

# FUTURE-PROOFING **PANDEMIC** PREPAREDNESS AND RESPONSE:

A Comparative Analysis of the  
CA+ and IHR Amendments

06 October 2023

UNIVERSITY OF THE  
WITWATERSRAND,  
JOHANNESBURG



**OPEN SOCIETY  
FOUNDATIONS**

## Table of Contents

<b>Impressum and Acknowledgments</b> .....	<b>4</b>
<b>Abbreviations and Acronyms</b> .....	<b>5</b>
<b>Executive Summary</b> .....	<b>6</b>
<b>Introduction: The Need for a Pandemic Accord and IHR Amendments</b> .....	<b>13</b>
<b>Methodology</b> .....	<b>14</b>
<b>Legal Characteristics of Health Treaties and Regulations</b> .....	<b>16</b>
<b>Pandemic Instruments, Mechanisms and Provisions: An Illustration of their Real-Time Application</b> .....	<b>20</b>
<b>Findings</b> .....	<b>21</b>
<i>Declaration of Pandemics versus Public Health Emergencies of International Concern (PHEICs)</i> .....	21
Introduction .....	21
Objective of Instrument Provisions .....	21
Relevant Provisions.....	21
Areas of Concern .....	21
Cross-references and incompatibilities .....	22
Opportunities for Consensus .....	22
Analysis .....	22
Summation .....	27
<i>Common but Differentiated Responsibilities (CBDR)</i> .....	29
Introduction .....	29
Objective of Instrument Provisions .....	29
Relevant Provisions.....	29
Areas of Concern .....	30
Cross-References/Incompatibilities .....	30
Opportunities for Consensus .....	30
Analysis .....	31
Summation .....	34
<i>Research and Development (R&amp;D)</i> .....	35
Introduction .....	35
Objective of Instrument Provisions .....	35
Relevant Provisions.....	35
Areas of Concern .....	36
Cross-References/Incompatibilities .....	36
Opportunities for Consensus .....	36
Analysis .....	37
Summation .....	40
<i>Pathogen Access and Benefit Sharing (PABS)</i> .....	42
Introduction .....	42
Objective of Instrument Provisions .....	42
Relevant Provisions.....	42
Areas of Concern .....	42
Cross-References/Incompatibilities .....	43
Opportunities for Consensus .....	43
Analysis .....	43
Summation .....	50
<i>One Health</i> .....	51
Introduction .....	51
Objective of Instrument Provisions .....	51
Relevant Provisions.....	51
Areas of Concern .....	51

Cross-References/Incompatibilities .....	52
Opportunities for Consensus .....	52
Analysis .....	52
Summation .....	57
<i>Supply Chain and Logistics .....</i>	<i>59</i>
Objective of Instrument Provisions .....	59
Relevant Provisions.....	59
Areas of Concern .....	60
Cross-References/Incompatibilities .....	60
Opportunities for Consensus .....	60
Analysis .....	61
Summation .....	63
<i>Co-Development and Transfer of Technology and Know-How .....</i>	<i>65</i>
Introduction .....	65
Relevant Provisions.....	65
Areas of Concern .....	66
Cross-References/Incompatibilities .....	66
Opportunities for Consensus .....	66
Analysis .....	66
Summation .....	69
<i>A New Financial Mechanism for Pandemic Preparedness and Response .....</i>	<i>69</i>
Introduction .....	69
Relevant Provisions.....	70
Areas of Concern .....	70
Cross-References/Incompatibilities .....	71
Analysis .....	71
Summation .....	76
<i>Compliance and Accountability .....</i>	<i>77</i>
Introduction .....	77
Relevant Provisions.....	78
Areas of Concern .....	79
Opportunities for Consensus .....	79
Cross-References/Incompatibilities .....	79
Analysis .....	80
Summation .....	82
<b>Conclusion .....</b>	<b>82</b>

# Impressum and Acknowledgments

**Date of Publication:** October 2023  
**Suggested citation:** University of the Witwatersrand, 'Future-Proofing Pandemic Preparedness and Response: A Comparative Analysis of the CA+ and IHR Amendments' (2023)

This work was commissioned by Wits RHI and the Wits Health Consortium at the University of the Witwatersrand. Dr Fifi A Rahman (Principal Consultant, Matahari Global Solutions) conceptualised the report and was the lead author, researcher, and analyst. Ian Jones proofread the report and edited for structure.

The University of the Witwatersrand is renowned for its academic and research excellence, its commitment to social justice and the advancement of the public good. It is spread over seven campuses in Braamfontein and Parktown in Johannesburg, with the Wits Rural Campus based on the outskirts of the Kruger National Park. It houses 33 schools within five faculties and is renowned for its research into the health sciences and humanities. It is home to 60 research entities and 420 National Research Foundation rated researchers, with over 90% of its research published in international high-impact journals. Wits is home to about 40 000 students and 5 500 staff. It is the co-owner of a specialist teaching hospital. Students also train in four public hospitals and dozens of clinics.

Wits University would like to thank Kiti Kajana from the Open Society Foundations for funding this report.

This report was informed by the experience and insights of 32 country negotiators, legal experts, and experts in pandemic prevention, preparedness and response. Our thanks to country negotiators and experts who requested anonymity. In addition, our thanks to experts interviewed for this report (listed alphabetically by surname):

Dr Yewande Alimi	AMR and One Health Unit Lead, Africa Centres for Disease Control and Prevention (Africa CDC)
Dr Chukwuma Anyaika	Director of Public Health, Nigeria and Chair to Nigeria's Technical Committee for the Pandemic Treaty and IHR Amendments
Thiru Balasubramaniam	Geneva Representative, Knowledge Ecology International
Professor Gian Luca Burci	Adjunct Professor of International Law at the Graduate Institute of International and Development Studies
Dr Ngozi Erondu	Technical Director, Global Institute for Disease Elimination (GLIDE)
Professor Larry Gostin	Professor of Global Health Law at O'Neill Institute at Georgetown University
James Packard Love	Director, Knowledge Ecology International
Dr Sultani Hadley Matendecheero	Deputy Director General for Health, Ministry of Health Kenya, and Vice Chair of the WHO Working Group on Amendments to the International Health Regulations 2005 (WGIHR),
Paul Molinaro	Chief, Operations Supply and Logistics, World Health Organization
Dr Ebere Okereke	Chief Executive Officer, Africa Public Health Foundation
Professor Suerie Moon	Co-Director at the Global Health Centre and Professor of Practice for the Interdisciplinary Programmes, Graduate Institute of International and Development Studies
Sangeeta Shashikant	Third World Network

Thanks are also extended to experts who reviewed sections of this report and provided useful comments and feedback:

