GLOBAL HEALTH CENTRE | 2022

INTERNATIONAL SHARING OF PATHOGENS, GSD AND BENEFITS

WORKSHOP SERIES REPORT

GENEVA GRADUATE INSTITUTE

GLOBAL HEALTH CENTRE

This report was drafted by Adam Strobeyko, Geneva Graduate Institute. The report does not necessarily reflect the views of any affiliated or co-organizing entity or participant.

Global Health Centre

Geneva Graduate Institute
Chemin Eugène-Rigot 2 | Case Postale 1672
1211 Geneva 21 | Switzerland

Tel +41 22 908 4558
Fax +41 22 908 4594
Email globalhealth@graduateinstitute.ch

graduateinstitute.ch/globalhealth

TABLE OF CONTENTS

List of Abbreviations	
ABS	Access and Benefit Sharing
CBD	Convention on Biological Diversity
CC	Collaborating Centre
DCVMN	Developing Countries Vaccine Manufacturers Network
DSI	Digital Sequence Information
G4IDR	Support Group for Global Infectious Disease Response
GISAID	Global Initiative on Sharing Avian Influenza Data
GISRS	Global Influenza Surveillance and Response System
GSD	Genomic Sequencing Data
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IHR	International Health Regulations
INB	Intergovernmental Negotiating Body
INSDC	International Nucleotide Sequence Database Collaboration
IP	Intellectual Property
IVPPs	Influenza Viruses of Pandemic Potential
IVTM	Influenza Virus Traceability Mechanism
MAT	Mutually Agreed Terms
MLS	Multilateral System
MTA	Material Transfer Agreement
NIC	National Influenza Centre
PBS	Pathogen and Benefit Sharing
PIC	Prior Informed Consent
PIP Framework	Pandemic Influenza Preparedness Framework
Plant Treaty	International Treaty on Plant Genetic Resources for Food and Agriculture
PPR	Pandemic Prevention, Preparedness and Response
R&D	Research and Development
SMTA	Standard Material Transfer Agreement
TOR	Terms of Reference
WHA	World Health Assembly
WHO	World Health Organization

EXECUTIVE SUMMARY

The international sharing of pathogens, genomic sequencing data (GSD) and related benefits is one of the most technically, legally and politically challenging issues for preventing or managing potential pandemics. Throughout this report, we refer to them collectively as pathogen- and benefit- sharing (PBS).

The topic of PBS is likely to be important to both the negotiations of a new pandemic instrument and the amendment of the International Health Regulations (IHR 2005). To address this issue, the Global Health Centre at the Geneva Graduate Institute co-organized a series of two workshops which sought to familiarize members of Geneva-based permanent missions and government officials from capitals with the central issues of existing PBS governance and to identify the potential options for strengthening existing arrangements.

The first workshop, co-organized with the permanent missions of Indonesia and the United Kingdom, consisted of an information session on core issues related to the PBS governance. It included presentations on the functioning of PBS under the Global Influenza Surveillance and Response System (GISRS), Pandemic influenza preparedness Framework (PIP Framework), Convention on Biological Diversity (CBD) and the Nagoya Protocol. The last session of the workshop, for which a speaker from the South Centre, representatives of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the Developing Countries Vaccine Manufacturers Network (DCVMN) were invited, consisted of a discussion on different perspectives on PBS. The workshop participants asked questions about the major obstacles to PBS and discussed different options for the sharing of benefits under existing frameworks. Questions were raised about the relationship between the existing PBS frameworks, a prospective pandemic instrument and amended IHR.

The second workshop, co-organized with the permanent mission of the Republic of Korea and in partnership with Support Group for Global Infectious Disease Response (G4IDR)[1], sought to identify available options for the PBS reform. To help address this question, the Global Health Centre circulated a draft discussion paper titled "**What are the options? Pathogen-, GSD- and Benefit-Sharing in an International Instrument**." The workshop began with a presentation of the discussion paper and identification of the relevant international frameworks which currently govern PBS. The paper presentation was followed by a discussion of the access and benefit sharing system for sharing plant genetic resources under the International Treaty on Plant Genetic Resources for Food and Agriculture (Plant Treaty). The second session of the workshop turned to identifying the scope of possible commitments in a new PBS mechanism. Workshop participants discussed the importance of PBS in the context of ongoing pandemic instrument and IHR amendment negotiations. Questions were raised about the treatment of the PIP Framework as a model for PBS governance, as well as about timing and the scope of potential new commitments.

1 G4IDR members include Kenya, Mexico, Morocco, Peru, The Republic of Korea, Singapore, Türkiye, and The United Arab Emirates.

WORKSHOP 1: INTERNATIONAL SHARING OF PATHOGENS, GSD AND BENEFITS: A PRIMER

1 NOVEMBER 2022

Co-convenors of the workshop: Government of Indonesia, Government of the United Kingdom, Global Health Centre at the Geneva Graduate Institute

Background

The first workshop consisted of an information session outlining key instruments and arrangements which make up existing arrangements for PBS governance. Experts were invited to provide brief presentations and to answer questions from members of permanent missions and officials from the capitals. The workshop was attended by 39 in-person participants and 40 participants online. The participants represented 37 Geneva-based permanent missions.

In Session 1, the experts outlined the functioning of existing PBS arrangements for influenza. Session 2 concentrated on the CBD, the Nagoya Protocol and their relation to PBS. Session 3 featured a range of views on PBS and included the representatives from the South Centre, IFPMA and DCVMN.

Outcomes

SESSION 1: PATHOGEN, GSD AND BENEFIT-SHARING FOR INFLUENZA: HOW DOES IT WORK?

PRESENTATION:
VIRUS, GSD AND BENEFIT SHARING FOR INFLUENZA THROUGH GISRS

Wenqing Zhang, Head, Global Influenza Programme, WHO

In the first session of the workshop, Wenqing Zhang explained the functioning of GISRS. GISRS was established in 1952 and currently consists of 158 institutions in 124 WHO Member States. It is coordinated by the WHO and supported by the hosting countries. GISRS is driven by the needs of public health globally with regard to influenza viruses which are constantly evolving.

