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WHAT ARE THE OPTIONS? PATHOGEN-, GSD- AND BENEFIT- SHARING IN AN INTERNATIONAL INSTRUMENT

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List of abbreviations

ABS	Access and Benefit Sharing
BMEPP	Biological Material with Epidemic or Pandemic Potential
CBD	Convention on Biological Diversity
CIOMS	Council for International Organizations of Medical Sciences
CoP	Conference of Parties
DDBJ	DNA Data Bank of Japan
DSI	Digital Sequence Information
EU	European Union
GISRS	Global Influenza Surveillance and Response System
GLASS	Global Antimicrobial Resistance and Use Surveillance System
GSD	Genomic Sequencing Data
IHR	International Health Regulations
INSDC	International Nucleotide Sequence Database Collaboration
IP	Intellectual Property
IVTM	Influenza Virus Traceability Mechanism
IVPPs	Influenza Viruses of Pandemic Potential
MAT	Mutually Agreed Terms
MERS	Middle East Respiratory Syndrome
MTA	Material Transfer Agreement
NCBI	US National Center for Biotechnology Information
NP	Nagoya Protocol
PBS	Pathogen and Benefit Sharing
PIC	Prior Informed Consent
PIP Framework	Pandemic Influenza Preparedness Framework
PPR	Pandemic Prevention, Preparedness and Response
SII	Specialised international access and benefit-sharing (ABS) instrument
SMTA	Standard Material Transfer Agreement
TOR	Terms of Reference
WHA	World Health Assembly

I. INTRODUCTION

The COVID-19 pandemic has highlighted the importance of rapid, reliable, fair and equitable international sharing of pathogen samples, genomic sequencing data (GSD) and related benefits. For brevity, we refer to this set of issues as pathogen- and benefit- sharing (PBS) throughout this paper. Ideally, such sharing would be transparent, rapid and systematic, and would strengthen capacities for surveillance, understanding of pathogens, the development of medical countermeasures, and ensure equitable access to such countermeasures – including vaccines, diagnostics and therapeutics. However, the global governance of PBS is currently an incomplete and complex patchwork of arrangements that is inadequate for meeting these objectives.

Developing a more equitable, predictable global system for PBS, agreed by WHO Member States and relevant stakeholders, is fundamental for pandemic prevention, preparedness and response (PPR). Predictability and equity have become important concerns in the ongoing negotiation of a pandemic instrument and in the process to amend the International Health Regulations (IHR) (2005). (For brevity, we refer to these two processes jointly as those towards an "international instrument," as it has not yet been decided whether one or both instruments will address PBS. We also generally use "Member States" rather than "States Parties" to refer to states that may agree to PBS obligations in an international instrument.)

PBS is one of the most technically, legally and politically complex issues on the table. In light of this complexity, this paper seeks to clarify the debate by laying out a range of options to govern PBS. The paper describes existing arrangements that could be expanded upon, summarises the already agreed language on principles and commitments from existing legal texts and extrapolates from these to sketch the contours of a potential multi-component ecosystem for PBS governance.

II. BACKGROUND: THE GLOBAL GOVERNANCE OF PBS

A. WHAT IS PBS?

In day-to-day practice, scientists, laboratories, governments and industry regularly share pathogen samples and GSD with each other for purposes of research, development and the production of medical countermeasures. However, since the mid-2000s, cross-border outbreaks of emerging infectious disease have been followed by controversies around PBS. Such controversies emerged roughly in parallel with the negotiation of the "Nagoya Protocol" (see below) and the conditions of access and benefit- sharing with regard to biological and genetic resources. Indonesia temporarily suspended international sharing of samples of H5N1 Influenza in 2007 due to concerns over accessing vaccines developed from their use, citing the Convention on Biological Diversity's (CBD) principle of sovereignty over biological resources. This decision prompted the negotiation of the Pandemic Influenza Preparedness Framework (PIP Framework) adopted by the World Health Assembly (WHA) in 2011.[1] Hailed as a "milestone in global health governance"[2], the PIP Framework established a system that places fair and equitable benefit-sharing on equal footing with rapid and timely access to Influenza Viruses of Pandemic Potential (IVPPs). The PIP Framework remains the only multilaterally-negotiated framework designed to govern PBS to date. Since 2011, controversies in the global flow of pathogen samples re-appeared with Middle East Respiratory Syndrome (MERS) in 2013[3], Zika in 2015–16 and Ebola in 2014–16.[4] In all such cases, concerns have been raised either over the interrupted sharing of pathogen samples and/or over the inequitable sharing of benefits. In a climate of growing uncertainty, periodic calls have been made to strengthen PBS governance in general and during cross-border outbreaks in particular.

B. APPLICABLE INTERNATIONAL FRAMEWORKS

1. THE INTERNATIONAL HEALTH REGULATIONS (2005)

The IHR (2005) do not explicitly require State Parties to share pathogen samples or GSD during outbreaks. Article 6.2[5] of the IHR (2005) only requires that parties communicate "timely, accurate and sufficiently detailed public health information" on notifiable events to WHO. Nevertheless, pathogen-sharing has been, for the most part, standard practice among parties to the IHR (2005) within the spirit of international collaboration on surveillance and response. A proposal has been made to specify an explicit requirement to share GSD in the on-going process to amend the IHR.[6]

1 World Health Organization, "Pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits." 2011, [Online]. Available: https://apps.who.int/iris/bitstream/handle/10665/44796/9789241503082_eng.pdf. D. P. Fidler, "Indonesia's decision to withhold influenza virus samples from the World Health Organization: implications for international law," *ASIL Insight*, vol. 11, no. 4, 2007.

2 D. P. Fidler and L. O. Gostin, "The WHO Pandemic Influenza Preparedness Framework: A Milestone in Global Governance for Health," *JAMA*, vol. 306, no. 2, pp. 200–201, Jul. 2011, doi: 10.1001/jama.2011.960.

3 J. Youde, "MERS and global health governance," *Int. J. Can. J. Glob. Policy Anal.*, vol. 71, no. 1, pp. 119–136, Mar. 2015, doi: 10.1177/0020702014562594.

4 A. Rizk, A. Bezruki, G. L. Burci and S. Moon (2020), "Everybody Knows This Needs To Be Done, But Nobody Really Wants To Do It": Governing Pathogen- And Benefit-Sharing (PBS). Global Health Centre Working Paper No. 23. https://repository.graduateinstitute.ch/record/298843?ln=en

5 Article 6.2 of the IHR (2005) states that "Notification: Following a notification, a State Party shall continue to communicate to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern."