Rachael Crockett	Senior Policy Advocacy Manager, Drugs for Neglected Diseases Initiative (DNDi)
Steve Solomon	Principal Legal Officer, World Health Organization
Dr Adam Strobeyko	Postdoctoral Researcher, Governing Pandemics initiative, Global Health Centre, Geneva Graduate Institute of International and Development Studies

# Abbreviations and Acronyms

BBNJ	Biological Diversity Beyond National Jurisdiction treaty <sup>1</sup>
CBD	Convention on Biological Diversity
CFE	Contingency Fund for Emergencies
COP	Conference of Parties
EFPIA	European Federation of Pharmaceutical Industries and Associations
FCTC	Framework Convention on Tobacco Control
GSD	Genome sequence data
IHR	International Health Regulations
INB	Intergovernmental Negotiating Body
IP	Intellectual property
IPPPR	Independent Panel for Pandemic Preparedness and Response
IPSN	International Pathogen Surveillance Network
JFHTF	G20 Joint Finance–Health Ministers Task Force
LDC	Least-developed countries
LMICs	Low- and middle-income countries
MCM	Medical countermeasures
MCP	Medical Countermeasures Platform
PABS	Pathogen Access and Benefit Sharing
PHEIC	Public Health Emergency of International Concern
PPPR	Pandemic prevention, preparedness and response
R&D	Research and development
TRIPS	Trade-Related Intellectual Property Rights
UPR	Universal Periodic Review
UNFCCC	United Nations Framework Convention on Climate Change
WGIHR	Working Group on the International Health Regulations
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

---

<sup>1</sup> Agreement under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction. A/CONF.232/2023/4 (19 June 2023) < <https://documents-dds-ny.un.org/doc/UNDOC/LTD/N23/177/28/PDF/N2317728.pdf?OpenElement>> accessed 17 July 2023

# Executive Summary

The COVID-19 pandemic highlighted major shortcomings in the ability of the world to prevent, prepare for, and respond to pandemics. These shortcomings spanned multiple areas, including the surveillance of pathogens of pandemic potential, the effectiveness of International Health Regulations (IHR), and disparities in the supply of vaccines, diagnostics and therapeutics. Furthermore, as the Independent Panel for Pandemic Preparedness and Response (IPPPR) has pointed out, despite many warnings from scientific experts and international commissions, “COVID-19 still took large parts of the world by surprise”.<sup>2</sup> Furthermore, experts have pointed out shortcomings in the ability of the IHR regime to ensure that countries are sufficiently prepared for Public Health Emergencies of International Concern.<sup>3</sup>

These issues have led to efforts to reform the governance, regulation and international financing regimes for public health emergencies and pandemics. Complementing responses such as the World Bank’s Pandemic Fund, from a legal and regulatory standpoint, the most critical activities are the work of the Intergovernmental Negotiation Body (INB) on a Pandemic Accord (CA+) and efforts by States Parties to the Working Group on the International Health Regulations (WGIHR) to amend the 2005 IHR.

Negotiations relating to the CA+ and the IHR amendments are running concurrently and are due to be concluded by the World Health Assembly in May 2024. There are inevitably overlaps and inconsistencies in scope and content between the two instruments. Furthermore, there are questions relating to what subject matter belongs in each of the two instruments. These issues in part can be addressed through an analysis of the legal character of conventions and agreements based on Article 19 of the WHO Constitution and of regulations based on Article 21 of the same document. Treaties (including framework conventions) and regulations have different legal characters. In addition, these instruments differ in the extent to which they are binding. Remaining issues will be decided through negotiation.<sup>4</sup>

Furthermore, while proposals from some delegations have been made public (such as those from the European Union and Africa Group), it is not always clear which points are seen by countries as non-negotiable and where compromise might be possible.

This comparative analysis, consultation and research exercise was conducted to clarify issues relating to the inclusion of specific points in one or other instrument, to identify areas of concern and opportunities for consensus. From 3 May 2023 to 5 October 2023, a range of experts and country negotiators were interviewed on their key priorities, concerns and what they believed should be in the IHR versus the Pandemic Accord. These inputs were contextualized with desk review, including scholarship on the character of different legal instruments.

This analysis highlighted that **treaties and conventions** are designed to be:

- Political signals of priority.
- Facilitators of multilateral cooperation where domestic law and other policy (including other international instruments) have failed.
- Applicable to issues where universal adherence will take time to achieve.

**Regulations**,<sup>5</sup> on the other hand, pertain to:

- Technical and regulatory matters, and matters related to implementation<sup>6</sup> on a particular issue.
- Nomenclatures on technical terms.
- Standards (for example on safety and purity of pharmaceuticals), or
- Competencies.

In particular, the IHR and its provisions are designed to be:

---

<sup>2</sup> Independent Panel for Pandemic Preparedness and Response, ‘COVID-19: Make It The Last Pandemic’ (May 2021)

<<https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemicfinal.pdf>> accessed 1 August 2023

<sup>3</sup> Myungsei Sohn and others, ‘The problems of International Health Regulations (IHR) in the process of responding to COVID-19 and improvement measures to improve its effectiveness’ (December 2021) *Journal of Global Health Science*; Allyn L Taylor, ‘Solidarity in the wake of COVID-19: reimagining the International Health Regulations’ (2020) [396\(10244\)](#) *The Lancet* P82-83

<sup>4</sup> Negotiations are usually finalised as a function of tradeoffs between parties and according to some scholars, a manifestation of structural power. Fifa A Rahman, *Negotiating Tactics, Tradeoffs, and Intellectual Property Politics: Chile and Malaysia in the Trans-Pacific Partnership* (2020) PhD thesis, University of Leeds; Susan Strange, ‘The Persistent Myth of Lost Hegemony’ (1987) 41(4) *International Organization* 551-574, 553; Christopher May, ‘Strange Fruit: Susan Strange’s Theory of Structural Power in the International Political Economy’ (1996) 10(2) *Global Society* 167-189, 174

<sup>5</sup> WHO Constitution, Article 21 < <https://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf>> accessed 24 August 2023

<sup>6</sup> Lidiya Teklemariam, ‘The Status of WHO Regulations Under International Law – ‘Agreements’ vs. ‘Regulations’ (2019)

<<https://oneill.law.georgetown.edu/the-status-of-who-regulations-under-international-law-agreements-vs-regulations/>> accessed 24 August 2023

- A first line of defence against health emergencies.
- Related to health systems readiness and resilience.<sup>7</sup>

Of note, the IHR were not originally designed for the mobilization of financial and human resources, although there is no reason why this could not change.

The analysis also uncovered numerous areas of concern, whether related to placement of legal provisions, overlaps and duplication, or the nature of specific provisions. Nine key contentious areas were identified:

### 1. *Declaration of Pandemics versus Public Health Emergency of International Concern (PHEIC)*

**Context:** Declaration of a PHEIC or pandemic triggers actions designed to ensure effective responses and control of the spread of infection. The timing of declarations is of particular importance given the need to respond swiftly to a health emergency.