Countries share virus samples and GSD for influenza via GISRS is defined under WHO Terms of Reference (TOR) and conducted through:

- National Influenza Centres (NICs) for seasonal viruses, influenza viruses of pandemic potential (IVPPs) and other influenza virus sharing;
- WHO Collaborating Centres (CCs) for influenza virus sharing & use with NICs, national laboratories, other CCs, industry and academia.

As defined in TOR, the sharing of GSD of IVPP viruses is done through publicly accessible databases, while sharing of seasonal and other viruses is conducted for specific activities (e.g. risk assessment) through the Global Initiative on Sharing Avian Influenza Data (GISAID) platform.

The public health benefits of GISRS include material (diagnostic reagents, reference viruses, potency reagents) and non-material (information, tools, data, guidance) benefits provided by WHO to participating laboratories, as well as PIP Framework benefits with regard to pandemic influenza, which include advance access to specific percentages of countermeasures in case of a pandemic and PIP Partnership Contribution for the functioning of the WHO programme.

In its 70 years of existence, GISRS proved to be an efficient network for the sharing of influenza viruses. However, GISRS does not contain or develop new international rules, as the sharing is done under the TOR, including those under the PIP Framework.

PRESENTATION:
PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK FOR THE SHARING OF INFLUENZA VIRUSES & ACCESS TO VACCINES AND OTHER BENEFITS (PIP)

Anne Huvos, PIP Framework Secretariat, WHO

The PIP Framework is an international access and benefit sharing instrument whose scope is influenza viruses with pandemic potential (IVPP). Its objective is to improve pandemic influenza preparedness by providing a framework for the sharing of pathogens and benefits "on an equal footing".[2] It was adopted by the 64th World Health Assembly (WHA) in 2011 as a non-legally binding instrument. The PIP Framework utilizes two types of standard material transfer agreements (SMTAs) that become binding contracts for their parties: SMTA1 for sharing within GISRS, and SMTA2 for transfers outside the network.

The PIP Framework is an innovative instrument that involves WHO Member States, industry, civil society, and scientific institutions. Benefit sharing under the PIP Framework is facilitated by clear expectations and tools to track and monitor the sharing of materials. All recipients of PIP Biological Materials from outside the GISRS network must sign a legally binding SMTA2 with WHO, under which they commit to specific form of benefit sharing. PIP thus establishes a system based on reciprocity: Member States are expected to share IVPPs with GISRS in a "rapid, systematic, and timely" manner.[3] They can do so with a certainty that further sharing outside of GISRS (particularly to pharmaceutical companies) will be done in accordance with benefit sharing commitments covered in SMTA2.

There have been 89 SMTA2 agreements signed to date: 14 with vaccine and antiviral manufacturers (Cat. A); 2 with manufacturers of other pandemic response products (Cat. B); and 73 with other, e.g. academic, institutions (Cat. C). For vaccine and/or antiviral manufacturers, the commitment is to provide to WHO, in real time, at least 10% of their future pandemic influenza vaccine production.[4]

Manufacturers that use GISRS also pay an annual PIP Partnership Contribution. 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. WHO uses the contribution to strengthen preparedness capacities in countries where they are weak and to establish a pandemic response fund for

2 Principle (3) of PIP Framework 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".

3 Principle (5) and Section 5.1.1 of PIP Framework refer to "rapid, systematic and timely" sharing of H5N1 and other influenza viruses with human pandemic potential.

4 Section 5 & Annex 2 PIP Framework.

influenza: 270$ million USD has been collected from manufacturers and $70 million USD are being held in reserve, to be used at the time of influenza pandemic.[5]

DISCUSSION: COMMENTS, QUESTIONS AND ANSWERS

After their presentations, the experts were asked to outline some of the challenges with regard to the sharing of influenza viruses. Experts responded that, to this date, seasonal sharing has not encountered major obstacles and that there is no shortage of seasonal influenza vaccines. However, some issues arose with regard to the timing of the release of the seasonal influenza vaccine by the manufacturers who received candidate viruses for seasonal vaccine production.

Questions were also raised about equity and the quid-pro-quo sharing of 10% of vaccine production with WHO under SMTA2 in return for the access to pathogen samples. Experts responded that the PIP Framework has not yet been tested in terms of access to vaccines, as there has been no influenza pandemic since its formation. Therefore, the current arrangements are designed to address future pandemics and vaccine production commitments. Once the commitments are triggered, the vaccines shared with WHO would be distributed to developing countries that need them most.

Currently, there are legally binding agreements in place with 14 largest vaccine manufacturers. In exchange for the future sharing of 10% of their vaccine production, pharmaceutical companies gain access to GISRS and to the candidate viruses for development of seasonal influenza vaccines. The Model SMTA2 also differentiates between several benefit sharing options for manufacturers to choose from.[6]

Another comment concerned the potential impact of national export restrictions during a potential pandemic upon the benefit sharing arrangements under the PIP Framework. Covid-19 pandemic has demonstrated that states can close borders and block manufacturers from donating their vaccines to WHO. However, there currently exists no legal mechanism under PIP Framework for stopping the countries from doing so.

Another question was whether the PIP Framework could be considered a model for a new PBS instrument that could result from the Intergovernmental Negotiating Body (INB) process or the IHR amendment. According to the experts, a new system could be broader in scope and include more sectors (tourism, travel, transport, trade) that could contribute to the system of access and benefit sharing. Any new system would also have to be consistent with the Nagoya Protocol and there is an ongoing discussion within the CBD and Nagoya governance concerning the criteria for identification of a specialized international instrument under Art. 4.4 of the Nagoya Protocol.

The PIP Framework and GISRS only apply to influenza. Therefore, the next session of the workshop turned to describing PBS outside of influenza.

