

The WHO CA+ Discussions on Pathogen Access and Benefit Sharing: State of Play

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ABSTRACT

This brief explores the scope of a World Health Organization (WHO) pathogen access and benefit-sharing (PABS) mechanism as a possible outcome of the negotiations ongoing in the WHO Intergovernmental Negotiating Body (INB) for a WHO Convention, Agreement or other Instrument (WHO CA+) for pandemic prevention, preparedness, response and recovery (PPRR). After seven sessions of the INB, substantial differences remain between developed and developing countries on the PABS system. While the text contains specific obligations on rapid sharing of pathogen material and genetic sequence information reflective of the primary interest of developed countries to get such access outside the framework of the Nagoya Protocol to the Convention on Biological Diversity through a specialized WHO instrument such as the PABS system under the WHO CA+, the current text continues to be weak in terms of effectively operationalizing fair and equitable-benefit sharing. To that end, it is critical that detailed provisions on standard material transfer agreements, data access relating to their genomic sequence information and specific obligations on monetary and non-monetary benefit-sharing by recipients of pathogen material and sequence information are included in the provisions establishing the PABS system. Therefore, it is important that the proposals that have been made in this regard by developing countries are incorporated in the draft negotiating text.

KEYWORDS: pandemic treaty, WHO, pathogen, access and benefit-sharing, genetic sequence data, standard material transfer agreement, Nagoya Protocol

Ce rapport explore la portée d'un mécanisme d'accès aux agents pathogènes et de partage des avantages (PABS) de l'Organisation mondiale de la santé (OMS) comme résultat possible des négociations en cours au sein de l'organe intergouvernemental de négociation de l'OMS pour une convention, un accord ou un autre instrument de l'OMS (CA+ de l'OMS) pour la prévention, la préparation, la riposte et rétablissement en cas de pandémie. Après sept sessions de l'INB, des différences substantielles subsistent entre les pays développés et les pays en développement sur le système PABS. Bien que le texte contienne des obligations spécifiques sur le partage rapide du matériel pathogène et des informations sur les séquences génétiques, reflétant l'intérêt principal des pays développés à obtenir un tel accès en dehors du cadre du Protocole de Nagoya à la Convention sur la diversité biologique par le biais d'un instrument spécialisé de l'OMS tel que le système PABS dans le cadre du CA+ de l'OMS, le texte actuel continue d'être insuffisant en termes de mise en œuvre concrète d'un partage juste et équitable des avantages. À cette fin, il est essentiel que des dispositions détaillées sur les accords de transfert de matériel standard, l'accès aux données relatives à leur séquence génomique et les obligations spécifiques sur le partage des avantages monétaires et non monétaires par les bénéficiaires de matériel pathogène et d'informations sur les séquences soient incluses dans les dispositions établissant le système PABS. Il est donc important que les propositions faites à cet égard par les pays en développement soient intégrées dans le projet de texte de négociation.

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MOTS-CLÉS: traité sur les pandémies, OMS, agent pathogène, accès et partage des avantages, données sur les séquences génétiques, accord standard de transfert de matériel, protocole de Nagoya

KEY MESSAGES

"An effective multilateral PABS system can provide legal certainty against unfair exploitation of pathogen material and their sequence information and also enable consolidation of the benefits received at the multilateral level to support countries in pandemic preparedness and response."

"It will be important to ensure the benefit-sharing obligations under the PABS system are appropriately defined. Benefit-sharing should not be limited only to assured access to products made by utilizing accessed pathogens, but also include monetary contributions by recipients with whom pathogens are shared. Such monetary contributions can be used for improving preparedness and response capacities of developing countries."

"It will be critical for developing countries to ensure that both pathogen access and benefit sharing are part of a single mechanism anchored under the same instrument. If a benefit-sharing mechanism is adopted under the WHO CA+ under an article 19 approach but obligations on pathogen sharing are adopted under an article 21 opt out instrument, the mechanism will ultimately only create binding obligations on pathogen sharing. This would be completely contrary to the needs and expectations of developing countries regarding benefit-sharing."

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Este informe explora el alcance de un mecanismo de acceso a patógenos y distribución de beneficios (PABS) de la Organización Mundial de la Salud (OMS) como posible resultado de las negociaciones en curso en el Órgano Intergubernamental de Negociación (INB) de la OMS para un Convenio, Acuerdo u otro Instrumento de la OMS (WHO CA+) para la prevención, preparación, respuesta y recuperación ante pandemias (PPRR). Tras siete sesiones del INB, persisten diferencias sustanciales entre los países desarrollados y en desarrollo sobre el sistema PABS. Aunque el texto contiene obligaciones específicas sobre el intercambio rápido de material patógeno e información sobre secuencias genéticas que reflejan el interés primordial de los países desarrollados por obtener dicho acceso fuera del marco del Protocolo de Nagoya del Convenio sobre la Diversidad Biológica a través de un instrumento especializado de la OMS como el sistema PABS en el marco del CA+ de la OMS, el texto actual sigue siendo deficiente en cuanto a la puesta en práctica efectiva de un reparto justo y equitativo de los beneficios. Para ello, es fundamental que en las disposiciones por las que se establece el sistema PABS se incluyan disposiciones detalladas sobre los acuerdos normalizados de transferencia de material, el acceso a los datos relativos a su información sobre secuencias genómicas y obligaciones específicas sobre la distribución de beneficios monetarios y no monetarios por parte de los receptores de material patógeno e información sobre secuencias. Por lo tanto, es importante que las propuestas que han hecho a este respecto los países en desarrollo se incorporen al proyecto de texto de negociación.

PALABRAS CLAVES: tratado sobre pandemias, OMS, agente patógeno, acceso y participación en los beneficios, datos sobre secuencias genéticas, acuerdo normalizado de transferencia de material, Protocolo de Nagoya

I. The Rationale for a PABS Mechanism

The issue of establishment of a system for access and benefit-sharing (ABS) of pathogens under the WHO is important because samples of pathogens (including their genetic sequence information) that can cause infectious diseases and lead to international public health emergencies or global pandemics are critical resources to develop medical countermeasures such as vaccines and medicines. However, since the capacity to conduct research and development (R&D) and manufacturing of such medical countermeasures is predominantly in developed countries, it is also critical for an equitable global public health preparedness and response to future public health emergencies and pandemics that the benefits derived from utilizing accessed pathogens are shared fairly and equitably.