6 Proposed amendment to Article 6.2 of the IHR (2005) in WHA75/A75/18: United States of America's (2022)

2. THE PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK (2011)

The PIP Framework is widely credited as an innovative instrument that involves not only Member States and WHO, but also industry, civil society, and scientific institutions. The PIP Framework established a system based on reciprocity: countries with IVPPs share them with WHO's laboratory network (Global Influenza Surveillance and Response System - GISRS); in exchange, companies obtaining these samples from the GISRS laboratories commit to provide, through WHO, benefits related to their use. Adopted by consensus by the WHA as a non-legally binding instrument, the PIP Framework utilises Standard Material Transfer Agreements (SMTAs) of two types: SMTA1 for sharing within GISRS and SMTA2 for transfers outside the network, in particular to pharmaceutical companies. SMTAs become binding contracts for their parties. The PIP Framework is widely credited for injecting principles of equity that are currently missing from the IHR and lays out the basis of a multilateral benefit-sharing system that is "on equal footing" with pathogen-sharing.[7]

3. THE CONVENTION OF BIOLOGICAL DIVERSITY (1992) AND NAGOYA PROTOCOL (2010)

The Convention on Biological Diversity (CBD), adopted in 1992 and with 196 Parties as of November 2022, confirms and reinforces the principle of national sovereignty over biological and genetic resources, and mandates that sharing of such resources must be based on Prior Informed Consent (PIC)[8] and Mutually Agreed Terms (MAT)[9]. The Nagoya Protocol (NP), adopted in 2010 and with 138 Parties as of November 2022, was negotiated to better articulate the CBD's benefit-sharing provision and clarify its enforcement and implementation. Negotiations on Nagoya took place at the same time as those towards the PIP Framework, and both can be seen as reflecting concerns regarding the governance of biological and genetic resources. Taking into account concerns raised during the PIP Framework negotiations, the NP refers in its preamble to State Parties being "*mindful* of the International Health Regulations (2005) of the World Health Organization and the importance of ensuring access to human pathogens for public health preparedness and response purposes" (PP16) and introduces a number of flexibilities and adjustments: First, Article 4.4 exempts parties of specialised international access and benefit-sharing (ABS) instruments (SII) consistent with the CBD and the Protocol from the Nagoya regime. Parties to the NP have been negotiating the criteria that SII have to meet to fulfil the requirements of Article 4.4. Second, Article 8(b) requires that parties "pay due regard" to health emergencies in developing their national ABS legislation and consider the need for quick access to both genetic resources and related benefits. Third, the NP encourages the development of model contractual clauses (Article 19) and codes of conduct, guidelines, and best practices (Article 20) to promote the harmonisation of the terms of ABS.

Proposal for Amendments to the International Health Regulations (2005). https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_18-en.pdf

7 D. P. Fidler and L. O. Gostin, "The WHO Pandemic Influenza Preparedness Framework: A Milestone in Global Governance for Health," *JAMA*, vol. 306, no. 2, pp. 200–201, Jul. 2011, doi: 10.1001/jama.2011.960.

8 Article 15.5 of the CBD (1992): "Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party."

9 Art. 15.4 of the CBD (1992): "Access, where granted, shall be on mutually agreed terms [...]" and Article 19.2 of the CBD (1992) further states: "2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms."

C. THE CURRENT SCOPE OF PBS GOVERNANCE OF PATHOGEN SAMPLES AND GSD

1. ACCESS TO PATHOGEN SAMPLES

There are broadly two kinds of pathogen-sharing: First, the routine sharing of pathogens as part of everyday disease surveillance, as with seasonal influenza, and pathogen-sharing during disease outbreaks and pandemics, as with COVID-19 and Ebola, for example. While the latter often becomes the centre of discussions, ensuring the reliability, rapidity and equitability of the former is also critical.

Many parties to the CBD and the NP, including the European Union (EU)[10], consider pathogens to fall within its remit, requiring case-by-case negotiation of fair and equitable benefit-sharing or a specialised international ABS instrument (SII). Some stakeholders, such as the pharmaceutical industry[11], have argued that pathogens do not fall under the scope of the CBD and should not be governed by Nagoya at all. However, this is not the approach of many Nagoya State Parties, and seems unlikely to be accepted by them. IVPPs are the only pathogens governed by rules designed for PBS through the PIP Framework, which is also recognized as "a specialised international access and benefit-sharing instrument that is consistent with the Nagoya Protocol" by the European Union.[12] The rules for PBS are relatively clear for pandemic influenza, but not for other pathogens of pandemic potential nor for other pathogens of public health concern.[13]

2. ACCESS TO PATHOGEN GSD

No formal international rules have been negotiated specifically for the sharing of GSD or their related benefits. Sharing of GSD has been informally governed through scientific norms of cooperation, and the policies of digital platforms such as GISAID and the International Nucleotide Sequence Database Collaboration (INSDC). The INSDC is a joint effort by the DNA Data Bank of Japan (DDBJ), the US National Center for Biotechnology Information (NCBI) and the European Nucleotide Archive in the UK. The Conference of the Parties of the CBD/NP has been discussing the status and treatment of GSD – called Digital Sequence Information (DSI) in environmental law parlance – but it is unclear whether or when agreement will be reached. This issue is on the agenda of the next Conference of the Parties in December 2022. In November 2022, the WHO released guiding principles for GSD calling for rapid, open sharing of GSD while ensuring, among other principles, avenues for local capacity development, collaboration and cooperation with local institutions, clear acknowledgement and intellectual credit, equitable access to health technologies, and developing compliance and enforcement mechanisms.[14]

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10 EU Regulation No. 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, 2014 OJ L 150.

11 T. B. Cueni, "It's time to put an end to pathogen protectionism." *SwissInfo*, December 16, 2021. https://www.ifpma.org/global-health-matters/its-time-to-put-an-end-to-pathogen-protectionism/

12 Preambular Paragraph 16, EU Regulation No. 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, 2014 OJ L 150.

13 The WHO R&D Blueprint has developed a priority list of pathogens of pandemic potential. WHO has also developed other priority pathogen lists, including in 2017 for antimicrobial resistance, it identified 12 families of bacteria with growing multidrug resistance and virulence, commonly called "ESKAPE" pathogens: *Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa,* and *Enterobacter* species.