5 PIP Framework section 6.14.3.

6 For a discussion of different benefit sharing options, see: A. Rizk, A. Strobeyko, G.L. Burci, S. Moon 'What are the Options? Pathogen-, GSD- and Benefit-Sharing in an International Instrument', (2022) Global Health Centre.

PRESENTATION:
PATHOGEN AND GSD SHARING OUTSIDE INFLUENZA

Vasee Moorthy, Senior Advisor, Science Division, WHO

In Resolution WHA72(13), WHO was asked to collect information on implementation and public health implications of existing PBS arrangements and practices. Dr. Moorthy pointed to the results which revealed that, outside of influenza, there is a patchwork of varying practices and networks which often rely on longstanding arrangements between the researchers.

Because Covid-19 was not an influenza pandemic, the WHO was not able to rely on many of the mechanisms described above. Nevertheless, during the pandemic, large-scale, rapid and dispersed sharing of SARS-CoV-2 GSD has generally occurred and GISAID has played an important role in this process. Unable to rely on the global influenza laboratory network, WHO also established the WHO Covid-19 Reference Laboratory Network, where over 20 laboratories came together to provide a reference function and strengthen capacity. As the PIP Framework benefit sharing provisions did not apply, it was also impossible to reserve the 10% of real time pandemic vaccine production for Covid-19. Instead, the number of reserved vaccines was closer to 3% under the COVAX pillar of the ACT-A.

While the GSD sharing during the Covid-19 pandemic has been successful, this was not necessarily the case in other health emergencies. During the Ebola crisis, the GSD sharing was patchy. Common concerns included fears of adverse repercussions of open data sharing and questions about acknowledgment of the source of the data and about the access to medical products developed based on sequences. The non-monetary benefits appeared to be particularly important for providers from outside of developed countries.

When asked about current R&D initiatives, Dr. Moorthy pointed to existing program-related activities, such as strengthening of laboratory and surveillance capacities for different diseases. There is a need to make linkages between dispersed initiatives; Dr. Moorthy pointed to the R&D Blueprint for action to prevent epidemics as an important initiative which seeks to map out the capacities needed to address future pandemics. In conclusion, Dr. Moorthy highlighted that we are looking for a very efficient system, but numerous obstacles need to be overcome first.

SESSION 2: CONVENTION ON BIOLOGICAL DIVERSITY AND THE NAGOYA PROTOCOL: WHAT ARE THEY AND HOW DO THEY RELATE TO PANDEMICS?

Taukondjo Shikongo, Nagoya Protocol Access and Benefit Sharing Unit, Convention on Biological Diversity

Dr. Shikongo started the session by providing background information about the CBD. The CBD was adopted in 1992 and it now has 196 Parties. The objective of the CBD is to preserve biodiversity and to promote the sustainable use of its components and the fair and equitable sharing of benefits arising from the utilization thereof. The Nagoya Protocol (2010) to the CBD, which regulates in some detail access to genetic resources and the fair and equitable sharing of benefits arising from their utilization, was also relevant in the context of workshop discussions. The protocol entered into force in 2014 and currently has 138 Parties.

Both the CBD and the Nagoya Protocol reinforce the sovereign rights of states over their genetic resources. Access to genetic resources is subject to the prior informed consent (PIC) of the provider country and is to be conducted under mutually agreed terms (MAT), which include the

sharing of benefits arising from utilization of genetic resources. The sources of benefits may include utilization of genetic resources, subsequent applications and commercialization. The resulting benefits can be monetary or non monetary in nature, with different types of benefits listed in the Annex to the Nagoya Protocol.

This bilateral system has resulted in more legal certainty for users and providers of genetic materials. It also contains relevant provisions for PBS: Art. 8(b) of the Nagoya Protocol requires State Parties to "pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally". Art. 4(4) of the Protocol also explains that it would not apply in a situation where another access and benefit-sharing instrument applies that is consistent with and does not run counter to the objectives of the CBD and the Nagoya Protocol. The CBD and Nagoya Protocol governance are currently working on guidelines that would help determine the criteria for identifying such a specialized instrument.

One of the emerging issues under CBD and Nagoya Protocol has been the access to and sharing of Digital Sequence Information (DSI, or genetic sequence data - GSD - in public health discourse). Questions arose with regard to principles which apply to DSI and whether it is to be treated like a genetic resource. The core issues which arise with respect to DSI concern inequity with regard to data sharing and access to vaccines, clarity on what benefit sharing arrangements apply, and the linkage to emerging infectious diseases (EID).

In conclusion, Dr. Shikongo highlighted that human disturbance of biodiversity is increasingly linked with the spread of pathogens and that an approach based on fairness, equity, increased collaboration and communication would be in everyone's interest.

DISCUSSION: COMMENTS, QUESTIONS AND ANSWERS

During Q&A, workshop participants posed questions about the functioning of CBD and the applicability of the Nagoya Protocol to pathogens. Dr. Shikongo explained that the CBD Secretariat and the ABS Nagoya Protocol Unit are both located in the same space in Montreal.

Questions were also raised about the suitability of the bilateral PBS system under the CBD and Nagoya Protocol for the sharing of pathogens. Dr. Shikongo responded that public health emergencies may require other forms of sharing and this is why they are mentioned explicitly in Art. 8(b) of the Nagoya Protocol, dealing with 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, and they can potentially be dealt with under another framework that is designated as a specialized instrument within the meaning of Art. 4(4) of the Protocol. The situation of DSI also requires special consideration, since the databases are currently only held by a few countries and the issue is being addressed across different international fora. It is therefore important for any future frameworks and initiatives to adopt a multi-sectoral approach and to explicitly address the sharing of DSI in particular.

The final session of the first workshop turned towards the discussion of different perspectives on existing and future PBS systems.