Under 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, an international treaty that has been ratified by most WHO member States, pathogens are genetic resources. The parties to the Protocol have an international obligation to ensure fair and equitable sharing of benefits arising from their utilization with the country providing the genetic resources.¹ Article 4(2) of the Nagoya Protocol, however, allows parties to develop and implement other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention on Biological Di-

versity and the Protocol. Thus, parties to the Nagoya Protocol can adopt other international agreements like the FAO International Treaty on Plant Genetic Resources for Food and Agriculture that establishes a multilateral system for enabling facilitated access to plant genetic material held in national gene banks or used in research programmes through a Standard Material Transfer Agreement (SMTA) that lays down terms and conditions regulating exchanges of plant genetic material, preventing their misuse, and ensuring that any commercial benefits that arise are fairly and equitably shared. Indeed, besides requiring parties to consider the importance of genetic resources for food and agriculture and their special role for food security while developing and implementing their access and benefit-sharing legislation or regulatory requirements, the Nagoya Protocol also requires parties to pay due regard to cases of present or imminent health emergencies and take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries.²

However, there is no mechanism in the WHO governing access to pathogens and fair and equitable sharing of benefits arising from their utilization, except for the WHO Pandemic Influenza Preparedness Framework (PIP Framework) that provides a system for providing access to influenza pathogens of pandemic potential and the sharing of benefits arising from the utilization of pathogen material accessed under the PIP Framework.³ The absence of an ABS mechanism within WHO for other pathogens is a significant gap. During the COVID-19 pandemic as well as previous global health emergencies, even when developing countries have promptly provided access to pathogen samples and their sequence information to the WHO, the benefits from utilizing these samples in developed countries have not been shared equitably with developing countries.

Nevertheless, the WHO secretariat has established some mechanisms in partnership with selected developed countries to foster rapid access to pathogen samples. In November 2020, the WHO secretariat announced the establishment of the WHO BioHub.⁴ The BioHub seeks to enable sharing of biological materials of epidemic or pandemic potential through laboratories designated as a WHO BioHub Facility. In 2021, the WHO concluded a memorandum of understanding with Switzerland to recognize a Swiss biosafety laboratory in Spiez, Switzerland, as the first WHO BioHub Facility. Another initiative of the WHO secretariat in partnership with Germany is the WHO Hub for Pandemic and Epidemic Intelligence which promotes a multistakeholder model of collaborative surveillance that, among others, promotes greater sharing of data and information (including in relation to pathogen material) between communities and countries.⁵

These initiatives of the WHO secretariat have been established without seeking approval of the WHO governing bodies. They were

¹ See Article 5 (1), The Nagoya Protocol on Access and Benefit-Sharing (“... benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources...”).

² Article 8(b), Nagoya Protocol.

³ WHO, Pandemic Influenza Preparedness Framework. Available from <https://www.who.int/initiatives/pandemic-influenza-preparedness-framework>.

⁴ WHO, WHO Biohub System. Available from <https://www.who.int/initiatives/who-biohub>.

⁵ WHO, The WHO Hub for Pandemic and Epidemic Intelligence. Available from <https://pandemichub.who.int/>.

not created through a process that included all WHO member States. The nature of these initiatives is reflective of the interest of developed countries in securing rapid access to information about pathogens, including samples of pathogen material and sequence information, to safeguard their health security without the corresponding benefit-sharing obligations.⁶

In the ongoing negotiations in the WHO Intergovernmental Negotiating Body (INB) for a WHO convention, agreement or other Instrument (WHO CA+) for pandemic prevention, preparedness, response and recovery (PPRR) (hereinafter referred to as 'the pandemic treaty'), developed countries have proposed to establish international obligations to facilitate rapid access to pathogen samples and their genetic sequence information. In this context developing countries have made the demand for establishment of an effective system in WHO that assures prompt, adequate and concrete benefit-sharing arising from the utilization of such samples and information a core demand in the INB negotiations.

II. Access and Benefit-Sharing in the INB texts

The conceptual zero draft of the WHO CA+⁷ that was developed in November 2022 by the Bureau of the INB recognized the sovereign right of States over their biological resources and proposed a draft provision stating that the parties to the WHO CA+

"... [shall/should] develop provisions on access and benefit-sharing to promote rapid and transparent sharing, in a safe and secure manner, of pathogens with pandemic potential and genetic sequence data on the one hand, and fair and equitable access to benefits arising from such sharing on the other, by establishing a comprehensive system for access and benefit-sharing, taking into account relevant elements of the Convention on Biological Diversity and its Nagoya Protocol, including by building upon or adapting mechanisms and/or principles contained in existing or previous instruments, such as, but not limited to, the FAO International Treaty on Plant Genetic Resources for Food and Agriculture and the WHO Pandemic Influenza Preparedness Framework."

However, in concrete terms, the conceptual zero draft was more specific in proposing obligations on pathogen sharing to facilitate rapid access to pathogens while it only committed to developing provisions on benefit-sharing in the future.⁸

During discussions on the conceptual zero draft at the third session of the INB, developing countries had stressed on the need to ensure access and benefit sharing (ABS) as a standalone provision with access to pathogen samples including their genetic sequence data (GSD) and sharing of benefits derived thereof being placed on an equal footing. Developing countries pointed to the need for ABS as an operational mechanism to access technology and know-how for

diversification of production of all medical necessities during pandemics. Developing countries cautioned against "... final outcomes whether through the IHR amendment process or the INB process, where access to pathogens and genetic sequence data is prioritised without a clear and comprehensive benefit sharing mechanism."⁹ Some developing countries also stressed the need for global surveillance mechanisms to ensure that laboratories that handle highly contagious and infectious pathogens for research purposes share their biomarkers, biobanks and information about their research activities.¹⁰

The third session of the INB mandated the Bureau to prepare the zero draft with legal provisions based on the conceptual zero draft and the inputs received from member States. The zero draft was presented at the fourth session of the INB for a first reading.