14 WHO (2022). Guiding Principles for Pathogen Genome Data Sharing. https://apps.who.int/iris/handle/10665/364222

3. BENEFIT SHARING FOR PATHOGEN SAMPLES AND GSD

Benefit-sharing can apply in practice to several sectors and in different ways. It can include:

- *Academic benefits*, such as acknowledgement of source, scientific collaboration, co-authorship and shared research funding between providers and receivers
- *Economic benefits*[15], such as access fees, shared ownership, licensing, upfront or milestone payments, salaries and preferential terms, joint ventures, joint ownership of intellectual property rights (IPR), and royalty rights over commercial utilization of pathogens as well as countermeasures
- *Outbreak-related benefits*, such as sharing related data and information and access to countermeasures including vaccines, diagnostics and therapeutics.
- *Systems strengthening benefits*, such as capacity building, technology transfer, and infrastructure development.

What may constitute fair and equitable benefit-sharing for pathogen samples and GSD will vary case by case, and it is not entirely clear how fairness and equity should be assessed. The PIP Framework's SMTA2s give some indication. Any recipient of PIP biological materials outside GISRS must commit to provide benefits to WHO that can be used for influenza pandemic preparedness and response. In the PIP Framework, receiving entities fall within three categories with different benefit-sharing options. Category A entities–vaccine and antiviral manufacturers–must choose from 2 of the 6 prescribed options; Category B entities–entities that produce diagnostics or other pandemic response products–must choose 1 of 6 options; and Category C entities–all other entities– must 'consider providing benefits' (**Table 1**). An assessment of 14 SMTA2s signed with influenza product manufacturers found that "all companies selected the benefits that involved donations of products and reserving products for pandemics to be sold at affordable prices to WHO, rather than benefits involving granting licences to or ownership of intellectual property rights."[16]

15 For example, the annex to the Nagoya Protocol states that monetary benefits may include: (a) Access fees/fee per sample collected or otherwise acquired; (b) Up-front payments; (c) Milestone payments; (d) Payment of royalties; (e) Licence fees in case of commercialization; (f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity; (g) Salaries and preferential terms where mutually agreed; (h) Research funding; (i) Joint ventures; (j) Joint ownership of relevant intellectual property rights.

16 A. Rizk, A. Bezruki, G. L. Burci and S. Moon (2020), "Everybody Knows This Needs To Be Done, But Nobody Really Wants To Do It": Governing Pathogen- And Benefit-Sharing (PBS). Global Health Centre Working Paper No. 23. https://repository.graduateinstitute.ch/record/298843?ln=en

Table 1. Summary of Benefit-Sharing Options in PIP Framework's SMTA2[17]

CATEGORY A (Select 2/6)	CATEGORY B (Select 1/6)	CATEGORY C (Consider)
Donate % of real-time vaccine production to WHO	Donate diagnostic kits to WHO	Consider contributing to the measures listed below, as appropriate: • Donations of vaccines; • Donations of pre-pandemic vaccines; • Donations of antivirals; • Donations of medical devices; • Donations of diagnostic kits; • Affordable pricing of pandemic products; • Transfer of technology and processes; • Granting of sublicenses to WHO; • Laboratory and surveillance capacity building.
Reserve % of real-time vaccine production at affordable pricing to WHO	Reserve diagnostic kits at affordable pricing to WHO	
Donate antivirals to WHO	Support laboratory and surveillance capacity strengthening	
Reserve antivirals at affordable pricing to WHO	Support transfer of technology, know- how and/ or processes	
License on technology, know-how, processes or products needed for the production of influenza vaccines, antivirals or adjuvants to developing country manufacturers, on mutually agreed fair terms	License on technology, know-how, processes or products needed for the production of influenza vaccines, antivirals or adjuvants to developing country manufacturers, on mutually agreed fair terms	
Royalty-free license to developing country manufacturers or WHO for production of influenza vaccines, antivirals or adjuvants	Royalty free license to developing country manufacturers or WHO for production of influenza vaccines, antivirals or adjuvants	

17 WHO (2022). Standard Material Transfer Agreements (SMTA2s). https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/standard-material-transfer-agreement-2-(smta2)

III. SPECTRUM OF OPTIONS FOR GOVERNING PBS: EXAMPLES FROM CURRENT PRACTICE

Current approaches to governing PBS could be used, expanded, or amended to strengthen PBS governance globally and/or for a broader set of pathogens. This section examines each instrument in turn:

A. BILATERAL NEGOTIATIONS

With the exception of IVPPs, bilateral, case-by-case, negotiations between parties are the default option for negotiating access to pathogen samples and GSD and their related benefits. Compliance with the Nagoya Protocol requires prior informed consent (PIC) of the sending state and mutually agreed terms (MAT) between sending and receiving parties (that can be public or private laboratories or research institutions). In emergency situations, bilateral negotiations for PBS can delay pathogen-sharing, such as during the Zika epidemic in Brazil (2015-2016), or benefit-sharing, such as during the Ebola epidemic in West Africa (2014-2016).[18] Negotiating leverage may also be highly unequal between the two parties.

B. MATERIAL TRANSFER AGREEMENTS (MTAs)

Material Transfer Agreements (MTAs) are contractually binding between their parties and are the instruments through which MATs are usually negotiated for PBS. MTAs are instruments familiar to laboratories and research institutions that legally bind their parties with regard to the conditions for the exchanges of biological samples and the sharing of benefits arising from their use. 'Model' MTAs, a wide variety of which have been generated by scientific institutions, can speed bilateral negotiations by clarifying in advance the expected overall contours of a final agreement and are often shared bilaterally between institutions ahead of negotiations. The WHO released a Draft R&D Blueprint MTA Tool[19] in 2020 with options and explanations of various benefit-sharing provisions. While 'model' MTAs are modifiable through negotiations, 'standard' MTAs, such as those of the PIP Framework, provide a pre-agreed standardized text (though it may still contain a selection of options). At present, the Standard Material Transfer Agreements 2 (SMTA2s) of the PIP Framework, used exclusively for IVPPs, are the only WHO-backed SMTAs with commercial entities with predictable benefit-sharing arrangements.

18 A. Rizk, A. Bezruki, G. L. Burci and S. Moon (2020), "Everybody Knows This Needs To Be Done, But Nobody Really Wants To Do It": Governing Pathogen- And Benefit-Sharing (PBS). Global Health Centre Working Paper No. 23. https://repository.graduateinstitute.ch/record/298843?ln=en

19 World Health Organization, "Draft R&D Blueprint MTA tool." n.d. [Online]. Available: https://apps.who.int/blueprint/mta-tool/.