SESSION 3: PERSPECTIVES ON SHARING PATHOGENS, GSD AND BENEFITS

Discussion between:

- ***Nirmalya Syam, Senior Programme Officer, South Centre;***
- ***Thomas Cueni, International Federation of Pharmaceutical Manufacturers Association (IFPMA);***
- ***Rajinder Kumar Suri, Developing Country Vaccine Manufacturers Network (DCVM)***

Nirmalya Syam started by saying that, in a pandemic situation, rapid access to pathogens and GSD is critical. At the same time, it is crucial to legally guarantee prompt, rapid and adequate sharing of benefits arising from the utilization of such pathogens. Thus, adequate legal commitments are needed upfront. Syam further argued that there is a need for a PBS mechanism under a pandemic instrument that would enable for access and benefit sharing on an equal footing consistent with the CBD and Nagoya Protocol and include GSD, treated as a genetic resource, within its scope. Terms of access and benefit sharing could be established through standard material transfer agreements (SMTAs) under the new PBS mechanism. He finished by highlighting the importance of the model adopted by the PIP Framework, particularly with regard to the principle of placing access and benefit sharing on an equal footing and its role in increasing confidence and predictability in global response to pandemics.

Thomas Cueni responded by saying that the main objective of the CBD is the conservation of biodiversity and that pathogens should not be covered by its scope. In the context of pandemics, public health considerations and rapid access to pathogens should therefore override other concerns. Cueni then argued that the main failure during the Covid-19 pandemic concerned equitable rollout of vaccines. Therefore, there is a need to speak about a social contract where countries with manufacturing capacities would commit to share in real time what they have. He cited the Berlin Declaration in which pharmaceutical companies signed up to put aside part of their real time production for rollout by the WHO, Gavi, COVAX and UNICEF.[7] In closing, Thomas Cueni argued that we need to distinguish between the objectives of the CBD and the overarching principle of ensuring effective pandemic preparedness and response.

Rajinder Kumar Suri, who took the floor next, endorsed the sharing of medical countermeasures during a pandemic, but spoke about the need to decouple it from the sharing of pathogens and their GSD in order to ensure speedy response and vaccine development during an emergency. Dr. Suri outlined the challenges which face the development of new vaccines, which include the regulatory pathways and financing: while DCVM members supplied 60% of Covid-19 vaccines, they only received 5% out of the total of $5.6 billion R&D funding in 2020-2021. Dr. Suri finished by highlighting the importance of an innovative approach where all stakeholders, including the industry, would be involved and regional global imbalances would be addressed by means of a new pandemic treaty.

DISCUSSION: COMMENTS, QUESTIONS AND ANSWERS

The workshop participants asked about the barriers to benefit sharing. Dr. Suri responded that the main barriers concern the speed of sharing countermeasures and the laboratory capacities in developing countries. Mr. Cueni argued that most important barriers concern obstacles to benefit generation which force the companies to close down their research departments because they are not profitable. With regard to the sharing of GSD in the databases, Nirmalya Syam responded

7 IFPMA (2022): Berlin Declaration – Biopharmaceutical industry vision for equitable access in pandemics. Retrieved via: https://www.ifpma.org/wp-content/uploads/2022/07/IFPMA_Berlin-Declaration_Biopharmaceutical-industry-vision-for-equitable-access-in-pandemics-1.pdf (Last accessed 30.11.2022).

that there is a need to incentivize sharing of sequence information through pre-agreed commitments on benefit sharing.

Another workshop participant argued that the CBD does apply to pathogens, because the objectives of the Convention are to be implemented in an integrated and connected manner. He mentioned the ongoing efforts to collect pathogens and their GSD and to keep them in databases (examples include the WHO BioHub Facility in Switzerland). Furthermore, pharmaceutical companies make profits out of the use of pathogens and, therefore, the latter should be considered to fall under the scope of the CBD. In closing, he mentioned the possibility of having an ongoing system for the sharing of benefits and surveillance of pathogens in light of the One Health approach.

The first workshop finished with a recognition of an increased willingness to tackle PBS in the ongoing processes of negotiations of the pandemic instrument and IHR amendment.

WORKSHOP 2: INTERNATIONAL SHARING OF PATHOGENS, GSD, AND BENEFITS: WHAT ARE THE OPTIONS?

25 NOVEMBER 2022

Co-convenors of the workshop: Republic of Korea in partnership with the Group for Global Infectious Disease Response or G4IDR (Members: Kenya, Mexico, Morocco, Peru, The Republic of Korea, Singapore, Türkiye, and United Arab Emirates), Global Health Centre at the Geneva Graduate Institute

Introduction

The second workshop built upon previous discussions and concentrated on identifying the options for reform of the existing PBS governance system. It was attended by 31 in-person participants and 19 participants online. The participants represented 29 Geneva-based permanent missions.

The workshop began with a presentation of the draft discussion paper "What are the options? Pathogen-, GSD- and Benefit-Sharing in an International Instrument" which was circulated among the participants. Steve Solomon acted as a discussant for the paper. The paper discussion was followed by a presentation of access and benefit sharing under the FAO “Plant Treaty”, which aimed to familiarize health officials with the access and benefit sharing system in the field of agriculture. The workshop participants discussed the potential features of a new PBS system and its funding model in the context of the ongoing pandemic instrument and IHR amendment negotiations.

In the second session of the workshop, options for governing PBS in the pandemic instrument were presented in the form of a “Strawman” figure which featured in the discussion paper (see Figure 1 below). The intention behind the figure of the “Strawman” was to invite critique and help envisage a multilateral PBS ecosystem and identify possible commitments in an international instrument. The workshop participants were asked to comment and provide feedback on the solutions envisaged in the discussion paper.