**Areas of Concern.** Concerns centre on several key areas: ensuring a robust definition of ‘pandemic’ that allows for flexibility in fast-evolving pandemic scenarios; ensuring the most pragmatic and logical placement of definition/declarations within either the IHR or the CA+; alignment of definitions across the two instruments; assessing the need for an earlier ‘intermediate health alert’ to ensure more timely responses; and defining what different declarations should trigger.

**Opportunities for Consensus.** There are no legal obstacles to a pandemic definition and mechanism for declaration of a pandemic being included in the IHR, to ensure that all States Parties (even any non-ratifiers of the Pandemic Accord) are alerted when a pandemic situation has emerged. Nor are there legal obstacles to a pandemic declaration in the IHR being able to trigger operation of the Pandemic Accord. At the time of writing, countries seem to be leaning towards inclusion of the definition of a pandemic in the IHR.

Discussions on what declarations should trigger are at a preliminary stage. However, several actors have suggested that declaration of a PHEIC is too late to trigger financing to achieve sufficiently timely responses, and that an earlier ‘intermediate public health alert’ might be needed to trigger response financing. A further open question is whether explicit linkages between declarations and specific actions are desirable, given uncertainty in the evolution of outbreaks.

To come closer to consensus, parties may consider the following questions:

1. In which instrument should definitions of PHEICs and pandemics be included? How can definitions be aligned across the two instruments?
2. What should be the key elements of a pandemic definition?
3. Is an intermediate public health alert needed and what would it trigger?
4. What should be triggered by the declaration of (a) a PHEIC and (b) a pandemic?

### 2. *Common but Differentiated Responsibilities (CBDR)*

**Context:** The CBDR principle has roots in climate change agreements – notably notions that industrialized countries have historically contributed more carbon dioxide emissions, and have more resources available, and therefore should shoulder more responsibility for addressing climate change challenges. Some have suggested that a similar principle should apply to pandemic prevention, preparedness and response and be written into the Pandemic Accord and IHR.

**Areas of Concern.** Countries that oppose inclusion of CBDR argue that the concept is non-transferable from a climate change to a pandemic/health emergencies context. Some countries see a middle ground with the use of different terminology (maintaining the principle that industrialized countries have more responsibility, given their greater capacities and resources) but others believe that changes in language will dilute the provision and render it meaningless. There are also concerns that CBDR would disincentivize countries with limited capacity and resources from developing core IHR competencies.

**Opportunities for Consensus.** Countries have strong positions in this area, and consensus may be dependent on concessions/tradeoffs in other areas. Broadly speaking, there are three positions: CBDR does not belong in

---

<sup>7</sup> WHO, Article-by-Article Compilation of Proposed Amendments to the International Health Regulations (2005) submitted in accordance with decision WHA75(9) (2022), Article 2



the Pandemic Accord; CBDR is necessary and language should not be modified; and CBDR is necessary but terminology can be adapted as long as the principle is maintained that countries with more resources have differentiated responsibilities. Some also suggest that CBDR is necessary to ensure countries can meet obligations on One Health, and additionally for countries to realise higher levels of responsibility on pathogen access/benefit-sharing provisions if they house more pharmaceutical manufacturers and have greater resources.

To come closer to consensus, parties may consider the following questions:

1. Can equivalence be drawn between contributions to greenhouse gas emissions and contributions to pandemic tools inequity?
2. To what extent has CBDR in treaties been effective at mobilizing action?
3. What practically would inclusion of CBDR mean financially for countries?
4. Does CBDR need to be included so that less-developed countries receive support for development of IHR competencies and/or One Health capacities or would it risk undermining compliance and accountability mechanisms relating to core capacities?

### 3. *Research and Development (R&D)*

**Context:** During the COVID-19 pandemic, access to products such as vaccines and drugs was driven by ability to pay rather than public health need. In addition, a lack of transparency on pricing led to some discrepancies in tiered pricing for countries of different income status. Attaching conditionalities to public funding of R&D has been proposed as a mechanism to ensure more equitable availability of products and greater transparency in pricing.

**Areas of Concern.** The provisions in the Bureau Text, an amended version of the CA+ 'zero draft', allow for a high degree of discretion on inclusion of conditions in R&D funding agreements and publication of these terms. Notably, the addition of 'as appropriate' and 'in accordance with national laws' signals sensitivity around concrete commitments to transparency in R&D funding agreements. In addition, the Bureau Text seems to have combined two previously separate obligations, relating to inclusion of conditions in public funding agreements and publication of R&D contract terms. An obligation to publish contract terms does not ensure that public R&D funders use their leverage to attach pro-access conditions to their funding. Given its position on pricing confidentiality, industry is likely to resist moves to promote greater transparency in prices of products and pricing policies.

**Opportunities for Consensus.** Public funding of R&D and procurement provide opportunities to influence the pricing and access policies and practices of product developers and manufacturers. A key issue in this area is the degree to which countries will be willing to include access and pricing transparency conditions in publicly funded R&D funding agreements and purchasing agreements. Countries hosting extensive R&D and manufacturing activities may be reluctant to impose such conditionalities.

Approaches for R&D capacity-building proposed in the IHR are unlikely to be contentious. However, R&D capacity-building is also included in the CA+, raising questions about mechanisms of compliance and whether R&D capacity-building in relation to pandemics and PHEICs would be discussed separately.

Moving closer to consensus will require the consideration of the following questions:

1. What examples exist of affordable pricing and price transparency provisions in government-funded R&D contracts? How have these worked in practice?
2. At what stage of R&D and procurement could conditions be applied to ensure more equitable access to health tools?
3. What is the best mechanism for monitoring R&D capacity-building? Are separate mechanisms needed for the Pandemic Accord and IHR?

### 4. *Pathogen Access and Benefit Sharing (PABS)*

**Context:** Access to pathogen samples and genome sequence data is essential for much new product development. Some countries have queried why they should make samples and data available then be unable to access or afford products subsequently developed. PABS is intended to ensure that countries contributing to a global public good gain a share of the benefits deriving from use of this global public good.



**Areas of Concern.** Some negotiators are concerned that a PABS system would result in ‘transactional’ sharing of pathogens and genetic sequence data, with sharing dependent on guarantees of access to products or technology transfer. Others are concerned that a PABS system would result in significant costs associated with compliance checks, drawing upon their experiences with the Nagoya Protocol. Furthermore, there are concerns that the Bureau Text is insufficiently clear on how a PABS system would work in practice. In addition, it is not clear what conditions could be placed on industry, as non-signatories to a Pandemic Accord.