In further development of the provision on PABS based on the conceptual zero draft and inputs from member States in the INB, the Bureau proposed the following provision in the zero draft:

"The need for a multilateral, fair, equitable and timely system for sharing of, on an equal footing, pathogens with pandemic potential and genomic sequences, and benefits arising therefrom, that applies and operates in both inter-pandemic and pandemic times, is hereby recognized. In pursuit thereof, it is agreed to establish the WHO Pathogen Access and Benefit-Sharing System (the "PABS System") under this WHO CA+. The Parties are mindful that the PABS System, or parts thereof, could be adopted under Article 21 of the WHO Constitution, should such an approach be agreed. The terms of the PABS System shall be developed no later than XX with a view to their provisional application consistent with Article 35 hereof."¹¹

While including a proposal to establish a Pathogen Access and Benefit Sharing (PABS) system, the zero-draft laid down specific obligations regarding facilitating access to pathogens and their sequence information.¹² Thus, it proposed that each party shall in a rapid, systematic, and timely manner (within hours from identification of a pathogen with pandemic potential) provide the pathogens and subsequent variants to a laboratory designated as part of a WHO coordinated laboratory network (WCLN) and upload their sequence information to one or more publicly accessible databases of its choice.¹³ It proposed that access to the pathogens be provided by the WHO-recognized laboratory to a recipient subject to an SM-TA.¹⁴ However, there was no elaboration of how, by which entity and by when the SM-TA would be developed, or whether the SM-TA would also apply to sharing of sequence information of pathogens.

Regarding benefit-sharing, the zero-draft specified only two types of benefits – sharing 20 percent of the products developed by using pathogens accessed under the system with the WHO, and

6 See Edward Hammond, "Questions swirl about proposed WHO pathogen collection: Effort to 'shortcut' the Nagoya Protocol raises fairness and equity and other issues", TWN Briefing Paper, January 2021. Available from https://www.twn.my/title2/briefing_papers/twn/Questions%20about%20proposed%20WHO%20pathogen%20collection%20Jan2021%20Hammond.pdf.

7 WHO document A/INB/3/3, 25 November 2022. Available from https://apps.who.int/gb/inb/pdf_files/inb3/A_INB3_3-en.pdf.

8 South Centre, WHO proposed instrument on pandemics: the Conceptual Zero Draft needs substantial improvement to address global public health needs, Statement on WHO Proposed Instrument on Pandemics, 9 December 2022. Available from <https://www.southcentre.int/statement-on-who-proposed-instrument-on-pandemics-9-december-2022/>.

9 Nithin Ramakrishnan, "WHO: Will the Zero Draft of pandemic legal instrument incorporate calls for equity?", TWN Info Service on Health Issues (Jan23/05). Available from <https://www.twn.my/title2/health.info/2023/hi230105.htm>.

10 *ibid.*

11 WHO document, WHO/INB/4/3, 1 February 2023. Available from https://apps.who.int/gb/inb/pdf_files/inb4/A_INB4_3-en.pdf.

12 *ibid.*, article 10.

13 *ibid.*

14 *ibid.*

commitment by countries with manufacturing facilities to facilitate the shipment of pandemic related products to the WHO.¹⁵ There was no mention of any other non-monetary or monetary benefit-sharing.

The fourth session of the INB agreed to a proposal by the Bureau to undertake a first reading of the zero draft and thereafter undertake sequential discussions on each chapter in a drafting group composed of member States only, where textual suggestions could be made. It was also agreed to continue with this process at the fifth session of the INB. The meeting concluded with the insertion of textual language in the zero draft from interventions by member States. The INB also agreed that member States could submit written proposals reflecting the suggestions made at the fourth (INB 4) and fifth (INB 5) sessions by 14 April 2023. It was also agreed that the INB would organize informal intersessional work between INB4 and INB5, including on chapter 3 of the zero draft which contains the provisions on the PABS system.

The fifth session of the INB agreed on a process for advancing the discussions. The INB agreed that a compilation reflecting all inputs received during INB 4 and INB 5 as well as written textual proposals and a Bureau's text including options where feasible based on all submissions received and included in the compilation document, will be distributed to facilitate the work of the INB drafting group, on the continued understanding that nothing is agreed until everything is agreed. Thus, it was unclear going into the resumed fifth session of the INB in June 2023 whether the zero draft, the compilation text or the Bureau's text would be the basis of further work.¹⁶ This situation generated uncertainty, inter alia, on the scope and elements of the proposed PABS system.

III. Textual Suggestions on PABS from Developing Countries

The critical challenge in establishing an ABS system is to ensure that it is effective in binding recipients of biological material such as pathogens and its genetic sequence data to obligations on benefit-sharing. The sharing of biological material takes place with pharmaceutical companies or research institutions based on an agreement called a 'material transfer agreement'. This agreement is a legally binding contract between the entities providing the biological material and the entities receiving the same. An international legal instrument on ABS may establish standardized terms of this contract known as the 'standard material transfer agreement' (SMTA). The terms of the SMTA can also include benefit-sharing commitments.

For example, under the WHO PIP Framework, the SMTA requires recipients of biological material from the WHO that manufacture vaccines or antivirals to commit to at least two of the following benefit-sharing commitments: 1) donate at least 10% of real-time pandemic vaccine production to WHO; 2) reserve at least 10% of real-time pandemic vaccine production at affordable prices to WHO; 3) donate at least X treatment courses of needed antiviral medicine

¹⁵ *ibid.*
¹⁶ Viviana Munoz Tellez, "Assessing the State of Play in the WHO Pandemic Instrument Negotiations", Policy Brief No.121, 18 July 2023, South Centre, Geneva. Available from https://www.southcentre.int/wp-content/uploads/2023/07/PB121_Assessing-the-State-of-Play-in-the-WHO-Pandemic-Instrument-Negotiations_EN.pdf.

for the pandemic to WHO; 4) reserve at least X treatment courses of needed antiviral medicine for the pandemic at affordable prices; 5) grant licenses to developing countries on fair and reasonable terms on technology, know-how, products and processes for which it holds the intellectual property right for the production of influenza vaccines, adjuvants, antivirals and diagnostics; 5) grant royalty-free licenses to manufacturers in developing countries and the WHO on IP which can be sub-licensed.¹⁷

It will be important to ensure the benefit-sharing obligations under the PABS system are appropriately defined. Benefit-sharing should not be limited only to assured access to products made by utilizing accessed pathogens, but also include monetary contributions by recipients with whom pathogens are shared. Such monetary contributions can be used for improving preparedness and response capacities of developing countries.

To this end, several developing countries including Argentina, Brazil, Bangladesh, India, Indonesia, Malaysia, Costa Rica, Pakistan, Namibia, South Africa and the Africa Group submitted proposals on the zero draft.