C. INFORMAL RULES: e.g. GUIDELINES, CODES OF CONDUCT, PRINCIPLES

Practices around PBS seem to have been governed by informal norms of scientists or guidelines established by institutions. The Guidelines of the Council for International Organizations of Medical Sciences (CIOMS), for example, include a section on the sharing of biological materials which, though not overtly addressing benefit-sharing, emphasise the use of MTAs. WHO has released guiding principles related to PBS, including the Guiding Principles for Pathogen Genome Data Sharing (2022)[20] for pathogen GSD and the Guiding Principles of the WHO BioHub System (2022)[21] for pathogen samples. In both cases, acknowledgement of source, collaboration and cooperation, transparency, and fair and equitable distribution of benefits are emphasised. The WHO Guiding Principles for Pathogen Genome Data Sharing (2022) identify equitable access to health technologies and infrastructures that can sustain data generation, management and analysis as particularly important elements of data-sharing. Timeliness, representativeness, transparency and accessibility of the data also contribute to the public health value of pathogen genomic data.

D. SURVEILLANCE NETWORKS AND TRACKING SYSTEMS

Tracking systems can make the sharing of samples, GSD and/or related benefits more visible. Among the infectious disease agents that WHO surveils, GISRS, established in 1952, monitors influenza. GISRS operates year-round for the timely sharing of influenza viruses and surveillance information. This function is governed by the WHO Terms of Reference (TOR) for participating centres. In joining GISRS, individual national health authorities agree to the TORs, including committing the country's sharing of influenza viruses and surveillance data with WHO. A subset of the viruses – those with pandemic potential – is governed by the TORs in the annex of the PIP Framework. The Influenza Virus Traceability Mechanism (IVTM), a tool of the PIP Framework, is the only system that tracks exchanges of samples of IVPPs between institutions and makes such virus-sharing transparent and traceable. WHO also manages other surveillance systems, such as the Global Antimicrobial Resistance and Use Surveillance System (GLASS), recently established in 2015, for antimicrobial resistance.

E. INTERNATIONAL FRAMEWORK: e.g. PIP FRAMEWORK

The PIP Framework has been proposed as a model for a broader framework applicable to non-influenza pathogens. However, influenza is seen as a unique case both because of the pre-existence of GISRS and because of the need to produce annual seasonal influenza vaccines, which generates financing from industry for the system. Influenza vaccine, antiviral and diagnostic manufacturers that use the WHO-GISRS make an annual financial contribution to WHO. Currently, the annual PIP Partnership Contribution is $28 million USD, equivalent to 50% of the running costs of GISRS, as set by the PIP Framework. Some of the key principles agreed in the PIP Framework – such as putting pathogen-sharing on equal footing with benefit-sharing – and the mechanisms to implement those principles (e.g. use of SMTAs and the channelling of benefits through WHO) could be built upon or adapted for other pathogens. Alternative financing arrangements are likely to be needed, since other pathogens do not necessarily have a seasonal vaccine market, as influenza does, from which to draw financing. An example from another regime is the ABS framework operationalized by the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (2001) (for more details, see **Box 1**).

20 WHO (2022). Guiding Principles for Pathogen Genome Data Sharing. https://apps.who.int/iris/handle/10665/364222

21 WHO (2022). The WHO BioHub: Guiding Principles. https://www.who.int/initiatives/who-biohub#principles. The WHO BioHub System is presented in more detail below.

Box 1. Example: access and benefit sharing under the Plant Treaty (2001)[22]

The International Treaty on Plant Genetic Resources for Food and Agriculture (2001), known as the Plant Treaty, was designed to pool selected plant genetic resources (listed in Annex I of the treaty) for facilitated access and to direct a portion of monetary and non-monetary benefits derived from research and product development (i.e. new plant varieties) to commonly identified conservation and sustainable use-related priorities in developing countries.[23]

The Plant Treaty establishes a multilateral system of access and benefit sharing that started operating in January 2007: plant genetic resources from State Parties and selected international collections are included in a global gene pool, administered and available to recipients under the pre-agreed terms of the SMTA.[24] The benefits, which include exchange of information, access to and transfer of technology, capacity-building and the sharing of financial benefits arising from commercialization, do not go back directly to the provider, but are to be shared through the multilateral system, including through a Benefit-sharing Fund.

Article 6 of the SMTA operationalizes benefit-sharing arising from commercialization, giving recipients of plant genetic resources (i.e. samples of seeds and other planting material) two options. The first option states that the recipient "shall pay a fixed percentage of the sales of the commercialized Product" (Art. 6.7), or, if the Product is restricted for further research and breeding, "is encouraged to make voluntary payments" (Art. 6.8). The second option allows the recipient to opt out of the above and "make payments at a discounted rate" provided that this rate is on sales of all products using genetic materials "belonging to the same crop" (Art. 6.11). Under both options, the recipient "shall make available…all non-confidential information resulting from research and development, is encouraged to share non-monetary benefits as well as to place a sample of the Product into a collection that is part of the Multilateral System." (Article 6.9).

In practice, recipients of plant genetic resources who commercialize a product incorporating material received through the system, can decide to either pay 0.77 per cent of their net sales of the commercialized product over a defined period or pay a discounted rate of 0.5 per cent on the sales of all products that use plant genetic resources for a defined period and obtain, in return, access to all genetic material of that crop.[25] The system has not generated significant user-based payments and the main source of monetary benefits flowing into the Benefit-sharing Fund has consisted of voluntary contributions, coming from governments (in some cases on behalf of the national commercial seed sector), other institutional donors and private seed sector associations.

22 International Treaty on Plant Genetic Resources for Food and Agriculture, Food and Agriculture Organization of the United Nations (2009), https://www.fao.org/3/i0510e/i0510e.pdf

23 M. Halewood, I. L. Noriega and S. Louafi, *Crop Genetic Resources as a Global Commons: Challenges in International Law and Governance*. New York: Routledge, 2013.

24 Standard Material Transfer Agreement, https://www.fao.org/3/bc083e/bc083e.pdf

25 D. Manzella, "The Design and Mechanics of the Multilateral System of Access and Benefit Sharing" in: M. Halewood, I. L. Noriega & S. Louafi, *Crop Genetic Resources as a Global Commons: Challenges in International Law and Governance*. New York: Routledge, 2013.