Conversely, other negotiators are concerned that, without a PABS system, Global South countries that contribute to scientific progress would still be slow to receive the resulting benefits. A model developed for influenza enables companies to access samples and data in return for either product donations or technology transfer, but the latter option has never been selected. Furthermore, there are concerns that countries with a strong R&D industry might not ratify the Pandemic Accord, making the PABS mechanism significantly weaker.

**Opportunities for Consensus.** Although companies would not be party to the Pandemic Accord, influence could be exerted through (1) conditionalities in public R&D contracts (see above) and (2) through offering companies ‘something of value’, as in the influenza model. The WHO International Pathogen Surveillance Network (IPSN) could provide an infrastructure for pathogen and sequence sharing. Although it has been suggested that inclusion of a PABS system in the Pandemic Accord would add compliance costs on top of those associated with the Nagoya Protocol,<sup>8</sup> where a specialized instrument on PABS is developed, the Nagoya Protocol would no longer apply.

Outstanding issues include how accountability would be written into PABS mechanisms, how benefits would be assessed, and how processes would be integrated with existing pathogen platforms or those in development.

Detailed provisions on a PABS system could be included in the Pandemic Accord, ensuring that the revised IHR are fully aligned. Consideration would need to be given to the legally binding nature of the system (whether it is ‘opt-out’ under Article 21 or ‘opt-in’ under Article 19 of the WHO constitution).

Moving closer to consensus will require the consideration of the following questions:

1. Could a PABS model be developed based on the existing influenza (PIP Framework and GISRS) model?
2. Would a new PABS system add significantly to compliance costs?
3. Could a PABS model be designed that promotes technology transfer as well as product donation?
4. How exactly would a PABS system operate in practice?

## 5. *One Health*

**Context:** The One Health approach recognizes the interdependency of animal, human and environmental health. The One Health formulation developed by the ‘Quadripartite’ alliance of global agencies has a strong focus on pandemic prevention and limiting the impact of pandemics.

**Areas of Concern.** Countries broadly acknowledge the importance of preventing zoonotic spillover and increasing competencies at the human-animal-environment interface. Opposition to inclusion of One Health in the CA+ focuses on: (1) lack of financial and human resources to meet obligations; (2) limited Member State consultation on current global One Health policy; (3) lack of a mandate to negotiate given the need to involve other government departments. A separate protocol or agreement on One Health was suggested as a possible alternative to inclusion in the CA+.

Supporters of One Health provisions are concerned that if commitments are not included in the CA+, an important opportunity to advance the One Health approach would be lost.

**Opportunities for Consensus.** Some countries were keen to see robust financing and technical support provisions before committing to One Health obligations. Others believe that a separate agreement on One Health is necessary to ensure multi-ministry buy-in, and to ensure that Member States have oversight of One Health definitions and approach. The possibility of a transition period for implementation was raised but would not address the mandate issue.

---

<sup>8</sup> Covington, ‘The Impact of the Nagoya Protocol on Global Pathogen-Sharing’ (January 2023)

The IHR amendments propose building capacities on collaborative surveillance networks to detect public health events at the human–animal–environment interface. The amendments do not explicitly refer to One Health terminology, and therefore may be more palatable. Furthermore, the provision is loosely phrased and enables countries to make progress according to their own capacities. However, progress may still be dependent on inclusion of a financial mechanism within the IHR, as many low- and middle-income countries (LMICs) have insufficient resources to build these networks. Member States will also need to consider whether it is appropriate to insert provisions focused on this interface in regulations targeted predominantly at human health.

When signing up to treaties, countries have ‘opt-in/opt-out’ powers<sup>9</sup>, which could be used to avoid deadlock should mandatory One Health commitments be preferred.

In brief, moving closer to consensus will require the consideration of the following questions:

1. Is there a common understanding of the One Health approach and is it endorsed by all Member States?
2. What financial and technical assistance would need to be provided to ensure One Health obligations were met in less-developed countries?
3. What appetite is there for a separate One Health instrument? Would one be feasible?

## 6. *Supply Chain & Logistics*

**Context:** During the COVID-19 pandemic, distribution of medical supplies faced multiple practical obstacles. In addition, many countries struggled to gain access to medical products, particularly newly developed ones.

**Areas of Concern.** Some countries were concerned that distribution systems might share the shortcomings of the ACT-Accelerator model, which was felt to be opaque, insufficiently inclusive, not led by the needs of the Global South, and insufficiently accountable. Countries expressed the need for a new allocation mechanism to have adequate country oversight and influence. It was also suggested that distribution might need to be explicitly linked to production of pandemic-related products.

Other countries expressed concern that a proposed Supply & Logistics Network might be insufficiently collaborative with agencies outside WHO. The need for enhanced and more coordinated country import and logistics processes was also highlighted.

**Opportunities for Consensus.** Given reservations about how the ACT-Accelerator operated, many countries were concerned that a Medical Countermeasures Platform might replicate its shortcomings. Many countries see Section 13 CA+ as a way to remedy these deficiencies. Some form of a Supply & Logistics Network/Partnership was seen as necessary, but it was recognized that Member States needed to address logistical and bureaucratic challenges. The need for an allocation mechanism with appropriate governance structures was highlighted, complemented by increased transparency about volumes purchased to reduce the risk of hoarding of supplies. Such a mechanism could exist with a modified governance structure such as an advisory board that includes INB and IHR focal points, as well as civil society and independent experts.

Most suggested IHR amendments seem appropriately placed. Points in need of clarification include how allocation plans developed after the declaration of a PHEIC would be modified should a PHEIC evolve into a pandemic.

Moving closer to consensus will require consideration of the following questions:

1. How can countries be equitably represented in decision-making of an allocation/supply mechanism?
2. What lessons can the Medical Countermeasures Platform learn from the ACT-Accelerator experience?
3. Would a mechanism on supply be able to address equitable access without linkages to production? How should Article 13 be linked to production and what concrete production-related obligations can be created for Member States with manufacturing capacity?

## 7. *Co-Development and Transfer of Technology and Know-How*

**Context:** During the COVID-19 pandemic, access to medical products was limited by supply constraints, leading to inequitable access to newly developed products. Time-bound intellectual property (IP) waivers are seen as one possible way to increase supply in health emergencies.

---

<sup>9</sup> United Nations, ‘Guide to Practice on Reservations to Treaties’ (2011), Article 1.1.1  
<[https://legal.un.org/ilc/texts/instruments/english/draft\\_articles/1\\_8\\_2011.pdf](https://legal.un.org/ilc/texts/instruments/english/draft_articles/1_8_2011.pdf)> accessed 7 August 2023

**Areas of Concern.** Time-bound waivers are a contentious issue. It was suggested that opposition to time-bound waivers would continue to inhibit the development of regional manufacturing capacity for pandemic-related products. Concern was raised that high-income countries would be unlikely to accept both a PABS system and time-bound waivers, and therefore that difficult compromises might have to be made.