Outcomes

SESSION 1

BACKGROUND PAPER PRESENTATION

Anthony Rizk, Global Health Centre at the Geneva Graduate Institute
Discussant*: Steve Solomon, Principal Legal Officer, WHO*

In the first session of the workshop, the discussion paper "What are the options? Pathogen-, GSD- and Benefit-Sharing in an International Instrument" was presented. The paper presented a spectrum of existing PBS instruments and arrangements, which vary in the degree of formality and in the scope of pathogens covered by each instrument. The paper listed the following types of instruments and arrangements which exist in PBS governance:

- Bilateral negotiations, which constitute the default option for PBS for pathogens other than IVPPs. From a governance perspective, reliance on bilateral negotiations risks delaying PBS and the development of countermeasures during health emergencies.
- Material Transfer Agreements (MTAs) are binding contracts between parties. "Model" MTAs can speed up PBS negotiations. Expanded use of standardized MTAs (like SMTA2 under the PIP Framework) could ensure rapid, fair and more equitable PBS.
- Informal rules (Guidelines, Codes of Conduct, Principles), can be used to influence the norms of scientific practice. However, they do not have a binding force and can be easily ignored.
- International frameworks can be used to prepare for a pandemic by means of pre-agreed multilateral commitments for rapid, reliable, fair and equitable PBS. Currently, the PIP Framework, which is the only multilateral framework designed to govern PBS, only applies to pandemic influenza viruses.
- Surveillance networks and tracking systems (e.g. GISRS, IVTM), can be used to make sample and GSD sharing more visible and transparent. They generate trust among participants by enabling the understanding of pathogen sharing practices in real-time, but do not alone constitute obligations to share pathogens and benefits.
- Organizational policies (e.g. WHO BioHub, GISAID, INSDC) can be used to govern PBS which occurs on platforms. They play an important role in shaping PBS policies more widely, but do not alone constitute obligations beyond a given organization.

In summary, there currently exists a patchwork of PBS arrangements. Each of the above-mentioned instruments can be potentially expanded. We are left with questions about how these arrangements can apply to better ensure rapid, fair and more equitable PBS.

Steve Solomon responded that the patchwork of PBS arrangements presents a considerable challenge for WHO Member States in terms of choosing among many options and meeting the deadline of May 2024 for the negotiations of a pandemic instrument. Furthermore, he highlighted the importance of GSD and the absence of rules governing this issue area. GSD can be used to quickly produce diagnostics and vaccines. GSD reflects a continuum of technological development and is critical to areas such as synthetic biology, artificial intelligence and quantum computing which will impact public health in the years to come.

Steve Solomon finished by highlighting that PBS is one of the necessary elements in the operationalization of equity. It could be addressed by looking at the models and possibility of extension of existing instruments and, in particular, the PIP Framework. The PIP Framework succeeded because it provided for commitments on access and benefit sharing on an equal footing that were in the interest of all the relevant stakeholders. The question currently on the table for Member States is whether the PIP model can be expanded to cover other pathogens as well.

DISCUSSION: COMMENTS, QUESTIONS AND ANSWERS

Questions arose about the difference between the markets for seasonal influenza and other pathogens. The PIP Framework addresses a unique situation where industry members can profit in the large seasonal influenza market. Other pathogens do not present similar opportunities, making pharmaceutical companies reluctant to invest into the potentially unprofitable markets for other pathogens. Steve Solomon responded that this situation raises important questions in relation to the potential expansion and funding of the PIP Framework and the GISRS system to include pathogens of pandemic potential. He argued that new forms of financing commitments would be necessary to address this issue.

Another question concerned the difference between the COVAX model and the PIP Framework

SMTA2 mechanism. In a written submission received by the Global Health Centre after the workshop, Luisa Belloni (Project Officer, WHO) explained that the main difference between COVAX and SMTA2 concerns the timing of secured vaccines: under SMTA2s, companies commit to provide 10% of their future pandemic production in real time to the WHO. This ensures that WHO will have access to 10% of the global pandemic vaccine production at the same time as other advance supply contract holders (governments), ensuring a more predictable, equitable and fair access to critical pandemic response supplies by all countries. The SMTA2s are signed directly between WHO and vaccine manufacturers: the vaccines delivered to WHO will be free of charge and WHO will be in charge of allocating them to countries, based on their public health needs.

A question was raised whether manufacturers that do not have a routine influenza business are still bound by the PIP Framework. Luisa Belloni responded that, under the PIP Framework, entities that receive PIP Biological Materials (PIP BM) from GISRS are required to sign an SMTA2 with WHO. The manufacturers that do not have routine influenza production and do not request PIP BM from GISRS, are not required to sign an agreement with WHO. Moreover, the GSD is currently not included in the definition of PIP BM, meaning that manufacturers are not required to sign an SMTA2 if they only use GSD to produce a pandemic vaccine. The WHO Secretariat is currently working towards approaching manufacturers to voluntarily conclude an SMTA2-like agreement for GSD committing the manufacturer to provide a specific percentage of future pandemic influenza vaccine production to WHO. The manufacturers that have already concluded an SMTA2 with WHO are bound to supply their pandemic vaccine to WHO, regardless of the technology being used.

PRESENTATION:
ACCESS AND BENEFIT SHARING UNDER THE FAO PLANT TREATY

Tobias Kiene, Technical Officer, International Treaty on Plant Genetic Resources for Food and Agriculture, FAO

Tobias Kiene started by highlighting that global food security and agriculture are marked by interdependence and rely on continuous trans-border flow of plant genetic resources. Without human management, many varieties of crops would cease to exist. Therefore, global interdependence and the need to keep using the resources were two important criteria that were taken into account when FAO Member States agreed to adopt the Plant Treaty in 2001.

The Plant Treaty seeks to conserve, share and use plant genetic resources. It is a legally binding instrument with the objectives of conservation, sustainable use of plant genetic resources and the fair and equitable sharing of benefits arising from their use. The Plant Treaty remains in harmony with CBD, but it establishes a specific system for food security and sustainable agriculture.

The Plant Treaty establishes a Multilateral System (MLS) that applies to 64 crops (listed in the Annex of the treaty) which provide around 80% of global plant-derived food. The MLS establishes a gene pool and a framework for contracting between providers and recipients of plant genetic resources. The access to plant genetic resources is governed by the Standard Material Transfer Agreement (SMTA) which sets specific, unchangeable terms and conditions for every material transfer. Intellectual property or other rights that limit access cannot be claimed on the material received from the system. If a new product is developed which incorporates material received from the system, it is subject to benefit-sharing rules which apply to subsequent commercialization. This solution increases transparency and legal certainty with regard to access and benefit sharing. The system has been used very widely and resulted in the reported number of 2.6 million notified accessions, 6.4 million transfers and over 90,600 SMTAs.

