandemic potential has been a part of these texts. The INB was unable to reach an agreement by the Seventy-seventh WHA in May 2024 as originally planned. It is continuing its negotiations by building upon text submitted to the assembly that contains some provisionally agreed upon contents (*62*), to finish its work by the Seventy-eighth WHA in May 2025 or earlier (*63*).

Challenges in developing an ABS mechanism for pathogens in the pandemic instrument

The ABS mechanism in the draft texts of the pandemic instrument adopts a structure similar to that of the PIPF. For example, the "proposal for negotiating text of the WHO pandemic agreement", issued on October 30, 2023, provides for: *i*) the establishment of a WHO-coordinated laboratory network (WCLN), which comprises recognized laboratories where parties may share pathogen samples through relevant public health authorities and authorized laboratories; and *ii*) the development of an SMTA to be used with the transfer of samples from a laboratory in the WCLN to a recipient. The SMTA is expected to include the commitments of recipients to set aside a minimum of 20% (10% as a donation and 10% at affordable prices to the WHO) of the production of pandemic-related products for real-time access by the WHO in the event of a pandemic, as well as to provide an annual contribution based on the recipient's nature and capacity (*6*). Although the ABS provisions were significantly reduced immediately before the WHA in 2024 in an attempt to reach a consensus by deferring the discussion of details to a separate document, the draft still contains the concept of the WCLN and descriptions

Table 2. Existing ABS mechanisms and their implications for ABS for pathogens with pandemic potential

Elements of the agreement (*Ref.*)	Implications of the agreement to the WHO CA+
Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) (*48*)	
- Facilitates access to plant genetic resources for food and agriculture for research and breeding, particularly to those important from the perspective of food security listed in Annex I as a "list of crops covered under the Multilateral System".	The ABS mechanism in the WHO CA+ could be applied to a list of pathogens that fulfill certain criteria similar to the ITPGR's approach; however, the scope of the pathogens is still under debate.
- Establishes a multilateral ABS mechanism for plant genetic resources (no DSI), where recipients gain access from a common pool without bilateral negotiations with providers.	Although a bilateral negotiation on access and benefits between a provider and a recipient is not required in the ITPGR, an SMTA still needs to be concluded for every access. A simpler procedure for access may be needed in the pandemic instrument to incentivize the industry's participation.
United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas beyond National Jurisdiction (BBNJ agreement) (*54*)	
- Establishes a multilateral ABS mechanism for marine genetic resources in areas beyond national jurisdiction and their DSI. The ABS mechanism has no list of genetic resources covered because the scope of marine genetic resources of areas beyond national jurisdiction to be targeted and collected is unlimited.	The intergovernmental negotiating body could decide not to apply the ABS mechanism in the pandemic instrument to a list of pathogens, as developing a list of pathogens that would fall under the scope of the instrument could be difficult.
- Establishes a clearing-house mechanism in the ABS mechanism whereby parties are required to provide information including the repository or database where DSI on marine genetic resources is deposited, and the location where all the collected marine genetic resources are deposited.	The pandemic instrument could develop a mechanism where parties are required to provide information on the database where GSD (or more broadly DSI) on pathogens with pandemic potential is deposited.
- Establishes a financial mechanism where monetary benefits from the utilization of marine genetic resources and their DSI, including commercialization, are expected to be shared fairly and equitably. Until new modalities for monetary benefit-sharing are adopted, developed parties are required to make annual contributions to the fund.	The pandemic instrument could establish a financial mechanism where the monetary benefits from the utilization of pathogens and their GSD, including commercialization, are expected to be shared by the user as well as annual contributions from parties to the fund.

*For elements and implications of the Pandemic Influenza Preparedness Framework (PIPF) (*20*), refer to Table 3.

of the set-asides (*62*). Following the PIPF's success, this new ABS mechanism for pathogens seems to be a feasible idea at first glance; however, it has numerous inherent challenges in addressing pandemics (Table 3).