The potential for time-bound waivers to stifle innovation of pandemic-related products was also raised. There were some suggestions that IP discussions should be restricted to World Intellectual Property (WIPO) or World Trade Organization (WTO) contexts. Doubts were expressed about inclusion of IP in the IHR, as the IHR primarily relate to response rather than prevention/preparedness and because of the risk of politicization.

**Opportunities for Consensus.** Many HICs have IP waiver provisions in their domestic laws, which are dependent on action by a minister of health (or equivalent official), which implies recognition that IP is not solely the realm of WTO or WIPO. However, the text stating that countries should make efforts to support time-bound waivers during pandemics will likely remain controversial. It may be difficult to obtain agreement on both a PABS system and time-bound waivers – suggesting that concessions in this area would be dependent on what was accepted on PABS or on other contentious areas.

The IHR amendments propose that countries ensure domestic laws contain IP waivers/exemptions. While IP is predominantly a function of response rather than prevention, PHEIC declarations are also a function of response and were introduced in 2005. Hence, from a constitutional standpoint, there is no reason to exclude IP from the IHR, although some suggested that IHR IP provisions should preserve the soft coordination and ‘first line of defence’ function.

Moving closer to consensus will require consideration of the following questions:

1. To what degree are countries prepared to tradeoff on IP for gains in other areas?
2. Should IP issues only be discussed in WIPO or WTO contexts?
3. Is IP only relevant to response and therefore not appropriate for inclusion in the IHR?
4. Is there any evidence that waiver/compulsory licensing measures stifle innovation and reduce pharmaceutical company investments?

## 8. *A New Financial Mechanism for Pandemic Preparedness and Response*

**Context:** Global funding is required to support pandemic preparedness, prevention and response. Currently, global funding is provided predominantly through the World Bank’s Pandemic Fund, and during the COVID-19 pandemic from selected donors and global health agencies. Possible alternatives include an entirely new financial mechanism or provision of funding through WHO.

**Areas of Concern.** Key issues of concern include the need for a new financial mechanism to be structured with oversight from Member States, whether WHO is able to operate as a bank on a large scale, and the fact that the IHR are currently not designed to contain a financial mechanism. In addition, there are concerns that inclusion of a financial mechanism in the CA+ but not the IHR could limit its scope and application.

**Opportunities for Consensus.** Negotiators were reluctant to support the World Bank’s Pandemic Fund as the financing mechanism within either the CA+ or the IHR, due to lack of oversight by Member States. WHO was seen as a possible alternative, given that it already disburses funding through the Contingency Fund for Emergencies (CFE). However, this is relatively small scale and WHO may not be equipped for larger-scale banking functions.

The potential to raise funds from alternative sources, including global bodies benefiting from pandemic prevention, was also raised. Other potential mechanisms include debt swaps, which are of high importance to least-developed countries. However, some organizations holding debt are not party to the agreement, so redrafting of current text would be required.

The IHR were not originally designed for resource mobilization. A financing mechanism could be included in the CA+ with a cross-reference to its use for strengthening of core IHR capacities. However, not all countries would necessarily be party to the CA+ and IHR negotiations could be concluded before the CA+ is finalized. While not technically constitutionally appropriate, this might require inclusion of a financing mechanism in the IHR. The implications of this shift would need to be carefully assessed.

Consensus in this area is highly dependent on practical arrangements, the likelihood of the CA+ successfully being established, and the desire of Member States to have a financial mechanism with the widest possible membership.

Moving closer to consensus will require the consideration of the following questions:

1. How feasible would it be to expand the CFE to support country response?
2. What governance structures are needed to ensure transparency and accountability for a financial mechanism?
3. How would inclusion of a financial mechanism within the IHR change how they are implemented?
4. Should certain alerts or declarations trigger response financing? What scenarios have been modelled that could guide decision-making?

## 9. *Compliance and Accountability*

**Context:** Post-pandemic reviews high highlighted shortcomings in the mechanisms established to coordinate COVID-19 responses (including the ACT-Accelerator) and in implementation of the IHR leading up to the COVID-19 pandemic.

**Areas of Concern.** Separate compliance and implementation committees (i.e. without joint meetings) could run the risk of fragmentation. Mechanisms for IHR compliance were felt to be weak, but there were concerns that a peer-review mechanism, for example, might be punitive rather than supportive. From this, some countries were concerned about the balance between increasing accountability, while simultaneously encouraging transparency and trust. In addition, there was a perceived lack of clarity surrounding peer-review mechanisms and how they would interact with the COP and the Implementation and Compliance Committee.

**Opportunities for Consensus.** As most multilateral regulatory instruments include some form of compliance mechanism, the key questions around feasibility relate to the sufficiency of resourcing for compliance and whether proposed mechanisms can enhance accountability without being punitive. There were concerns that peer-review mechanisms may lead to ‘shaming’ of countries. It was also felt that development of country IHR competencies would depend on financing mechanism agreements.

Compliance mechanisms in international treaties often take time to mature and may evolve after initial agreement to reflect shifts in scientific consensus and to address challenges in implementation. The exchange of reliable information is dependent upon both trust and transparency; however, existing treaties vary in the approaches taken to encourage transparency and trust between parties.<sup>10</sup> Possible options include self-reporting, a global stocktake, and an implementation and compliance committee.<sup>11</sup>

Coming closer to consensus could require consideration of the following questions:

1. What are the advantages and disadvantages of a peer-review mechanism?
2. What is the role for onsite visits? Are they an adequate replacement for peer review mechanisms?
3. Could sufficient financial resources be raised for the effective operation of an IHR Implementation and Compliance Committee?
4. Would a joint compliance mechanism or a Complementarity Committee be needed to ensure alignment across instruments?

---

<sup>10</sup> Strobeyko, A., Morich, D., Burci, G. L., Moon, S. 'Synthesis: Implementation and Compliance Tools In International Law And Pandemic Rulemaking' in: Burci et al. 'Implementation and Compliance in International Law: Implications for Pandemic Rulemaking.' Global Health Centre Discussion Paper, Geneva Graduate Institute, 2023. Retrieved via: <https://repository.graduateinstitute.ch/record/301626>, p. 27

<sup>11</sup> Daniela Morich and Adam Strobeyko, 'Lessons from Multilateral Environmental Agreements: Mechanisms For Implementation, Compliance And Disputes Resolution' in Burci et al. 'Implementation and Compliance in International Law: Implications for Pandemic Rulemaking.' Global Health Centre Discussion Paper, Geneva Graduate Institute, 2023. Retrieved via: <https://repository.graduateinstitute.ch/record/301626>, p. 26

# Introduction: The Need for a Pandemic Accord and IHR Amendments

The COVID-19 pandemic highlighted significant shortcomings in the world's ability to respond in a coherent and equitable way to an emerging new threat to health. It was punctuated by overlapping and interlinked challenges, including the hoarding of supplies many levels above what individual countries needed, poor transparency and oversight into vaccine allocation mechanisms, shortages of essential medical supplies such as oxygen, and questions about the efficacy of International Health Regulations (IHR) for pandemic preparedness and response.