The key elements of the textual suggestions from these countries on the proposed PABS system under the WHO CA+ are the following:

- WHO must have the obligation to ensure the full application of the PABS system to all WHO member States with respect to access to pathogens with human pandemic potential including genomic sequence data and fair and equitable sharing of benefits arising therefrom.
- The PIP Framework should operate synergistically with the PABS system
- The PABS system in its entirety shall apply to pathogens that have the potential to cause a public health emergency of international concern (PHEIC) under the International Health Regulations
- The scope of the PABS System may be extended to include other pathogens and their genomic sequence data currently being shared by Members, with additional fair and equitable benefit sharing commitments including appropriate amendments to the SMTAs
- The production of vaccines, diagnostics, therapeutics and other medical products for public health emergency of international concern and pandemic, irrespective of the technology, information or material used, implies the use of pathogens with human pandemic potential including genomic sequence data
- PABS materials should be specifically defined to include all pathogens of human pandemic potential, whether wild-type or modified, including their biological materials and parts of such material, and their genomic sequence and associated data

¹⁷ WHO, Pandemic Influenza Preparedness Framework: Standard Material Transfer Agreement 2 (SMTA 2), article 4. Available from https://cdn.who.int/media/docs/default-source/pip-framework/smta2/smta2-eng.pdf?sfvrsn=4d4f593d_2.

- Definition of other relevant terms like genetic sequence data, authorized national laboratories, qualified entities and WHO Coordinated Laboratory Network
- Obligation on the WHO Director General to apply the PABS system including SMTAs with respect to any sharing of PABS materials by any WHO member State through its authorized national laboratories.
- Establishment of a WHO Coordinated Laboratory Network of authorized national laboratories to achieve the objectives of the PABS system.
- Authorizing WHO DG to recognize specific authorized national laboratories in the WHO network as WHO Collaborating Centre for a region or sub-region based on balanced representation between developed countries and developing countries.
- Responsibility on WHO DG to ensure that each region and sub-region has sufficient capacity and facilities to undertake thorough risk assessment and response activities as set out in the Terms of Reference of the WHO Coordinated Laboratory Network including inter-laboratory sharing of outcomes arising from utilization of PABS materials.
- Sharing PABS Materials with other laboratories within the WHO Coordinated Laboratory Network will imply the consent of the provider member State for the onward transfer and use of PABS Materials to Qualified Entities (e.g., manufacturers of vaccines, diagnostics and therapeutics) that have signed SMTA with WHO.
- WHO shall be responsible to facilitate the funds required to cover the costs related to shipment of PABS Materials to and within the WHO Coordinated Laboratory Network.
- All transfers of PABS Materials by an authorized national laboratory to another authorized national laboratory of its choice, and further transfers within the WHO Coordinated Laboratory Network shall be subject to the provisions of an SMTA (SMTA 1).
- Qualified entities outside the WHO Coordinated Laboratory Network can receive and use PABS materials subject to another SMTA (SMTA 2).
- Any entity using or benefitting from the PABS System shall make an annual monetary contribution to WHO for improving preparedness and response of public health emergency of international concern and pandemic.
- WHO DG will propose to the Executive Board which proportion of contributions should be used for inter-PHEIC/pandemic preparedness measures, and which proportion should be reserved for response.
- WHO DG shall put in place a transparent traceability mechanism that uses an electronic system to track in real time the movement of PABS materials into, within and out of the WHO Coordinated Laboratory Network.
- Establishment of a WHO PABS Sequence Database with obligations on member States to take necessary measures to ensure that genomic sequence data within the scope of the PABS System are shared through the WHO PABS Sequence Database. Any sharing of genomic sequence data by laboratories within WHO Coordinated Laboratory Network shall be through the WHO PABS Sequence Database.
- Laboratories within the WHO Coordinated Laboratory Network shall not transfer genomic sequence data to entities outside the WHO Coordinated Laboratory Network unless the entity is a Qualified Entity and has signed SMTA2.
- Prohibition on laboratories within the WHO Coordinated Laboratory Network from uploading the genomic sequence data to any other databases.
- Access to the WHO PABS Sequence Database to registered users with verified institutional accounts from institutions registered with the WHO. Such access shall be subject to a click wrap Data Access Agreement and other specific terms and conditions.
- Other Databases may link with WHO PABS Sequence Database subject to terms and conditions of Data Access Agreement with WHO PABS Sequence Database.
- Implementation of the PABS system to be overseen by the World Health Assembly with advice from the WHO DG. An independent PABS Advisory Group established to monitor and provide guidance on the functioning of the PABS system. DG to report to the WHA on status of implementation of PABS system, particularly monetary contributions and SMTA1 and SMTA2.
- Transparency obligations on WHO to make publicly available list of registered users of WHO PABS Sequence Database, monetary contributions received from users of PABS system, SMTA2s concluded with qualified entities.
- WHO activities including WHO Hub for Pandemic and Epidemic Intelligence, WHO BioHub System to be governed by the PABS system.
- Member States shall consider measures for recognition of the PABS System as a specialized international instrument within the meaning of the Nagoya Protocol, five years after the PABS System including its WHO PABS Sequence Database and benefit sharing becomes operational.
- Obligations on member States to ensure the fair, transparent, equitable, effective and efficient operationalization and functioning of the PABS System including its various components in good faith.
- Obligation on member States to ensure the compliance of non-state actors with the components of the PABS System.

- Obligation on member States to urgently facilitate the immediate shipment to WHO of products that Qualified Entities have committed to supply under SMTA2 during a public health emergency of international concern or a pandemic.

IV. PABS in INB Bureau's Text

Following the textual proposals from member States, the fifth meeting of the INB was resumed as agreed at the end of the June 2023 session of the INB drafting committee. Before the meeting, the Bureau invited member States "... to ensure that relevant ideas and concepts are addressed in the Bureau's text, rather than suggesting detailed revisions of wording."¹⁸ However, the Bureau's text¹⁹ excluded several critical textual proposals from developing countries, including proposals relating to the PABS system.