Under the Plant Treaty, benefit sharing operates on a multilateral level: State Parties agree to provide monetary and non-monetary benefits to the MLS. The benefits under the MLS include facilitated access, exchange of information, access to and transfer of technology, capacity-building and the monetary benefits resulting from commercialization of plant genetic resources by users of the system. Ultimately, the benefits should come back to the farmers in the developing countries. This can be achieved through the projects financed by the Benefit Sharing Fund (BSF). The user-based payments generated from commercialization were considered by many Contracting Parties to not be at the level originally envisaged. Currently, negotiations are ongoing on an idea of establishing a subscription system to make the time lag between access and commercialization payment shorter by establishing a subscription fee payable on yearly basis. The amendment of the SMTA and the possible enlargement of the list of crops covered by the Plant Treaty are also under discussion. In conclusion, Tobias Kiene recognized the increased role of GSD in the area of plant genetic resources for food and agriculture. The discussions to address GSD through a wide range of policy options are currently ongoing and linked with a parallel process under the CBD.

DISCUSSION: COMMENTS, QUESTIONS AND ANSWERS

Workshop participants asked questions related to the financing of the MLS and the BSF. Tobias Kiene responded that it was never foreseen that user-based payments arising from the commercialization would finance the BSF at a sufficient level and that the financing was always dependent on other sources of income, such as the voluntary contributions by State Parties. The issue with this financing method is the lack of long-term predictability and sustainability.

Steve Solomon commented that the subscription model offers an interesting perspective for the future PBS financing arrangements in public health. He also mentioned a mechanism based on public financing and conditionalities, as well as the UNITAID model of micro-contributions from travelers, as possible models for future PBS financing arrangements.

Tobias Kiene was asked about the tracking method used to trace how many SMTAs have been concluded. He responded that the Plant Treaty Secretariat receives information about each SMTA, as the plant genetic resources providers have to report every two years about the SMTAs that they have concluded. The reporting can also be done in real-time online, through the system called Easy-SMTA.[8] A Digital Object Identifier system is also in place to help trace individual samples of plant genetic material.

Another question concerned the intellectual property rights related to the products which result from the use of plant genetic material obtained from the MLS. Tobias Kiene responded that one of the main objectives of the MLS is to guarantee the free flow of plant genetic resources. In a case where a new product is developed on the basis of plant genetic material received from the MLS, the level of protection of the product (e.g. by means of a patent) will be decisive for the determination of the payment due to commercialization.

The final set of questions concerned GSD and the scope of WHO's mandate to work on Guiding principles for pathogen genome data sharing. Steve Solomon responded that the guidelines are not Member State approved and that they form part of WHO's general efforts to promote equitable data sharing. When asked how to ensure that GSD is used exclusively for health purposes and not for commercial purposes, Anthony Rizk commented that access and benefits could operate through separate pathways in a future PBS system.

8 Easy-SMTA, https://mls.planttreaty.org/itt/ (Last accessed 01.12.2022).

SESSION 2

PRESENTATION:
"STRAWMAN": OPTIONS FOR GOVERNING PBS IN THE PANDEMIC INSTRUMENT

Suerie Moon, Global Health Centre at the Geneva Graduate Institute

Discussants:

- ***Elisa Morgera, Professor of Global Environmental Law and Director of the Strathclyde Centre for Environmental Law & Governance, University of Strathclyde;***
- ***John McCauley, Director, Worldwide Influenza Centre, The Francis Crick Institute, London***

The next session began with Prof. Moon's presentation of a "Strawman" figure (**Figure 1**). The figure provided a hypothetical framework which identified reform options for PBS governance. It included 6 possible commitments for the State Parties:

- → to share samples in a timely, expeditious and multilateral manner
- → to share GSD and other related data in a timely, expeditious and multilateral manner
- → to share benefits in a timely, expeditious, fair, equitable and multilateral manner
- → to commit to transparency for both pathogen sample/GSD and benefit sharing, including a tracking mechanism and transparency of agreements
- → to support capacity building for the safe and secure collection, storage, analysis and sharing of pathogen samples and related data
- → to provide sustainable financing to fulfill the above commitments