These shortcomings led to calls for a revisiting of the international legal framework governing global and country action before and during potential Public Health Emergencies of International Concern (PHEICs), as well as a review of what happens when such PHEICs turn into pandemics. These concurrent negotiations comprise the Pandemic Accord (CA+) and the amendments to the IHR:

**Pandemic Accord** In December 2021, the World Health Assembly (WHA) established an Intergovernmental Negotiating Body (INB) to draft and negotiate an international instrument on pandemic prevention, preparedness and response, now known as the CA+. The key outcome of ongoing negotiations will be a draft instrument that will be submitted for consideration by the 77th World Health Assembly in May 2024. A 'zero draft' of the Pandemic Accord was published in February 2023, providing an opportunity for all stakeholders to comment. On 22 May 2023, a Bureau's Text was published, which consolidated all diverging country negotiator feedback into specific options.

**IHR Amendments** Updating of the IHR was recommended by the Independent Panel on Pandemic Preparedness and Response.<sup>12</sup> In 2022, the WHA approved a resolution to halve the period for IHR amendments to take effect from two years to one year. A two-year amendment process was also approved, with a view to a package of reforms being presented to the WHA in May 2024. The Working Group on Amendments to the International Health Regulations has published a compilation of the proposed amendments made by Member States.<sup>13</sup>

At the same time, WHO began internal consultations on a **medical countermeasures platform (MCP)** that would operate in the interim prior to the CA+ coming into force and being ratified by country legislative bodies. It was envisioned that the MCP would be a multi-disease, end-to-end platform facilitating the rapid development of, and equitable access to, pandemic tools, building on learnings from the Access to COVID-19 Tools Accelerator (ACT-A), Pandemic Influenza Preparedness Framework (PIP) and other relevant inter-agency initiatives.

In May 2023 an options paper was produced following months of discussions on a prototype working group. However, this has yet to receive country support. In addition, it has received heavy critique, including that it has "more or less the same stakeholders and largely following the same overall ideas"<sup>14</sup> and has been designed without significant input from the Global South.<sup>15</sup> While not currently mentioned in either the CA+ or IHR texts, the medical countermeasures platform is contained in a draft declaration for the United Nations High Level Meeting on Pandemic Preparedness and Response planned for September 2023.

---

<sup>12</sup> Independent Panel for Pandemic Preparedness and Response, 'COVID-19: Make It The Last Pandemic' (May 2021) <<https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemicfinal.pdf>> accessed 1 August 2023

<sup>13</sup> WHO, 'Article-by-Article Compilation of Proposed Amendments to the International Health Regulations (2005) submitted in accordance with decision WHA75(9)' (2022) <[https://apps.who.int/gb/wgihhr/pdf\\_files/wgihhr1/WGIHRCompilation-en.pdf](https://apps.who.int/gb/wgihhr/pdf_files/wgihhr1/WGIHRCompilation-en.pdf)> accessed 11 May 2023

<sup>14</sup> Els Torreele, Dr Joanne Liu, Michel Kazatchkine, 'Opinion: Fighting epidemics takes equitable medical countermeasures' Devex (13 June 2023) <<https://www.devex.com/news/opinion-fighting-epidemics-takes-equitable-medical-countermeasures-105676>> accessed 4 July 2023

<sup>15</sup> Priti Patnaik, 'WHO Medical Countermeasures Platform Takes Route from New York to Geneva [UNGA-PPR Text]' *Geneva Health Files* (23 June 2023) <<https://genevahealthfiles.substack.com/p/exclusive-who-medical-countermeasures>> accessed 5 July 2023



# Methodology

This report sets out key overlaps and complementarities of the CA+ Pandemic Accord draft and the proposed IHR amendments, and the medical countermeasures platform where relevant. It examines competing mandates, operational differences, commonalities, appropriateness in placement within each instrument, and feasibility of proposals.

The analysis is based on a desk review of the draft instruments/amendments and peer-reviewed literature, and key informant interviews. The draft instruments referred to in this analysis are:

- Bureau Text of the WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (WHO CA+) (A/INB/4/3, 1 February 2023).<sup>16</sup>
- Working Group on the International Health Regulations (WGIHR) informal briefing session on other mechanisms related to compliance.<sup>17</sup>

A semi-structured questionnaire was designed around nine key thematic areas:

1. Pandemic and PHEIC declarations.
2. Common but differentiated responsibilities.
3. Research and development capacities.
4. Pathogen access and benefit sharing.
5. One Health.
6. Supply chain and logistics
7. Co-development and transfer of technology and know-how
8. A new financial mechanism for pandemic preparation and response.
9. Compliance and accountability.

A total of 32 individuals were interviewed, comprising 15 country negotiators and government representatives (five from Africa, four from Europe, three from Latin America and the Caribbean, and three from Asia), six legal experts, three One Health experts, one public health expert, one supply and logistics expert, and six civil society experts. Most negotiators and legal experts were repeatedly consulted during the writing of this report for validation and verification substance and context, both in-person and virtually. Interviews were transcribed using Otter.ai and thematically analysed. After identifying key themes, a further in-depth search of the literature was conducted to find triangulating and corroborating documents and studies. To avoid having a global health architecture that is a “pandemic puzzle of fragmented obligations”,<sup>18</sup> textual proposals and thematic issues were assessed along the parameters in [Figure 1 below](#), and opportunities for consensus were triangulated from both legal expert and negotiator testimony.

The executive summary of this report was distributed and presented to WHO AFRO Health Ministers and officials at the WHO AFRO Regional Committee meetings on 28<sup>th</sup> August 2023, held in Gaborone, Botswana.

**Disclaimers.** Negotiator opinions and positions represent a snapshot at a point in time. All quotes from negotiators and experts are accompanied by the date of interview. Given the dynamic nature of negotiations, positions may shift as trade-offs and concessions are made. At time of writing, there are plans to develop a Second Edition of this document as negotiations progress. Additionally, the views and opinions expressed in this report are those of the speakers and do not necessarily reflect the views or positions of the author, University of the Witwatersrand or Open Society Foundations.