The Bureau's text presented two options on ABS under article 12 of the text. Under the first option in article 12 A, Parties recognize the requirement of sharing of pathogens, GSD and the benefits arising from their utilization and agree to establish a system or systems for sharing of those benefits. This option merely provides an in-principle recognition of the need for one or multiple PABS systems but postpones the discussions on their establishment to future negotiations. However, there are other provisions in the Bureau's text on sharing of pathogens and GSD, which could continue to operate in the absence of the PABS system or while it is under development.

This option delinks pathogen access from benefit-sharing. Option 12A (2) states that "Recognizing that biological materials-sharing and multilateral benefit-sharing are equally important parts of the collective action for global public health, the Parties are mindful that the system(s) could be structured as either a unified system or two mutually supportive systems, and all or parts thereof could be adopted under Article 21 of the WHO Constitution, should such an approach be agreed (emphasis added)." Thus, it conceives of potentially separate systems for pathogen access and benefit-sharing operating as 'mutually supportive systems'. It also leaves scope for the envisaged systems to be adopted under separate instruments under article 19 and article 21 of the WHO Constitution.

It will be critical for developing countries to ensure that both pathogen access and benefit sharing are part of a single mechanism anchored under the same instrument. If a benefit-sharing mechanism is adopted under the WHO CA+ under an article 19 approach but obligations on pathogen sharing are adopted under an article 21 opt out instrument, the mechanism will ultimately only create binding obligations on pathogen sharing. This would be completely contrary to the needs and expectations of developing countries regarding benefit-sharing.

The second option in article 12B of the Bureau's text places "... sharing of pathogens with pandemic potential, including their genomic sequences, components and related information ..." on an

equal footing with sharing of monetary and non-monetary benefits arising from their utilization, including access to pandemic related products. However, this option also includes the possibility of either a unified PABS system or two mutually supportive systems. This option also defers further development of the details of the PABS system to the future.

Though the details of the PABS system under the second option are deferred to future negotiations, article 12B(5) lays down specific binding obligations on biological materials sharing.

The second option in the Bureau's text also states that "Recipients of materials shall not claim any intellectual property or other rights in respect of the pathogens with pandemic potential, or their genomic sequences, components or related information." This is of limited value because it does not prevent recipients of biological material or their genomic sequence information from claiming intellectual property on products derived from utilization of the accessed material or sequence information.

Both options in the Bureau's text also states that the Parties agree to both monetary and non-monetary benefit sharing. However, there is no further elaboration on specific aspects of monetary benefit-sharing, even though some developing country proposals have elaborated on this aspect.

The second option in the Bureau's text also presents three options for non-monetary benefit-sharing: 1) a real-time obligation on the manufacturers to share 20% of doses with WHO for further distribution through the WHO Allocation Mechanism to developing countries in particular; 2) obligation on Parties to include in government-funded procurement or purchase agreements certain options such as delivery swaps, donation of doses, incentivization or promotion of production through subcontracting or licensing, encouragement for formulation and sharing of global access plans; and 3) upon declaration of a pandemic obligation on parties in a position to do so to make all possible efforts to donate pandemic-related products to countries in need, without prejudice to the possibility for the parties to organize direct donations to countries in need. In case pandemic-related products are in short supply parties would also have the obligation to ensure the product manufacturers reserve a certain percentage of their production of such products on a quarterly basis for sales to LDCs and developing countries.

The first option regarding non-monetary benefits is based on the text in the zero draft. The second and third options are more aligned to textual proposals from the European Union. They place the obligations for benefit-sharing on States parties and not manufacturers who had access and utilized the pathogen material and sequence information from the PABS system.

In sum, the second option of the Bureau's text ignored proposals from developing countries, including detailed texts of SMTAs and the proposed WHO Sequence Database for access to pathogen genetic sequence data and associated information.

¹⁸ Nithin Ramakrishnan and K.M. Gopakumar, "WHO: INB Bureau proposes comments on pandemic instrument text, not textual proposals", TWN Info Service on Health Issues (Jun23/01), 12 June 2023, Third World Network. Available from <https://www.twon.my/title2/health.info/2023/hi230601.htm>.

¹⁹ WHO document, AA/INB/5/6, 2 June 2023. Available from https://apps.who.int/gb/inb/pdf_files/inb5/A_INB5_6-en.pdf.

V. Discussions on PABS since Resumed INB5

The resumed INB5 session concluded without a consensus to initiate textual negotiations on the Bureau's text. The INB only agreed to consider the Bureau's text as a basis for further work on the understanding that the INB may continue to refer to the compilation text. Several developing countries indicated the necessity to include different textual proposals made by Member States on the zero draft. The INB agreed to hold informal intersessional meetings to make progress in building consensus among the different proposals, including on article 12 on PABS.

However, no substantial progress was achieved through the informal intersessional meetings leading up to the sixth session of the INB in July 2023. Discussions continued at INB 6 on the Bureau's text. No formal discussion took place on PABS in this meeting, but it was proposed to continue informal drafting group discussions on challenging topics, including article 12. The INB6 decided to continue with the informal process. The informal meetings on article 12 were co-facilitated by Australia and Ethiopia.

The reports of the informal meetings were presented to the drafting group meeting of the INB in September 2023. The drafting group decided that the INB Bureau will develop and circulate to the INB for its consideration a proposal for a negotiating text of the WHO CA+ before the seventh meeting of the INB to be held in November 2023. The proposal for the negotiating text should be based on the discussions of the INB at its fourth, fifth and sixth sessions as well as the meeting of the drafting group, including its informal consultations and the reports of the co-facilitators of those consultations.

VI. PABS in Bureau Proposal for a Draft Negotiating Text

As agreed in the drafting group meeting, the Bureau prepared a draft negotiating text for the seventh session of the INB in November and December 2023. The INB must consider the text and decide on whether this text can be the basis for negotiations to commence. At the date of writing this paper, the INB has not agreed to do so.

Article 12 of the Draft Negotiating Text is reproduced below.

Article 12: Access and benefit-sharing

1. The Parties hereby establish a multilateral system for access and benefit sharing, on an equal footing, the WHO Pathogen Access and Benefit-Sharing System (WHO PABS System), to ensure rapid and timely risk assessment and facilitate rapid and timely development of, and equitable access to pandemic-related products for pandemic prevention, preparedness and response.

2. The WHO PABS System shall ensure rapid, systematic, and timely sharing of WHO PABS Material, as well as, on an equal footing, timely, effective, predictable and equitable access to pan-

demic-related products, and other benefits, both monetary and non-monetary, based on public health risks and needs, to strengthen pandemic prevention, preparedness and response.