First, in contrast to influenza, pathogens that will cause future pandemics or public health emergencies of international concern cannot be identified before their occurrence. This notion also extends to the countermeasures that will be effective in combating these health emergencies — including prophylaxis, diagnostics, and treatment. Therefore, it would be challenging for the WHO and relevant parties to identify manufacturers who would sign the SMTA during the pre-pandemic period. Additionally, incentives are low for manufacturers to sign the SMTA and obtain samples of unknown pathogens, as manufacturers cannot predict the type of pathogens they would gain access to through the WCLN and the future market value of the product they may develop against the pathogen in question. Third, in contrast to the PIPF, the calculation of a partnership contribution to the WCLN is impossible because the products required to counter the pandemic are currently unknown; therefore, product sales — part of the PC calculation formula — cannot be determined. Finally, if capacity building of the WCLN were to become part of the non-monetary benefits of the new ABS mechanism, the WCLN's broad scope may not be appealing to manufacturers considering participating in the system. Incentives for the PIPF contributors to pay their PC include their targeted allocation to capacity building for strengthening global influenza surveillance, which would, in turn, enable manufacturers to access important influenza pathogen samples. However, industry participation is essential to the success of the pandemic ABS mechanism; thus, the INB and the WHO Secretariat would need to address these challenges. In addition, industry engagement at the negotiation stage is key to ensuring that the mechanism provides incentives.

Although the WHO CA+ cannot simply copy the PIPF for the above reasons, the two instruments partially overlap in their scope, as the PIPF itself is an instrument on pathogens with pandemic potential, namely IVPP. Therefore, the WHO CA+ should not contain contradicting provisions, and its relationship with the PIPF needs to be clearly defined.

Uncertainty also stems from the operational and governance perspectives regarding the ABS mechanism proposed in the pandemic instrument's draft texts. For example, according to Article 21, Chapter III of the negotiating text: the COP can "establish subsidiary bodies to carry out the work of the COP", which may include "a panel of experts to provide scientific advice and a WHO Pathogen Access and Benefit-Sharing System Expert

Table 3. Challenges in developing an ABS mechanism for pathogens in the pandemic instrument, as compared to the Pandemic Influenza Preparedness Framework (PIPF)

Elements of the PIPF (An ABS mechanism for influenza viruses with pandemic potential)	Elements of the draft CA+ agreement (An ABS mechanism for any pathogens with pandemic potential)	Implementation Challenges
Establishes the WHO global influenza surveillance response system (WHO GISRS) as a voluntary network of laboratories and institutions sharing influenza samples.	Proposes to establish a WHO-coordinated laboratory network (WCLN) comprised of recognized laboratories where parties may share pathogen samples.	Manufacturers with the capacity to develop influenza vaccines have the incentive to sign an SMTA for gaining access to influenza samples from the WHO GISRS. In contrast, incentives are low for manufacturers to sign an SMTA to obtain samples of unknown pathogens, as manufacturers cannot predict the type of pathogens they would gain access to through the WCLN and the future market value of the product they may develop against the pathogen in question.
A Standard Material Transfer Agreement (SMTA) is signed by manufacturers with the WHO to receive influenza samples from the WHO GISRS. It includes commitments to set aside specific quantities of vaccines, antivirals, or diagnostic kits for donation or purchase by WHO in the event that an influenza pandemic emerges.	Recipients are granted access to pathogen samples by signing an SMTA that includes commitments to set aside a minimum of 20% of the pandemic-related products produced by the recipient as a result of using that pathogen including its sequence data for real-time access by the WHO during the pandemic.	For influenza, manufacturers who would have the most interest in signing the SMTA during the pre-pandemic period are manufacturers of influenza products. In contrast, identifying manufacturers who would sign the SMTA in the WHO CA+ during the pre-pandemic period would be challenging for two reasons: one, pathogens that will cause future pandemics or PHEICs cannot be identified before their occurrence; and two, the countermeasures that will be effective in combating these health emergencies also cannot be identified during the pre-pandemic/PHEIC period.
The SMTA also includes commitments of manufacturers to provide an annual partnership contribution (PC), which would be allocated to pandemic influenza preparedness capacity-building, response activities at the time of a pandemic, and the implementation of the PIPF.	Recipients are granted access to pathogen samples by signing an SMTA that includes commitments to provide an annual contribution based on the recipient's nature and capacity.	1. Product sales (as part of the PC calculation formula) can be estimated for manufacturers who sell seasonal influenza vaccines. In contrast, the calculation of a partnership contribution to the WCLN is impossible because the products required to counter the pandemic are currently unknown; therefore, product sales cannot be determined. 2. Manufacturers have the incentive to pay their PC to the PIPF because it will strengthen global influenza surveillance specifically, improving their chances of accessing important influenza samples. In contrast, the WCLN's broad scope to cover pathogens with pandemic potential may not be as attractive to manufacturers because their annual contribution would not be targeted to improve global surveillance for a specific type(s) of pathogens.