<sup>16</sup> Intergovernmental Negotiating Body, Bureau’s text of the WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (WHO CA+) (A/INB/5/6) <[https://apps.who.int/gb/inb/pdf\\_files/inb5/AINB56-en.pdf](https://apps.who.int/gb/inb/pdf_files/inb5/AINB56-en.pdf)> accessed 5 July 2023

<sup>17</sup> WGIHR informal briefing session on other mechanisms related to compliance <<https://who.zoom.us/rec/play/iimp3-oSYSi9ltQMTyLLRhDvETH-8g6pgUhc4YXmu3JKmjnnlybPbqnWmAonoC6DSMNUiKmbzP83Sv.1eQSZfBe9XFxl7Wk?canPlayFromShare=true&from=shareRecordingDetail&continueMode=true&componentName=rec-play&originRequestUrl=https%3A%2F%2Fwho.zoom.us%2Frec%2Fshare%2FiBtiqXgehqql0gDDuOEIJkxAutoj8GQaR5FzxSNrQ842Y70dPAMimKpaerKt6Nh.S0kioScxpl-ZAZCo>> accessed 18 April 2023

<sup>18</sup> Pedro Villareal, in Graduate Institute seminar, ‘Averting A Collision Course? Beyond The Pandemic Instrument and The International Health Regulations’ (26 April 2023) <<https://www.graduateinstitute.ch/communications/events/pandemic-instrument-and-ihr-event>> accessed 11 May 2023

**Notes on formatting of this report.** Quotes from negotiators, government representatives and experts obtained for this report are presented in blue, with the date of interview, and are center aligned. Excerpts from literature and documentation are preceded by :: :: and followed by details of the author and document cited. Each of the nine discussed areas has a boxed section titled Areas of Concern. These are Areas of Concern expressed by negotiators and experts and are subject to disclaimers in this section.



# Legal Characteristics of Health Treaties and Regulations

Treaties are the main legal tool regulating the relationship between states.<sup>19</sup> Treaty nomenclature varies and includes conventions, pacts and accords. Whether such instruments are treaties depends not on their labels but on their content and the legitimacy bestowed upon them by negotiating countries and international bodies.<sup>20</sup>

Over the course of negotiations on the Pandemic Accord, concerns have emerged as regards the name of the instrument – whether it should be named a Treaty, a Framework Convention, an Accord, or indeed whether it is more suited as a Regulation under Article 21 of the WHO Constitution. Some of these concerns originate from the sensitivity around international agreements within a United States context. In the United States, only six percent of international agreements have gone through the Senate ratification process,<sup>21</sup> illustrating the controversial nature of international agreements in the US. This has resulted in strategic positioning of issues within the proposed CA+ text and in the IHR, to which the US is already a party.

The IHR is an example of a regulation developed under Article 21. Article 21 of the WHO Constitution refers to authority to create regulations pertaining sanitary and quarantine requirements, procedures designed to prevent the international spread of disease, disease nomenclatures, diagnostics standards, pharmaceutical safety, purity, and potency standards, and advertising of pharmaceutical products. Article 19 pertains to ‘conventions or agreements with respect to any matter within the competence’ of WHO.<sup>22</sup>

A UK House of Commons Research Briefing has stated that the Pandemic instrument is more likely to be modelled as a ‘Framework Convention,’ rather than as a ‘conventional’ treaty.<sup>23</sup> What the pandemic instrument is eventually called is a decision for Member States. To facilitate decision-making, this section briefly describes characteristics of different legal instruments and their characteristics.

The concept of a framework convention is relatively recent. It is not a technical legal term, but there are common characteristics of established framework conventions that can inform a definition and help to establish legal characteristics of such an instrument. As such, a framework convention is a legally binding treaty<sup>24</sup> that creates general obligations, with more detailed rules and specific targets set in parallel or subsequent agreements between the parties,<sup>25</sup> thereby creating a ‘larger regulatory regime in a two-step procedure’.<sup>26</sup>

The reasons for selecting the term framework convention rather than treaty are political rather than legal, since framework conventions are a type of legal treaty. The rationale for adopting the term framework convention is often rooted in the inability to achieve consensus on certain issues, creating the need to delegate some issues to subsequent protocols. As Professor Nele Matz-Lück describes:

---

<sup>19</sup> Nele Matz-Lück, ‘Framework Conventions as a Regulatory Tool’ (2009) 3 *Goettingen Journal of International Law* 1, 439-458, p. 442

<sup>20</sup> U.S. Department of Health and Human Services, ‘International Agreements’ <<https://www.phe.gov/s3/law/Pages/International.aspx#:~:text=Under%20international%20law%2C%20a%20treaty,which%20makes%20it%20a%20treaty>> accessed 6 August 2023

<sup>21</sup> Congressional Research Service, ‘Treaties and Other International Agreements: The Role of the United States Senate’ 39 (2001) <<https://www.govinfo.gov/content/pkg/CPRT-106SPRT66922/pdf/CPRT-106SPRT66922.pdf>> accessed 6 August 2023

<sup>22</sup> WHO Constitution <<https://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf>> accessed 5 July 2023

<sup>23</sup> Dr Patrick Butchard and Bukky Balogun, ‘The WHO Pandemic Preparedness Treaty’ House of Commons Library (2 June 2023) <<https://researchbriefings.files.parliament.uk/documents/CBP-9550/CBP-9550.pdf>> accessed 6 August 2023

<sup>24</sup> Economic Commission for Europe, ‘Note by the Secretariat’ (October 2011) <<https://unece.org/fileadmin/DAM/hlm/sessions/docs2011/informal.notice.5.pdf>> accessed 1 August 2023

<sup>25</sup> Nele Matz-Lück, ‘Framework Conventions as a Regulatory Tool’ (2009) 3 *Goettingen Journal of International Law* 1, 439-458, p. 440

<sup>26</sup> *Ibid.*, p. 441



*The reasons for choosing a process that takes several steps to regulate an issue may be political rather than legal, e.g. when states agree on the urgency to address a question more generally but cannot reach consensus on all the details of a regulation without further (and potentially lengthy) negotiation.<sup>27</sup>*

– Professor Nele Matz-Lück, ‘Framework Conventions as a Regulatory Tool’ (2009)

While a framework convention is a type of treaty, the word treaty carries the weight of the intention of the contracting parties ‘to create legal rights and duties’.<sup>28</sup> Hence a framework convention plus subsequent protocols may be more palatable for areas of deadlock or where consensus will require time.