F. ORGANISATIONAL POLICIES: e.g. WHO BioHub, GISAID, INSDC

In the absence of clearly specified rules, the practices or policies of an organisation can also informally govern PBS, such as the WHO BioHub, GISAID or INSDC. The WHO BioHub System[26] is in a pilot testing phase and currently used exclusively for the non-commercial sharing of SARS-CoV-2 as a test-biological material with epidemic or pandemic potential (BMEPP). Similar to the PIP Framework, the BioHub System uses SMTAs to govern the legal relations between the BioHub and pathogen senders and receivers. Benefit-sharing arrangements for commercial sharing of BMEPPs (SMTA3s) have yet to be developed,[27] though existing SMTAs prevent parties from seeking to obtain intellectual property rights (Article 6 of SMTA1 and Article 3.1.4 of SMTA2) and entail a fair and equitable benefit-sharing arrangement that "aims to provide to all Member States and relevant partners, access to a range of public health information, tools, and products that may arise from the sharing of BMEPP" and, in the event of material benefits, that "all Parties will engage with WHO to distribute and provide such benefits on a fair and equitable basis." (Article 5 of SMTA1 and Article 4 of SMTA2).[28]

In summary, with the important exception of influenza, there is a patchwork of PBS arrangements for pathogens. Each component of this patchwork could be adopted, amended or expanded to govern PBS in an *ad hoc* manner. However, such a patchwork operates in the absence of a legally-binding normative foundation agreed upon by Member States. A pandemic instrument and/or revised IHR offers the possibility to provide such a foundation.

26 The WHO BioHub System is a response to WHA Resolution 74.7, Agenda Item 17.3, Paragraph 9(15) which requests the WHO Director General "to work together with Member States, the medical and scientific community, and laboratory and surveillance networks, to promote early, safe, transparent and rapid sharing of samples and genetic sequence data of pathogens of pandemic and epidemic, or other high-risk, potential, taking into account relevant national and international laws, regulations, obligations and frameworks, including, as appropriate, the International Health Regulations (2005), the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization and the Pandemic Influenza Preparedness Framework and the importance of ensuring rapid access to human pathogens for public health preparedness and response purposes".

27 WHO (2021). The WHO BioHub: Draft Concept Note 1.0. https://cdn.who.int/media/docs/default-source/2021-dha-docs/210617_whobiohubconceptnote_brochure-(1).pdf?sfvrsn=5e5a06f3_1&download=true

28 WHO (2022). Pilot Testing - WHO BioHub System. https://cdn.who.int/media/docs/default-source/campaigns-and-initiatives/biohub/20210923_who-biohub-pilot-testing-package-vfinal-for-webposting.pdf?sfvrsn=313e13b7_4

IV. OPTIONS FOR GOVERNING PBS: POTENTIAL ROLE OF AN INTERNATIONAL INSTRUMENT

A. PRINCIPLES AND AGREED LANGUAGE IN EXISTING INSTRUMENTS

International instruments often include principles that set their political context and guide interpretation and implementation of obligations and commitments. Negotiators could begin by building upon agreed language on PBS contained in existing international instruments.

In **Annex 1,** we have extracted the agreed language from the CBD (1992), Nagoya Protocol (2010), PIP Framework (2011) and WHA resolutions on the following eight PBS-related themes:

i. Sovereignty over biological resources
ii. Sharing of samples and benefits in an equitable manner / "on equal footing"
iii. Timely sharing of pathogens with pandemic potential
iv. Transparency, clarity and legal certainty
v. Consent
vi. Capacity building, technical assistance and transfer of technology
vii. Intellectual property
viii. Financing

B. POSSIBLE COMMITMENTS IN AN INTERNATIONAL INSTRUMENT

In light of the patchwork nature of the current arrangements, an international instrument offers the opportunity to make PBS more reliable, predictable, timely and equitable with legally-binding overarching international commitments, such as those to:

i. Share samples in a timely, expeditious and multilateral manner (e.g. through an international network of reference laboratories coordinated by WHO)
ii. Share GSD and other related data in a timely, expeditious and multilateral manner (e.g. through databases operating on designated principles such as the WHO Guiding Principles on Pathogen Genome Data Sharing[29])
iii. Share benefits in a timely, expeditious, fair, equitable and multilateral manner (including academic, economic, outbreak-related, systems strengthening benefits such as in-kind pandemic response products, technology and know-how)
iv. Commit to transparency for both pathogen sample/GSD- and benefit- sharing, including a tracking mechanism and transparency of agreements (e.g. databases, MTAs)
v. Support capacity-building for the safe and secure collection, storage, analysis and sharing of both physical pathogen samples and related data
vi. Provide sustainable financing to fulfil the above commitments

Taken together, the six commitments above could form the normative basis of a multilateral system

29 WHO (2022). Guiding Principles for Pathogen Genome Data Sharing. https://apps.who.int/iris/handle/10665/364222

of PBS. In principle, they should establish a logic of reciprocity between and among states. (For ease of reference, in **Annex 2**, we have extracted Article 9 on "Fair, equitable and timely access and benefit-sharing" of the Conceptual Zero Draft for the Consideration of the Intergovernmental Negotiating Body at its Third Meeting).[30]

Alternatively, groups of like-minded states could construct a "*minilateral*" system with the same commitments. However, the samples and GSD flowing through it would be less comprehensive without the participation of all states, and it would increase the risk of fragmenting equitable access to limited pandemic or outbreak response products.

The above commitments can be seen as a legal foundation for a global PBS system, with all states potentially contributing to and benefiting directly or indirectly from the system; this reciprocity provides the incentive to participate. At least four key questions arise. First, how closely can or should these commitments be **linked to one another**, and how can **accountability and compliance** be ensured? For example, if a state does not commit to or actually share samples or GSD when relevant, should it be entitled to receive benefits through a multilateral stockpile? Or if a state does not commit to or actually share benefits when relevant, such as IP, should it be entitled to continue accessing samples or GSD? Second, who should decide which pathogens fall within the **scope** of these commitments, and how can such a list be updated in a timely manner? Third, who should make the **judgement** of whether the benefits arising from shared samples or GSD are shared in a fair and equitable manner in any specific case, and how? Finally, how **specific** can or should commitments be in an international legal instrument vs instruments that can be tailored more easily to specific cases or contexts (e.g. organisational policies, contracts such as MTAs)?