3. The Parties shall implement the WHO PABS System:

(a) in a manner to strengthen, expedite and not impede research and innovation

(b) at all times, both during and between pandemics;

(c) in a manner to ensure mutual complementarity with the PIP Framework; and

(d) with governance and review mechanisms, to be determined by the Conference of the Parties.

4. The WHO PABS System shall have the following components:

(a) WHO PABS Materials sharing:

i. Each Party, through its relevant public health authorities and authorized laboratories, shall, in a rapid, systematic and timely manner: (1) provide WHO PABS Material to a laboratory recognized or designated as part of an established WHO coordinated laboratory network; and (2) upload the genetic sequence of such WHO PABS Material to one or more publicly accessible database(s) of its choice, provided that the database has put in place an appropriate arrangement with respect to WHO PABS material.

ii. The WHO PABS System shall be consistent with international legal frameworks, notably those for the collection of patient specimens, material and data, and will promote findable, accessible, interoperable and reusable data available to all Parties.

iii. The Parties shall develop and use a standard material transfer agreement (a PABS SMTA), which may be concluded through electronic means, and which shall include relevant biosafety and biosecurity rules, to be used with the transfer of WHO PABS Material from a laboratory recognized or designated as part of an established WHO coordinated laboratory network to any Recipient.

iv. Recipients of WHO PABS Material shall not seek to obtain any intellectual rights on WHO PABS Material.

(b) PABS multilateral benefit-sharing:

i. Benefits, both monetary and non-monetary, arising from access to WHO PABS Materials, shall be shared fairly and equitably, pursuant to a PABS SMTA, which may be concluded through electronic means.

ii. The PABS SMTAs shall include, but not be limited to, the following monetary and non-monetary benefit-sharing obligations:

1. in the event of a pandemic, real-time access by WHO to a minimum of 20% (10% as a donation and 10% at affordable prices

to WHO) of the production of safe, efficacious and effective pandemic-related products for distribution based on public health risk and need, with the understanding that each Party which has manufacturing facilities that produce pandemic-related products in its jurisdiction shall take all necessary steps to facilitate the export of such pandemic-related products, in accordance with timetables to be agreed between WHO and manufacturers; and

2. on an annual basis, contributions from Recipients, based on their nature and capacity, to the capacity development fund of the sustainable funding mechanism established in Article 20.

(c) The Parties shall also consider additional benefit-sharing options, including:

i. encouragement of manufacturers from developed countries to collaborate with manufacturers from developing countries through WHO initiatives to transfer technology and know-how and strengthen capacities for the timely scale-up of production of pandemic-related products;

ii. tiered-pricing or other cost-related arrangements such as no loss/no profit arrangements, for purchase of pandemic-related products, that consider the income level of countries; and

iii. encouragement of laboratories in the WHO coordinated laboratory network to actively seek the participation of scientists from developing countries in scientific projects associated with research on WHO PABS Materials.

5. In the event that pandemic-related products are produced by a manufacturer that does not have a PABS SMTA under the WHO PABS System, it shall be understood that the production of pandemic-related products requiring the use of WHO PABS Materials, implies the use of the WHO PABS System. Accordingly, each Party, with respect to such a manufacturer operating within its jurisdiction, shall take all appropriate steps, in accordance with its relevant laws and circumstances, to require such a manufacturer to provide benefits in accordance with paragraph 4(b)(ii) of this Article.

6. The Parties shall develop a mechanism to ensure the fair and equitable allocation of pandemic-related products, based on public health risks and needs.

7. The Parties shall ensure that all components of the WHO PABS System are operational no later than 31 May 2025. The Parties shall review the operation and functioning of the WHO PABS System every five years.

8. The Parties shall ensure that such system is consistent with, supportive of, and does not run counter to, the objectives of the Convention on Biological Diversity and the Nagoya Protocol thereto. The WHO PABS System will provide certainty and legal clarity to the providers and users of WHO PABS Materials. The WHO PABS System shall be recognized as a specialized international access and benefit sharing instrument within the meaning of Article 4(4) of the Nagoya Protocol.

Article 12 of the proposed new draft negotiating text places access and benefit-sharing on an equal footing. However, it still lacks specific provisions on obligations under the SMTA which should govern the transfer of PABS material under the system. The new draft text also refers to only one SMTA between a laboratory recognized or designated as part of the WHO coordinated laboratory network and a recipient. There is no reference to any SMTA on the transfer of PABS material from a national public health authority or authorized laboratory to a laboratory under the WHO coordinated laboratory network.

The new draft negotiating text also provides a definition of terms relevant to the PABS system in article 1 – recipient (of WHO PABS material), WHO coordinated laboratory network, and WHO PABS material. These definitions to some extent reflect textual proposals made by developing countries on the zero draft. For example, the definition of WHO PABS material includes genetic sequence data of pathogens with pandemic potential, as proposed by developing countries.

However, the new draft negotiating text continues to defer full implementation of the PABS system to the future. Article 12(7) states that “The Parties shall ensure that all components of the WHO PABS System are operational no later than 31 May 2025.” This would imply that the PABS system will not be negotiated alongside the WHO CA+ but at a later stage. This could lead to loss of negotiating leverage for developing countries on one of their most key demands.

Article 12(4) also requires parties to upload the genomic sequence information of PABS material to one or more publicly accessible databases, provided that the database has put in place an appropriate arrangement with respect to WHO PABS material. This approach towards sharing of genomic sequence information of PABS material is contrary to what has been proposed by developing countries – establishment of a WHO Sequence Database with access to recipients with verified institutional accounts and subject to a click wrap data access agreement, with the possibility of other databases obtaining access through the WHO database for their verified institutional user accounts on the terms of the WHO data access agreement. It is also unclear in the draft provision what will be an appropriate arrangement between the country providing the genomic sequence information and the public database where this information is uploaded. Will this be governed by SMTA or a data access and use agreement? What will be the role of the WHO vis a vis public databases getting access to the sequence information on PABS material?