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Advisory Group" (*6*), but the nature and the function of such an advisory group remains unclear. The Bureau's text (*61*), which is an older draft than the negotiating text, contained a stand-alone article on a Benefit-Sharing Expert Committee (Article 25), which was provided with a mandate "to establish guidelines for benefit sharing, providing transparency and ensuring a fair and equitable sharing of benefits, and to report to the COP, as well as discharge all functions set out in the WHO CA+ and respond to the requests of the COP". Such committees are possibly envisioned to develop modules and materials to facilitate a deeper understanding of the provisions such as to achieve the effective implementation of the instrument, similar to various modules developed by the ITPGR Secretariat (*64,65*), FAQs developed by the PIPF Secretariat (*66*), or various guides and toolkits, including the International Health Regulations (2005) Toolkit for Implementation in National Legislation, developed by the WHO Secretariat (*67,68*).

Challenges in addressing an ABS mechanism for GSD of pathogens in the pandemic instrument

As mentioned previously, a multilateral mechanism for benefit-sharing through the use of DSI on genetic resources is currently being discussed in an ad hoc open-ended working group in the CBD, in parallel with the INB's work at the WHO. This raises additional issues.
The member states of the INB are actively discussing whether the ABS system in the WHO CA+ should be recognized as "a specialized international access and benefit-sharing instrument within the meaning of paragraph 4 of Article 4 of the Nagoya Protocol" (*6,62*). Theoretically, designating the WHO CA+ as an SII in the context of the NP is certainly helpful, as it will exempt those who are parties to both the NP and the pandemic instrument from benefit-sharing provisions under the NP with respect to the specific genetic resources covered by — and for the purpose of — the specialized instrument; these are, in this case, pathogens related to pandemics. However, clearly distinguishing whether a certain pathogen and its GSD would be considered under the ABS mechanism of the pandemic instrument or the multilateral benefit-sharing mechanism for DSI considered under the CBD may be challenging. For example, recent developments in vaccine research have focused on the highly conserved regions of various human pathogenic coronaviruses, which may be considered useful for developing a universal vaccine to protect populations against beta coronaviruses in general, rather than against a specific virus (*69*). Additionally, the difference between DSI (the term used in the CBD) and GSD (which can be considered to be narrower in definition) may also complicate ABS legislation for pathogens related to pandemics if the INB decides to use GSD in its final text, in line with other WHO documents including the PIPF.

Sections 4.2 and 4.3 discuss two sets of challenges that arise in the development of an ABS mechanism for pathogens in the pandemic instrument. One is attributed to the scope of this instrument to address pandemics broadly, rather than pandemics caused by specific pathogens, such as IVPP. Another is related to the parallel discussions happening in the CBD regarding an ABS mechanism for DSI (Table 4).

Possible scenarios for the ABS mechanism in the pandemic instrument

There are a few possible scenarios for, and elements from other existing ABS mechanisms that the INB could incorporate into, the ABS mechanism in the pandemic instrument. These approaches are not mutually exclusive, and pandemic instruments can adopt combinations of different approaches and elements.

The first is an ABS mechanism similar to the PIPF, as proposed in different versions of texts discussed by the INB (*6,60-62*). The structural similarity and feasibility challenges related to this approach were described extensively in the previous two sections — difficulties in identifying pathogens with pandemic potential, their countermeasures, and manufacturers of these countermeasures during the pre-pandemic period.

Second, the pandemic instrument could adopt the ITPGR's approach, which could be considered a variation of the PIPF model, wherein recipients are required to sign an SMTA to gain access to a list of pathogens related to pandemics, which would be covered

Table 4. Challenges in developing an ABS mechanism for pathogens in the pandemic instrument

Points	Challenges
1	There are inherent challenges in addressing pandemics broadly compared to influenza pandemics. The PIPF cannot simply be made to apply to an ABS mechanism for pathogens with pandemic potential because pathogens that will cause future pandemics or PHEICs cannot be identified before their occurrence. In addition, the countermeasures that will be effective in combating these health emergencies cannot be identified during the pre-pandemic period.
2	A multilateral mechanism for benefit-sharing through the use of DSI on genetic resources is currently being discussed in a working group in the CBD, in parallel with the INB's work at the WHO. These mechanisms have to be structured to avoid a situation in which a given pathogen with pandemic potential and its GSD/DSI is subject to both the ABS mechanism of the pandemic instrument and the multilateral benefit-sharing mechanism for DSI considered under the CBD.