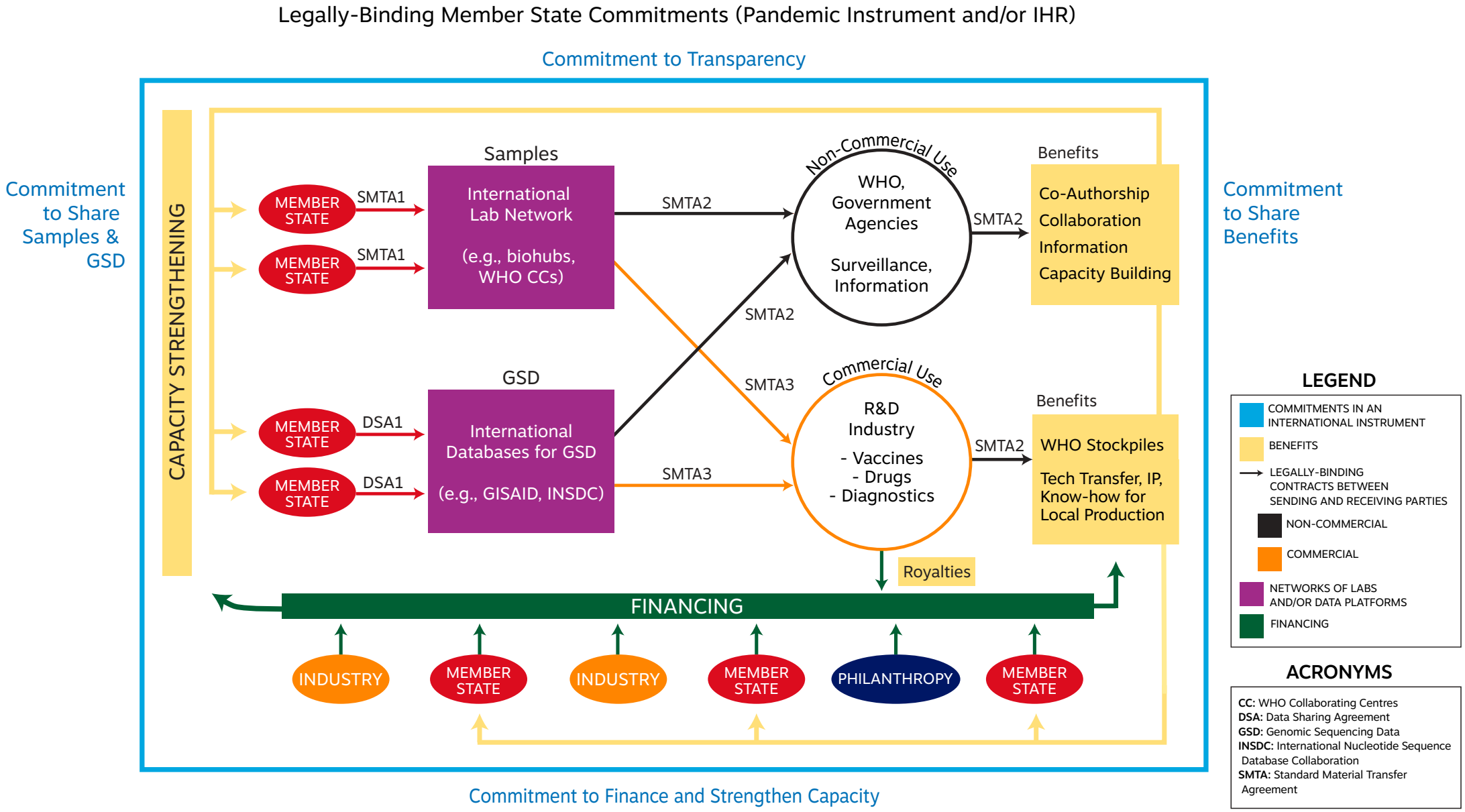
These questions may ultimately only be answered through processes of political negotiation and subsequent implementation. Nevertheless, it may still be useful to construct a "strawman" – a proposal meant to be critiqued and picked apart – that can help clarify thinking and perhaps draw the contours of a functioning ecosystem, to which we now turn.

C. FROM A SPECTRUM TO A SYSTEM

For the sake of clarity, Section III presented existing instruments for governing PBS as separate *components*, and Section IV.A presented a list of agreed language on *principles* and *commitments*. The case of influenza illustrates, however, that these *components, principles, and commitments* connect to form an ecosystem – they are not disjointed, but rather, interlocking pieces of a puzzle. Similarly, it is possible to envision how the pieces of a PBS ecosystem could function together, covering a broader range of pathogens and benefits. What could this look like? We propose a "strawman" of a PBS system in **Figure 1** below to stimulate discussion and debate.

30 Conceptual Zero Draft for the Consideration of the Intergovernmental Negotiating Body at its Third Meeting, Third Meeting of the Intergovernmental Negotiating Body to Draft and Negotiate A WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response, Geneva, 5-7 December 2022, A/INB/3/x.

Figure 1: "Strawman": Towards Envisioning a Functioning PBS System



Guiding the system could be the overarching principles and commitments to which states agree in an international instrument. Such commitments could be broad in scope, covering all pathogens of pandemic potential and including all parties to the instrument. The WHO Secretariat, an expert committee, and/or the Conference of Parties governing the instrument could determine whether a pathogen was within scope through a transparent and evidence-based process.[31] States would commit to share samples, GSD and benefits in a timely, expeditious, multilateral manner, to strengthen the capacity of all countries to do so, and to finance the system adequately ((**Figure 1**, see blue box, financing box and Member States in red ovals). States would share samples and GSD with a network of laboratories (including WHO BioHubs and/or Collaborating Centres) for physical samples and a network of databases (e.g. GISAID, INSDC (GenBank, EDA, DDBJ)) for GSD, both incorporating a tracking system for transparency (**Figure 1**, Member States in red ovals and networks in purple boxes). The sharing of samples and GSD could be governed by SMTAs with different terms for non-commercial and commercial use (**Figure 1**, orange arrows and circle for commercial use and black arrows and circle for non-commercial use).