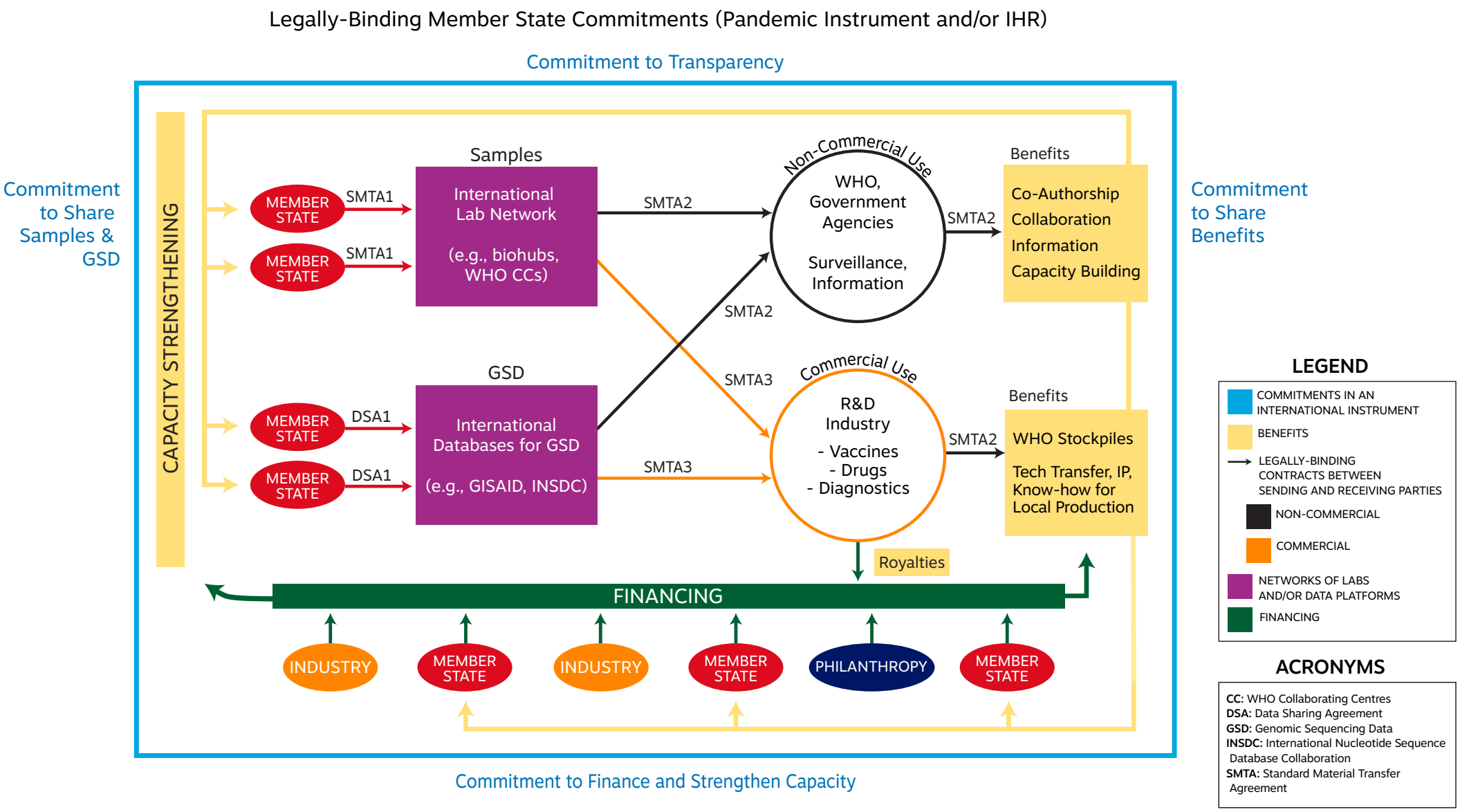
The question put on the table was how to bring the above-listed pieces together into a functioning PBS system.

One option would be to establish a multilateral, multi-pathogen system. The operation of the multilateral system would begin with the Member States sharing the pathogen samples with international lab networks and the GSD with international databases. The samples and GSD could then be shared for non-commercial use under SMTA2 with WHO and Government Agencies for the purpose of information and surveillance. The onward use of that data would be governed through SMTA2 and could generate benefits such as co-authorship, collaboration, information and capacity building. Both samples and GSD could also be channeled to commercial actors under SMTA3 for the purposes of countermeasure R&D. The transfer for commercial use under SMTA3 could result in benefits such as commitment to share a certain part of the production with WHO, as well as tech transfer, IP and know-how for local production. It could also result in royalties which, along other streams of funding, could be used to finance the fulfillment of other commitments. Ultimately, the benefits would flow back to the Member States that provide the samples and GSD.

The alternatives would be to preserve the status quo of patchwork arrangements, to expand individual instruments or to establish a minilateral (multi-pathogen) system among the like-minded countries.

The discussants and workshop participants were asked to comment upon and provide critical feedback on the figure of the "Strawman". Elisa Morgera, who acted as the first discussant, started by underlining the importance of the multilateral approach to PBS governance. She highlighted the need for specificity and long-term thinking when addressing equity and the flow of benefits to all the actors in the process. The model of the PIP Framework is relevant to these objectives,

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



as it provides specific PBS criteria (e.g., public policy risks and needs). Prof. Morgera also proposed to think more broadly about technology co-development and mutual capacity building, rather than relying upon the one-directional notion of the technology transfer, as the guiding considerations in the prospective PBS instrument. She spoke of the need to address the inequities in knowledge production which translates into inequities in response to public health crises. Prof. Morgera finished by noting that there is a need to develop a multilateral PBS system that would allow for multilateral monitoring, evaluation and learning of the application of the equity critera leading to adjustments over time. In that context, she supported the idea of a Benefits Committee to be included in prospective PBS arrangements. The Benefits Committee would include representation of different beneficiaries (private innovators, researchers in the Global South, database managers) and provide a venue for learning and adapting the PBS system to the changing needs of its participants.

John McCauley started by highlighting the unique character of the PBS for influenza: the fact that GISRS is already 75 years old and that we can predict what would happen in an event of an influenza pandemic since we know the relevant actors. He also acknowledged the contributions of influenza virological surveillance and GISAID to the Covid-19 pandemic response. The Worldwide Influenza Centre in London collaborated with 90 laboratories to exchange information about the virus samples. This collaboration also involves non-monetary benefits, such as sharing information and helping with publications. When commenting upon the figure of the "Strawman", John McCauley noted that MTAs can be very specific and cause problems to the laboratories due to the sheer volume of MTAs they receive. Therefore, a broader Standard MTA could work better. He also explained how commercial sharing of pathogen samples could become complicated, as you have to recognize the purpose for which the surveillance sample was originally taken from a patient. The legal implications of utilization of a biological sample under the Nagoya Protocol would also have to be cleared with the relevant national Nagoya Protocol focal point.

DISCUSSION: COMMENTS, QUESTIONS AND ANSWERS

The workshop participants were asked to comment on the "Strawman" figure. Comments were raised about the need to differentiate between pandemic and non-pandemic situations and to account for different actors and financing commitments in each field. Another comment highlighted the difficulty in distinguishing between commercial and non-commercial uses of pathogen samples, given that academic applications can be ultimately commercialized. Several comments concerned the timeline for the negotiation of a new pandemic instrument and the difficulty of developing a comprehensive PBS instrument within that time frame. The PIP Framework and the GISRS were proposed as models that could be extended and built upon for the purposes of PBS governance beyond influenza.