under a multilateral ABS system. Recipients would be expected to deposit a portion of their profits to a benefit-sharing fund in the multilateral system if new products were developed and commercialized. The fund would support capacity building for pandemic preparedness and response (*50*). The problem with this approach is that the limited scope of enlisted pathogens may become a hurdle for inviting recipients, as opportunities to develop countermeasures and sales are predicted to be infrequent. Furthermore, the need for recipients to sign an SMTA for every access may disincentivize their participation.

Lastly, the pandemic instrument could incorporate elements from the BBNJ agreement, wherein monetary benefits — from the utilization of pathogens and their GSD (or more broadly DSI), including commercialization — are expected to be shared fairly and equitably by the user through a financial mechanism established in the instrument. Developed parties are also expected to make annual contributions to the fund, comprising 50% of the party's assessed contribution to the budget adopted by the COP (*54*). The scope of ABS could be broad, as there would be no list of pathogens, in contrast to the ITPGR. This approach could be beneficial, as capturing pathogens that may cause a pandemic — including those that are currently unknown — in a list is unrealistic. Additionally, providing access to a wide range of pathogens may be a greater incentive for the industry than providing access to a small list of pathogens.

In any approach, the INB may inevitably decide to adopt ABS for pathogens, including a provision on benefit-sharing for the utilization of GSD or, more broadly, DSI, considering the current movement of discussion on ABS for DSI in the CBD and the fact that not only the virus sample but also their sequence data are required for vaccine sequence design in the production of mRNA vaccines, which played a unique role in controlling the COVID-19 pandemic (*70*). In this regard, there is an urgent need to analyze the potential effects of an ABS mechanism for pandemics on Japan's ABS policy and to identify the merits and challenges in the context of a developed country.

The impact of a new WHO mechanism for pathogens with pandemic potential on Japanese ABS policy

As ABS mechanisms are actively discussed in many fora, including the INB in the WHO, there is growing interest and value in mapping national policies on ABS (*14*). Therefore, it is important that information regarding Japan's ABS policy is accessible in a universal language. As previously mentioned, Japan has established national guidelines (not legislation), pertaining to genetic resource access and the fair and equitable sharing of benefits arising from their utilization for the NP's national implementation, issued jointly by the Ministry of the Environment; the Ministry of Health; the Ministry of Finance; the Ministry of Agriculture, Forestry and Fisheries; the Ministry of Education, Culture, Sports, Science and Technology; and the Ministry of Economy, Trade and Industry (*32*). The government of Japan does not require PIC with respect to genetic resources — a practice observed in numerous European countries, including the UK, where access controls are not put in place, thereby providing free access to genetic resources (*32,71,72*). Japan has historically supported SII recognition, designating the PIPF and ITPGR as SIIs under Article 4.4 (*33,52*). Designating the pandemic instrument as an SII allows recipients in NP parties to avoid the complex PIC process and mutually agreed terms from the provider country. Therefore, if Japan decides to become a member of a pandemic instrument, the authors assess that it will designate the pandemic instrument domestically as an SII.

Two issues related to recognizing the pandemic instrument as an SII are expected (Figure 1). First, because parties to the NP need to designate SIIs through and in accordance with their national ABS policy, a situation will arise where there will be a mix of countries that have designated the pandemic instrument as an SII versus those that have not. Potential recipients, particularly the industry including those in Japan, will be cautious about participating in the new ABS mechanism in fear that they will be responsible for benefits under two international agreements—the NP and the pandemic