A key question is how benefits could be negotiated, secured and distributed in an expeditious, fair, equitable and multilateral manner. Benefits flowing from non-commercial use (e.g. information or academic benefits such as authorship, collaboration, acknowledgment) tend to be easier to negotiate than those flowing from commercial use.[32] For commercial use, benefits options for influenza were constructed in advance in the PIP Framework. However, once we consider a wider range of pathogens, the relevant benefits are likely to vary case-by-case. For example, arrangements for benefits for a pathogen that spreads relatively slowly and is limited to a few countries may look very different from those required to address a fast-moving, large-scale pandemic such as Covid-19. Benefits arrangements for a pathogen for which a vaccine or therapeutic already exists may be different from those for which R&D is needed. And because little is known in advance about the particularities of the next potential pandemic, it may not be logical to fix benefit arrangements too rigidly in advance.

This uncertainty suggests that a flexible and trusted approach is needed to negotiate benefits, and to assess what is fair and equitable in a given context. This could be done bilaterally between two parties, e.g. government to government, government to firm, or lab to firm. That is, the actor sharing samples or GSD would assess whether the benefits it is to receive are fair and equitable – this is, in essence, the status quo. A multilateral alternative would be to delegate the case-by-case negotiation and oversight of benefits to a representative committee of States Parties or experts. This "Benefits Committee" could operate as a standing committee able to convene quickly in the event of a potential emergency, and be mandated to secure what it considers to be fair and equitable benefits.[33] Any agreements could be published upon execution, thereby also subjecting this judgement to the court of public opinion.[34]

Potential benefits could include academic, economic, outbreak-related and systems-strengthening benefits (as detailed in Section II.c.3). In cases of product development, benefits could include access to products for a multilateral stockpile, licensing of IP, transfer of technology, and/or royalties (**Figure**

31 Precedent for this exists in WHO's priority list of pathogens of pandemic potential, including Disease X (https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts), priority list of bacteria for which novel antibiotics are needed (https://www.who.int/news/item/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed), and the WHO fungal priority pathogens list (https://www.who.int/publications/i/item/9789240060241)

32 A. Rizk, A. Bezruki, G. L. Burci and S. Moon (2020), "Everybody Knows This Needs To Be Done, But Nobody Really Wants To Do It": Governing Pathogen- And Benefit-Sharing (PBS). Global Health Centre Working Paper No. 23. https://repository.graduateinstitute.ch/record/298843?ln=en

33 The Benefits Committee could be a separate committee under the auspices of the Pandemic Instrument, or a sub-committee or committee linked to the Emergency Committee of the IHR.

34 The system could build on that developed by the Medicines Patent Pool, which negotiates public health-oriented licenses to intellectual property for patented medicines. All draft licenses are reviewed by an Expert Advisory Group, which advises the Board. The Board of the MPP has responsibility for whether or not it approves a license negotiated by the staff, which operates in an analogous manner to a secretariat. The Expert Advisory Group publishes its assessment at the same time as the final license agreement, which is also published in its entirety at the time it is executed.

1, yellow boxes). Benefits could flow both bilaterally and multilaterally. For example, it may be logical for some benefits to go to source labs or countries (e.g. academic credit, a portion of royalties, access to products for communities who participated in clinical trials). For other benefits, a multilateral needs-based logic may make more sense, such as prioritising the supply of vaccines, diagnostics and treatments first to the hardest hit countries facing a shortage of countermeasures.

Financing of the overall system could come from a range of sources, including royalties, other fees, and contributions from Member States, industry, and/or philanthropic organisations. Recognizing that effective pandemic preparedness has benefits far beyond health (e.g. trade, tourism, education, agriculture), financial contributions could come from Ministries and non-state actors from a wide range of sectors. Financing could be deployed to support the overall functioning of the system, including maintaining international reference lab networks, databases, stockpile purchases, technology transfer and other capacity strengthening activities.

A Conference of the Parties (CoP) could regularly review how well the system functions and make changes as needed. A model Material Transfer Agreement or Data Sharing Agreement could serve as the starting point for negotiations for both bilateral and multilateral options (**Figure 1**, orange and black arrows). Benefits ultimately would flow back to Member States (**Figure 1**, yellow arrows).

V. CONCLUSION

PBS is a central but challenging issue on the table in current negotiations towards a pandemic instrument and amended IHR. Constructing a reliable, predictable and equitable system to govern PBS could serve the interests of a wide range of Member States, any of whom may be the source of or affected by a future pathogen of pandemic potential and/or require access to benefits in order to address the consequences of such a pathogen. This paper sought to clarify the issues for debate by articulating a range of options for governing PBS based on existing arrangements and previously agreed text in other instruments, and envisioning how they may fit together into a functioning ecosystem.

ANNEX 1: EXTRACTS OF AGREED LANGUAGE FROM THE CBD (1992), NAGOYA PROTOCOL (2010), PIP FRAMEWORK (2011) AND WHA RESOLUTIONS

	CBD (1992)	Nagoya Protocol (2010)	PIP Framework (2011)	WHA Resolutions
Sovereignty over biological resources	*Preamble* reaffirms that "States have sovereign rights over their own biological resources. *Art. 3*: "States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies…" *Art. 15.1:* "Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation."	*Preamble* reaffirms "sovereign rights of States over their natural resources…" Art. 6.1 refers to "the exercise of sovereign rights over natural resources"	*Principle (11)* recognizes "the sovereign right of States over their biological resources and the importance of collective action to mitigate public health risks"	*WHA60.28 (2007):* "Recognizing the sovereign right of States over their biological resources, and the importance of collective action to mitigate public health risks"
Sharing of samples and benefits in an equitable manner / "on equal footing"	*Art. 1:* refers to the "fair and equitable sharing of the benefits arising out of the utilization of genetic resources including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding."	*Art. 5.1:* "benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way…"	*Principle (3)* recognizes that "Member States have a commitment to share on an equal footing H5N1 and other influenza viruses of human pandemic potential and the benefits, considering these as equally important parts of the collective action for global public health"	*WHA60.28 (2007):* "Stressing the need for effective and transparent international mechanisms aimed at ensuring fair and equitable sharing of benefits, including access to, and distribution of, affordable diagnostics and treatments, including vaccines, to those in need, especially in developing countries, in a timely manner"
Timely sharing of pathogens with pandemic potential		*Art. 8(b):* each Party shall "Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may 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."	*Principle (5) and Section 5.1.1* refer to "rapid, systematic and timely" sharing of H5N1 and other influenza viruses with human pandemic potential.	