One of the workshop participants highlighted the importance of trust networks, as opposed to binding legal commitments, for PBS governance. Prof. Moon responded that the research conducted at the Global Health Centre has demonstrated that trust was indeed necessary to facilitate interaction between different actors but not sufficient. The research has also demonstrated that national laws governing PBS are increasingly prevalent in response to Nagoya obligations and the laboratories are ultimately subject to national legislation. Trust can be built through fair benefit sharing.

Another question concerned the commitment to transparency and the possible impact of transparency on rapid and equitable research. Prof. Moon responded that transparency with regard to the sharing of samples, GSD and the resulting benefits is an important part of trust in the PIP system. Transparency of the PBS could facilitate technology transfer so that more countries can manufacture, research and develop countermeasures for future health crises.

One of the workshop participants commented that the great value of GSD databases is that people can access data easily and that introduction of new bilateral or multilateral rules could impede upon the access to and exchange of data and, thus, have negative consequences for the effectiveness of pandemic response. John McCauley commented that the new PBS solutions would have to provide WHO CCs with flexibility necessary to allow for smooth sharing of pathogens and GSD.

Several workshop participants showed interest in the notion of co-development and the Benefits Committee. Prof. Morgera was asked about the compatibility of highly iterative and open-ended processes of participatory governance with the ongoing pandemic instrument negotiations. Prof. Morgera responded that representation of different actors (including researchers and industry) from developing countries is essential to the process. In that context, an inclusive Benefits Committee could facilitate the learning process, evaluation and monitoring, so that different actors could co-develop concrete solutions to problems related to inequities and inefficiencies of global pandemic response. The Committee could report these solutions to the Member States, under a treaty provision on monitoring and review of effectiveness.

CONCLUSION

The workshop organizers identified several key issues which arose throughout the two workshops. The importance of deciding what rules are needed to govern PBS in the context of the ongoing pandemic instrument and IHR amendment negotiations was highlighted. Furthermore, the discussions have shown that the proposed solutions should consider the needs of those charged with implementing the rules: the laboratories, companies and WHO CCs, among others. Finally, the workshop organizers agreed on the importance of envisioning a step-by-step development of a global PBS system for pandemics and of addressing it in the ongoing negotiation processes.

ANNEX 1: WORKSHOP 1 AGENDA

INTERNATIONAL SHARING OF PATHOGENS, GSD AND BENEFITS: A PRIMER

1 NOVEMBER 2022

PROGRAMME

12:00 PM	**ARRIVAL, REGISTRATION, BUFFET LUNCH**
12:30 PM	**WELCOMING REMARKS** **H.E. Ms. Grata Endah Werdaningtyas,** *Deputy Permanent Representative of Indonesia* **Ms Beth Arthy,** *Deputy Permanent Representative for Global Health, United Kingdom* **Professor Suerie Moon,** *Co-Director, Global Health Centre, Geneva Graduate Institute*
12:40 PM	**SESSION 1: Pathogen, GSD and benefit-sharing for influenza: How does it work?** **Wenqing Zhang,** *Global Influenza Surveillance and Response System, WHO* **Anne Huvos,** *Pandemic Influenza Preparedness Framework, WHO* **Q&A:** *15 minutes* **Pathogen, GSD and benefit-sharing in COVID-19** **Vasee Moorthy,** *WHO* **Q&A:** *15 minutes*
1:40 PM	**SESSION 2: Convention on Biological Diversity and the Nagoya Protocol: What are they and how do they relate to pandemics?** **Taukondjo Shikongo,** *Nagoya Protocol Access and Benefit Sharing Unit, Convention on Biological Diversity Secretariat* **Q&A:** *15 minutes*
2:15 PM	**COFFEE BREAK**
2:30 PM	**SESSION 3: Perspectives on sharing pathogens, GSD and benefits** **Nirmalya Syam,** *South Centre* **Thomas Cueni,** *International Federation of Pharmaceutical Manufacturers Association* **Rajinder Kumar Suri,** *Developing Country Vaccine Manufacturers Network* **Q&A:** *25 minutes*
3:20 PM	**CLOSING REMARKS**

ANNEX 2: WORKSHOP 2 AGENDA

INTERNATIONAL SHARING OF PATHOGENS, GSD AND BENEFITS: WHAT ARE THE OPTIONS?

25 NOVEMBER 2022

PROGRAMME

9:00 AM	**ARRIVAL, REGISTRATION, COFFEE**
9:30 AM	**OPENING REMARKS** **H.E. Seong-mee YOON**, *Ambassador and DPR for political affairs, Permanent Mission of The Republic of Korea in Geneva*
9:40 AM	**SESSION 1** **1. Background paper presentation** *Global Health Centre at the Geneva Graduate Institute* Respondents: **Steve Solomon**, *Principal Legal Officer, WHO* **Discussion/Q&A** **2. Access and benefit sharing under the FAO Plant Treaty** **Tobias Kiene**, *Technical Officer, International Treaty on Plant Genetic Resources for Food and Agriculture, FAO* **Discussion/Q&A** Moderator: **Daniela Morich**, *Global Health Centre at the Geneva Graduate Institute*
10:40 AM	**COFFEE BREAK**
11:00 AM	**SESSION 2** **Strawman: Options for governing PBS in the pandemic instrument** **Suerie Moon,** *Global Health Centre at the Geneva Graduate Institute* **a. Possible Commitments in an International Instrument** **b. Envisioning a multilateral PBS ecosystem** **Elisa Morgera**, *Professor of Global Environmental Law and Director of the Strathclyde Centre for Environmental Law & Governance, University of Strathclyde* **John McCauley**, *Director, Worldwide Influenza Centre, The Francis Crick Institute, London* **Discussion/Q&A** Moderator: **Gian Luca Burci**, *Global Health Centre at the Geneva Graduate Institute*
12:20 PM	**CLOSING REMARKS: ORGANIZERS** **Suerie Moon,** *Global Health Centre at the Geneva Graduate Institute*

GENEVA GRADUATE INSTITUTE

GLOBAL HEALTH CENTRE