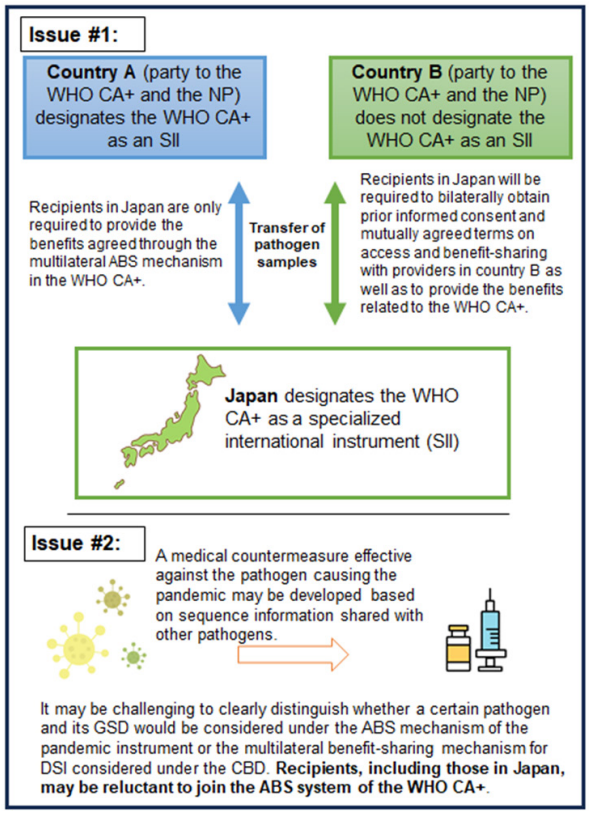

Figure 1. Potential issues caused by an ABS mechanism for pathogens with pandemic potential to Japanese policy implementation.

instrument — for the same pathogen and its DSI/GSD. Ensuring that ABS rights and obligations are not duplicated in the domestic implementation of the NP and other ABS agreements is important for participation. Second, because a clear-cut line is lacking between genetic resources of the NP and pathogens related to pandemics, recipients may still be reluctant to participate even if the pandemic instrument is designated as an SII in most NP parties. As highlighted previously, a situation may arise wherein a vaccine against a pandemic pathogen is developed using a conserved region of the virus family (*69*), thereby making it difficult to identify the pathogen and/or GSD originally utilized for product development. In this hypothetical situation, one may argue that benefits should be shared under the NP, whereas others may argue that benefits should be shared in accordance with the pandemic instrument. In the future, these issues related to legal certainty need to be thoroughly discussed among member states and also with potential recipients such as industry and academia to establish an effective ABS mechanism where pathogens are readily accessible and benefits are equitably shared. Structuring an effective ABS mechanism for pandemics is time-consuming; however, as the ABS mechanism is merely one component among the many arrangements in the agreement on pandemic prevention, preparedness and response, there is a risk of compromising the details for the sake of consensus.

This review presented an up-to-date account of recent developments of the ABS mechanisms in different international fora to highlight their relevance to the ongoing negotiations occurring in the health sector and to identify Japan's expected challenges with a new WHO ABS mechanism. While analysis in the Japanese context is helpful for understanding similar challenges faced by other developed countries, nation-specific analyses are essential as the ABS mechanism will impact countries differently depending on factors such as presence/non-presence of industry and its scale, and the status of domestic ABS legislation. Conducting such analyses in different country contexts will support an evidence-based approach towards building an ABS mechanism that ensures rapid access to pathogens and GSD as well as benefit-sharing that includes equitable access to medical countermeasures during pandemics.

Conclusion

The rapid sharing of pathogens and their GSD is essential for an effective response to health emergencies, and this aspect of access to pathogens, as well as benefit-sharing from their utilization, is a potential core element of the WHO CA+ that is currently being discussed in the WHO's INB. There are elements from the existing ABS mechanisms — including the PIPF, ITPGR and the BBNJ agreement — that the INB could incorporate to develop a new ABS system for pathogens related to pandemics. Additionally, the simultaneous discussion in the CBD to establish a multilateral benefit-sharing mechanism for DSI may further complicate the already-complex web of ABS legislation implemented by parties to the NP, if implemented alongside the new ABS mechanism for pandemics. Japan and some European countries, which do not require PIC for access to their genetic resources in their ABS policy, will continue contributing to the rapid provision of access to genetic resources, promoting surveillance, research, and development, while establishing bilateral negotiations with countries that require PIC and MATs under their ABS legislation. A need exists for facilitating global awareness of the ongoing negotiations at the WHO on ABS for pathogens with pandemic potential, particularly for industry and academia, which may facilitate rapid access to pathogens by providing legal certainty within the complex landscape of ABS legislation, as well as promote global equitable access to medical countermeasures against future pandemics.

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