The provisions under article 12(4)(b) (ii) on benefit-sharing are also weak. First, it conditions real-time access to 20% of the pandemic-related products to the WHO “in the event of a pandemic.” This seems to exclude the possibility of real-time access to such products before a pandemic outbreak through stockpiling of such products by the WHO. Second, only half of such products are to be given to WHO as a donation, the other half is to be purchased by the WHO at an affordable price. Given, the limited financial resources at the disposal of the WHO, this may become a significant

challenge for the WHO.²⁰

Thus, the new draft negotiating text on PABS in article 12 needs to be substantially improved and further clarified to reflect the interests of developing countries as expressed in the text proposals submitted by them on the zero draft.

VII. Proposals by Developing Countries at INB7

At INB7 developing countries submitted textual suggestions on the draft article 12 and related definitions under draft article 1. Through these proposals developing countries have re-introduced various elements of the PABS system that they had proposed in their textual suggestions on the zero draft.

These include new definitions of “authorized national laboratories”, and “genetic sequence data.” The definition of “pandemic-related products” is proposed to be expanded to clarify that “All products used for addressing public health emergencies of international concern are presumed as pandemic-related products regardless of the pandemic potential of such emergencies.” The definition of “recipient” of PABS material is also proposed to be clarified. It is also proposed that to be part of the WHO coordinated laboratory network an authorized national laboratory must meet the criteria for being so designated and also agree to comply with an SMTA applicable between providing and recipient laboratories in the WHO network. It is further proposed to modify the definition of “PABS material” to clarify that it includes both wild type as well as modified pathogens, as well as their biological materials and parts thereof, clinical specimens, as well as their genetic sequence data and associated meta data and clinical data.

The following changes are proposed in draft article 12: 1) article 12.1 should specify that the PABS system shall be transparent; 2) article 12.2 is redrafted to propose that the objective of the PABS system is to strengthen pandemic prevention, preparedness and response through rapid sharing of PABS material as well rapid, effective and equitable access to pandemic related products and other monetary and non-monetary benefits. Language conditioning benefit-sharing on the basis of a public health needs and risks assessment is proposed to be deleted. A new clause is proposed to make the PABS system applicable to pathogens that have the potential to cause a public health emergency of international concern under the IHR. The proposal also accords responsibility on the WHO secretariat for the implementation of the PABS system, in contrast to the obligation of implementation of the PABS system placed on parties to the WHO CA+ in the draft negotiating text proposed by the Bureau of the INB. Accordingly, the WHO Director-General is mandated to take all necessary measures to apply, implement and operationalize all aspects of the PABS system simultaneously, in a manner to strengthen, expedite and not impede research, innovation and fair and equitable distribution of benefits. The reference to fair and equitable distribution of benefits is proposed as new language to be added to article 12 (3) (a). This is appropriate as it introduces a balance between the objective of strengthening and expediting research using the PABS system and ensuring fair and equitable

²⁰ Sangeeta Shashikant, “WHO: Pandemic Access & Benefit Sharing System in Proposed Text Flawed”, TWN Info Service on Health Issues (NOV23/03), 5 November 2023, Third World Network. Available from <https://www.twn.my/title2/health.info/2023/hi231103.htm>.

benefit-sharing arising from the utilisation of the PABS system. In article 12(3) (c) additional language is proposed to clarify that while the WHO must ensure the complementarity of the PABS system with the PIP Framework, the scope of the PIP Framework is limited to influenza virus of pandemic potential. Moreover, it is proposed that the WHO must ensure that the PABS system is applied in all situations where the sharing of biological material including genetic sequence data of pathogens of pandemic or PHEIC potential takes place with the involvement of the WHO. This is important as this would ensure that the PABS system is also applicable to all WHO initiatives and partnerships relating to sharing of pathogens, such as the BioHub.

The proposal also suggests three components that should constitute the PABS system: 1) the WCLN, 2) SMTAs, and 3) a WHO PABS Sequence Database. It is notable that these components were also proposed by developing countries in their textual suggestions on the zero draft but have not been adequately reflected in the Bureau’s texts, including the proposed draft negotiating text. In fact, the new draft negotiating text does not mention any WHO sequence database and only refers to publicly accessible databases.

With regard to the WCLN, the proposal seeks to ensure that the WHO DG is mandated to establish the WCLN by linking authorized national laboratories designated by a party to provide PABS material to the PABS system. This means that PABS material can be shared only through authorized national laboratories with other laboratories in the WCLN. The WCLN laboratories can then share the PABS material outside the WCLN with recipient entities such as research laboratories. The proposed textual suggestions also make the WHO responsible for facilitating the funds required for the shipment of PABS material to WCLN laboratories by a developing country party. The WHO is also responsible for ensuring that each region and sub-region has sufficient capacities to undertake risk assessment and response activities, including inter-laboratory sharing of outcomes arising from utilization of PABS materials.

Developing countries have also proposed that the PABS system should have two types of SMTAs: 1) SMTA 1 relating to all transfer of PABS material from an authorized national laboratory to the WCLN and further transfers within WCLN, and 2) SMTA 2 between the WHO and recipient entities for onward transfer of PABS material from a laboratory in the WCLN to those recipient entities. The terms of SMTA 1 (to be annexed to the WHO CA+) include obligations on the provider and the recipient to inform the WHO of any transfer of PABS material to entity inside or outside the WCLN by recording the same in a PABS tracking mechanism. The recipient is also required to actively seek the participation of scientists from the originating laboratory of the PABS material, especially from developing countries, to the fullest extent possible, in scientific projects associated with research on the PABS material and actively engage them in preparation of manuscripts for presentations and publications. The recipient is further under the obligation to appropriately acknowledge in their presentations and publications the contributions of collaborators, in particular laboratories and countries providing PABS materials.

The proposed SMTA 2 requires the recipient to keep the WHO in-

formed of all uses of PABS material and pay the required monetary contributions for using the PABS system in a timely manner. In the event of a PHEIC or a pandemic, the recipient has to donate to the WHO at least 20 per cent of its real-time production of each pandemic-related product manufactured, for distribution by the WHO based on public health risk and need (a related obligation on parties to facilitate the immediate shipment of t; supply vaccines, therapeutics, diagnostics and other pandemic-related products at affordable prices to developing countries (marginal cost per unit plus 10% profit and “no profit, no loss” basis for least developed countries), and to comply with any allocation plan recommended by WHO; grant to WHO royalty-free non-exclusive licenses on standard terms and conditions to use its intellectual property, other protected technology and know-how used in the process of product development and manufacturing of pandemic related products, which the WHO shall sub-license on standard terms and conditions to manufacturers, especially in developing countries; share with the sub-licensees of the WHO, on request by the WHO, the complete regulatory dossier include the full technical knowhow and any material needed for development and production such as cell lines, hybridomas, plasmids, yeasts, or mammalian cells with sublicensees of the WHO. Furthermore, prior to the declaration of a PHEIC, the recipient is also required to share a part of its real-time production to address access needs in developing countries, including for purposes of a WHO stockpile, upon the recommendation of the WHO Director-General in consultation with the affected countries and the Emergency Committee (established under IHR). Any affected country may also request the Director-General to make such a recommendation.