Transparency, clarity and legal certainty		*Art. 6.3(a)* requires State Parties to take measures to "Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements"	*Section 5.2.2* recognizes "that greater transparency and access concerning influenza virus genetic sequence data is important to public health…"	
Consent	*Art. 15.5:* "Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party."	*Art. 6.1:* "access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources…"	*Section 5.1.2:* "Member States provide their consent for the onward transfer and use of PIP biological materials to institutions, organizations and entities, subject to provisions in the Standard Material Transfer Agreements."	
Capacity building, technical assistance and transfer of technology	*Art. 16.1:* each party undertakes "to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment" *Art. 16.2:* access and transfer "shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism…"	*Art. 22.1:* "The Parties shall cooperate in the capacity-building, capacity development and strengthening of human resources and institutional capacities to effectively implement this Protocol in developing country Parties…" *Art. 23:* "Parties undertake to promote and encourage access to technology by, and transfer of technology to, developing country Parties"	*Section 6.0.2,* benefit-sharing should operate to: "(ii) provide benefits, including, where appropriate, capacity building in pandemic surveillance, risk assessment, and early warning information and services to Member States […] (iv) build capacity in receiving countries over time for and through technical assistance and transfer of technology, skills and know-how and expanded influenza vaccine production, tailored to their public health risk and needs."	
Intellectual Property	*Art. 16.2:* "In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights." *Art. 16.5:* "The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives."	*Art. 6.3(g):* MATs may include "(ii) Terms on benefit-sharing, including in relation to intellectual property rights" The Annex to the Protocol clarifies that monetary benefits may include "(d) Payment of royalties" and "(j) Joint ownership of relevant intellectual property rights"	*Section 6.13.4:* "Influenza vaccine manufacturers who receive PIP biological materials may grant, subject to any existing licensing restrictions, on mutually agreed terms, a non-exclusive, royalty-free licence to any influenza vaccine manufacturer from a developing country, to use its intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of influenza vaccine development and production, in particular for pre-pandemic and pandemic vaccines for use in agreed developing countries." *Article 6.1 of PIP SMTA1 (intra-GISRS)* states that "Neither the Provider nor the Recipient should seek to obtain any intellectual property rights (IPRs) on the Materials."	*WHA60.28 (2007)* recognizes that "intellectual property rights do not and should not prevent Member States from taking measures to protect public health" *WHA61.21 (2008):* "Intellectual property rights are an important incentive in the development of new health care products. However, this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain."

Financing	*Art. 20.1:* "Each Contracting Party undertakes to provide, in accordance with its capabilities, financial support and incentives in respect of those national activities which are intended to achieve the objectives of this Convention, in accordance with its national plans, priorities and programmes." *Art. 20.2:* "The developed country Parties shall provide new and additional financial resources to enable developing country Parties to meet the agreed full incremental costs to them of implementing measures which fulfil the obligations of this Convention and to benefit from its provisions…" *Art. 21.1:* "There shall be a mechanism for the provision of financial resources to developing country Parties for purposes of this Convention on a "grant or concessional basis…" *Art. 20.3:* "The developed country Parties may also provide, and developing country Parties avail themselves of, financial resources related to the implementation of this Convention through bilateral, regional and other multilateral channels."	*Art. 25.6:* additionally refers to "financial and other resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels"	*Section 6.14.3:* "Influenza vaccine, diagnostic and pharmaceutical manufacturers, using the WHO GISRS, will make an annual partnership contribution to WHO for improving global pandemic influenza preparedness and response. It is decided that the sum of the annual contributions shall be equivalent to 50% of the running costs of the WHO GISRS. Such contributions will commence in 2012. The distribution between companies is to be based on transparency and equity, based on their nature and capacities. The Director-General in consultation with the "Advisory Group" will further define the specific amounts to be contributed by each company as well as the mechanism for implementation (see section 6.14.5 below). In so doing, the Director-General and the "Advisory Group" will collaborate with industry. The Director-General will report annually on the outcome to the Executive Board." *Section 6.14.3.1:* "Member States and other stakeholders are encouraged to consider making donations and in-kind contributions to WHO for improving global pandemic influenza preparedness and response." *Section 6.14.4:* "The contribution acquired under 6.14.3 shall be used for improving pandemic preparedness and response, inter alia, for conducting disease burden studies, strengthening laboratory and surveillance capacity, access and effective deployment of pandemic vaccines and antiviral medicines." *Section 6.14.5:* "The Director-General will propose to the Executive Board which proportion of contributions should be used for inter-pandemic preparedness measures, and which proportion should be reserved for response activities in the event of a pandemic, based on the advice of the "Advisory Group"."	

ANNEX 2: EXTRACT OF ARTICLE 9 OF THE "CONCEPTUAL ZERO DRAFT FOR THE CONSIDERATION OF THE INTERGOVERNMENTAL NEGOTIATING BODY AT ITS THIRD MEETING"

Article 9. Fair, equitable and timely access and benefit-sharing

1. The Parties [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.

2. Towards this end, each Party [shall]/[should]:

(a) Ensure **timely access to affordable, safe, efficacious and effective pandemic response products**, including diagnostics, vaccines, personal protective equipment and therapeutics, by means that include:

(i) measures to ensure their equitable distribution, in particular to developing countries according to public health risk and need

(ii) measures to develop national plans that identify priority populations and prioritize access to pandemic response products by health care workers, other frontline workers and persons in vulnerable situations, such as, indigenous peoples, refugees, migrants, asylum seekers and stateless persons, the elderly, persons with disabilities, persons with health conditions, pregnant women, infants, children and adolescents

(b) Promote and facilitate recognition of the system as a **specialized system for access and benefit-sharing,** by means that include:

(i) measures to engage with all relevant actors in the design, development and implementation of the system for access and benefit-sharing

(ii) commitments to facilitate real-time access by all countries to pandemic response products, based on public health need

(c) Promote rapid, regular and timely **sharing of pathogens, genetic sequence data** and relevant metadata through effective standardized real-time global and regional platforms, by means that include:

(i) measures to ensure that platforms are standardized, effective, real-time, and promote findable, accessible, interoperable and reusable (FAIR) data available to all Parties

(ii) measures to ensure consistency with international legal frameworks, notably those for collection of patient specimens, material and data

(iii) measures to ensure that laboratories handling pathogens of pandemic potential do so safely, securely, and in accordance with international best practice guidelines

(iv) measures to support and enhance biosafety and biosecurity as a prerequisite for sharing of pathogens and genetic sequence data.

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