The proposed SMTA 2 also requires that a recipient entity can further transfer PABS material to a third party only if the third party has concluded an SMTA with the WHO. The recipient will be required to report any such transfer to the WHO. Moreover, the recipient entity will be responsible for the compliance of all obligations with respect to PABS material that is transferred by it to third parties under a contract. The recipient entity also has to ensure that the PABS materials are not used by third parties for research, development or production, other than as directed by the recipient entity and that the PABS materials are returned to the recipient entity or destroyed at the end of their utilization in accordance with appropriate biosafety standards.

In both SMTA 1 and SMTA 2 it is proposed that any WCLN laboratory or any recipient that receives PABS material shall not seek or assert any intellectual property rights on the PABS material or parts thereof in any form, including any modified form or any use of the same.

It is also proposed that access to and use of genetic sequence data shall be subject to standard terms and conditions under a click-wrap data access agreement or database agreement, as applicable.

Further, it is proposed that any sharing of genetic sequence data within the WCLN laboratories and further sharing of such data by WCLN laboratories shall be through a “WHO PABS Sequence Database” consistent with its requirements and subject to the SMTAs. The WHO PABS Sequence Database is envisaged as a database

providing access to registered users with verified institutional accounts, which are users supported by an institution that have registered with the WHO, and whose credentials have been verified by WHO. It is proposed that the click-wrap data access agreement should include the following terms and conditions annexed to the WHO CA+:

- 1) Accessed data from the WHO PABS Sequence Database shall be used only for individual purpose and shall not be distributed to any third party that is not a registered user of the WHO PABS Sequence Database;
- 2) The data may not be used in any activity that may lead to the development or production of biological agents, toxins, weapons, equipment or means of delivery specified in the Biological Weapons Convention;
- 3) Prohibition on users from seeking or asserting any IP right over accessed genetic sequence data or any parts thereof, in any form including any modified form, or for any use;
- 4) The user has to pay the monetary contributions for using the PABS system in a timely manner;
- 5) Where the user is a recipient entity it agrees to be bound by the terms of SMTA 2;
- 6) The user shall actively seek the participation of scientists from the originating laboratory of the PABS material, especially from developing countries, to the fullest extent possible, in scientific projects associated with research on the genetic sequence data and actively engage them in preparation of manuscripts for presentations and publications;
- 7) The user shall appropriately acknowledge in their presentations and publications the contributions of collaborators, in particular laboratories and countries providing PABS materials;
- 8) Any user engaged in “Gain of function” research or any other research that genetically alters an organism in a way that may enhance its biological characteristics or functions shall inform and regularly update the WHO about the outcomes of the research and comply with any conditions imposed by the WHO to safeguard public health.

Other databases may link with the WHO PABS Sequence Database subject to a Database Access Agreement between the WHO and other databases. This agreement is proposed to include the following terms and conditions: access to be provided only to users with verified institutional accounts; the databases shall regularly provide the list of their registered users with contact details to the WHO; the database shall inform its users that access to the genetic sequence data from the WHO PABS Sequence Database is subject to the terms of the PABS Sequence Database and the Database Access Agreement.

In terms of governance of the PABS system, developing countries have proposed that implementation of the PABS system should be

overseen by the World Health Assembly through a PABS Advisory Committee.

VIII. Conclusion

As part of the implementation 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, an international treaty that has been ratified by most WHO member States, countries can regulate access to pathogen samples. Though the Nagoya Protocol follows a bilateral approach wherein the terms of access to genetic resources and sharing of benefits arising from their utilization are based on mutually agreed terms between the provider country and the recipient, the Nagoya Protocol allows parties to adopt and implement other international agreements that are supportive of and do not run counter to the objectives of the CBD and Nagoya Protocol. Hence, member States of the WHO can establish a multilateral ABS system in the form of a PABS system. An effective multilateral PABS system can provide legal certainty against unfair exploitation of pathogen material and their sequence information and also enable consolidation of the benefits received at the multilateral level to support countries in pandemic preparedness and response.²¹

Thus, developing countries have been unequivocal in expressing that the negotiations for a pandemic treaty include a comprehensive access and benefit-sharing mechanism for all pathogens of

²¹ Sangeeta Shashikant, "Access and Benefit-Sharing System: A Key to Operationalize Equity for Pandemic Preparedness & Response", *Geneva Health Files*, Newsletter Edition #58, 6 December 2023. Available from <https://genevahealthfiles.substack.com/p/pathogen-access-benefit-sharing-pip-twn-inb-ihf>.

pandemic potential, placing access and benefit-sharing on an equal footing. In the different versions of the draft WHO CA+ from the conceptual zero draft to the proposed draft negotiating text, there appears to be consensus on the need to establish a PABS system. However, there continues to be substantial difference of views between developed and developing countries on the prioritization of establishing the PABS system as an outcome of the INB negotiations and on the specific obligations in respect of the terms of standard material transfer agreement governing access to pathogen material and their genomic sequence information, and the benefit-sharing obligations. For the developed countries rapid access to pathogen material and genetic sequence information under a specialized instrument outside the Nagoya Protocol is the primary motivation for a WHO PABS system. This is reflected in the fact that all versions of the draft texts on PABS have specific obligations on pathogen sharing to facilitate rapid access to pathogens while provisions on benefit-sharing have been either deferred to future negotiations or are weak.

It will be critical for developing countries to ensure that an effective PABS system with detailed provisions on SMTA, data access relating to their genomic sequence information and specific obligations on monetary and non-monetary benefit-sharing by recipients of pathogen material and sequence information are part of the outcome of the INB negotiations. These matters should not be deferred to future negotiations after the WHO CA+ is adopted. To this end, it is critical that the new proposed draft negotiating text on the PABS system is revised to reflect the proposals made by developing countries at the INB7 and future INB sessions.

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