A treaty or convention has a different legal character compared to regulations, in that it is used to mobilize political will<sup>29</sup> and ‘facilitate multilateral cooperation’ where domestic law and other policy responses (such as other international legal instruments) have been inadequate:



*Treaty law, often referred to as conventional international law, has received new prominence as a mechanism or a tool that can be used by states **to facilitate multilateral cooperation** in this era of globalization, as states increasingly recognize the need for international cooperation to attain national public health objectives **for which domestic law and other policy responses are increasingly inadequate.**<sup>30</sup>*

– Allyn L Taylor (2017) *International Encyclopedia of Public Health*

In addition, with the INB and IHR processes running concurrently, concerns have been raised about the potential for overlap, duplication, or inconsistencies across the different instruments. The relationship between the different instruments remains uncertain, and it is not currently clear how their implementation would be integrated and/or synergized. One interview with a Global South negotiator indicates that some thought has already been given to this issue:

---

*“We understand that ‘political issues’ should go into the [pandemic accord], which is governed under Article 19, although some provisions may go under Article 21. Whereas the amendments to the IHR are governed by Article 21. This makes a big difference for us because of the leverage we have to obtain gains in the INB depends on what happens with the amended IHR. And [another] problem is that the IHR deals with health emergencies overall and the INB with pandemics, so very limited circumstances. If we want to put very strong provisions in the INB text, at the end of the day they will be accepted in very, very limited circumstances i.e., a pandemic.”*

*(Global South negotiator, interviewed 4 July 2023)*

---

This illustrates several points. The statement about ‘political issues’ in the Accord speaks about the nature of accord/treaty/convention legal instruments (Article 19) versus regulations (Article 21).

---

<sup>27</sup> Nele Matz-Lück, ‘Framework Conventions as a Regulatory Tool’ (2009) 3 *Goettingen Journal of International Law* 1, 439-458, p. 450

<sup>28</sup> United Nations Treaty Collection, ‘Definitions’ < [https://treaties.un.org/Pages/overview.aspx?path=overview/definition/page1\\_en.xml#treaties](https://treaties.un.org/Pages/overview.aspx?path=overview/definition/page1_en.xml#treaties) > accessed 6 August 2023

<sup>29</sup> Maïke Voss and others, ‘A new pandemic treaty: what the World Health Organization needs to do next’ *LSE Blogs* (30 March 2022) < <https://blogs.lse.ac.uk/covid19/2022/03/30/a-new-pandemic-treaty-what-the-world-health-organization-needs-to-do-next/> > accessed 5 July 2023

<sup>30</sup> Allyn L Taylor, *Global Health Law: International Law and Public Health Policy*. *International Encyclopedia of Public Health*. 2017:268–81. doi: 10.1016/B978-0-12-803678-5.00238-1. Epub 2016 Oct 24. PMID: PMC7150305

According to Gian Luca Burci, legal scholar and former Legal Counsel at the WHO, the IHR 2005 are “the first line of defence against the international spread of infectious and other diseases”.<sup>31</sup> Their *raison d’être* pertains to the development, strengthening and maintenance of ‘core capacities’ to ensure timely surveillance and response, and the issuance of temporary recommendations to countries by the WHO Director-General. Burci also notes that the IHR are not an operational instrument for the mobilization of financial and human resources.<sup>32</sup>

The point the Global South negotiator makes above about the application of the Pandemic Accord in ‘limited circumstances’ raises questions about the need for both IHR and the Accord. One legal expert explains that treaty instruments are political signals of priority and are useful to advance issues where universal adherence will take time to achieve, and to ensure an issue remains prominent for a longer period of time:

---

*“What do you need a pandemic accord for, if issues like ABS [access and benefit sharing] are addressed through amendments in the IHR? That’s an important question, with lots of really good answers. One answer is that a pandemic accord is still needed to ensure a whole-of-government and whole-of-society approach to sustainably scale up pandemic prevention, preparedness and response. **Treaties are important signals of priority, both globally and nationally.** Another possible answer is that an accord **can help advance issues where universal adherence will take time.** On issues like compliance review mechanisms, adherence may take time to develop. With experience and trust in such mechanisms, states that are today hesitant may join over time. Other issues that an accord could advance with time include specific steps to strengthen human rights, for example by encouraging countries to establish or strengthen domestic human rights bodies at the national level to safeguard rights during pandemics. In sum, **a pandemic accord can be a key driver to ensure that PPR maintains a global profile and priority.** And that’s not a theoretical benefit; that’s evidence based. We know that because we see what has happened with the FCTC [Framework Convention on Tobacco Control] – a treaty where parliaments have acted decisively, even when they had flexibility under the treaty itself. Indeed, if you read the FCTC, it’s clear that countries have discretion in many areas. It very carefully preserves state sovereignty. Yet parliament after parliament have adopted laws prohibiting comprehensively smoking in public places, requiring even more prominent tobacco warnings on packaging, and more. This occurred at least in part because parliaments saw the treaty as an international standard at a very high level. The pandemic accord can help achieve similar decisive steps at the national and international level.”*

*(Legal expert, interviewed 4 May 2023; emphasis added)*

---

Conversely, in an article in Geneva Health Files, WGIHR chair Abdullah Asiri of Saudi Arabia stated that the IHR had the character of ‘unanimous acceptance’<sup>33</sup>, acting as an instrument for more universally accepted provisions. This is particularly relevant given that a Pandemic Accord is unlikely to be ratified by all Member States, given concerns around national sovereignty,<sup>34</sup> among other reasons. This reality means that negotiators are viewing inclusion of provisions in the IHR from a political standpoint, rather than just considering the legal character of the instrument. As legal expert Professor Suerie Moon describes:

---

*“A number of countries have been asking to have issues included in the IHR as a negotiating strategy, which makes sense in case they don’t get anything in a Pandemic Accord. And the US is unlikely to be legally bound by a pandemic accord and so the more you can get into a legally binding IHR – even if it’s not by some accounts as strong a legal obligation as a treaty – and bind*

---

<sup>31</sup> Gian Luca Burci, ‘The Legal Response to Pandemics: The Strengths and Weaknesses of the International Health Regulations’ (2020) *Journal of International Humanitarian Legal Studies* 11, 204-217, 206

<sup>32</sup> Gian Luca Burci, ‘The Legal Response to Pandemics: The Strengths and Weaknesses of the International Health Regulations’ (2020) *Journal of International Humanitarian Legal Studies* 11, 204-217, 207

<sup>33</sup> Priti Patnaik & Nishant Sirohi, ‘Countries Split Between Retaining Existing Scope on Surveillance Vs Widening Commitments on Equity in the Amendments to IHR’ *Geneva Health Files* (21 April 2023) < [https://genevahealthfiles.substack.com/p/exclusive-countries-split-between?utm\\_source=%2Fsearch%2Fcompliance&utm\\_medium=reader2](https://genevahealthfiles.substack.com/p/exclusive-countries-split-between?utm_source=%2Fsearch%2Fcompliance&utm_medium=reader2)> accessed 11 May 2023

<sup>34</sup> Daniel Funke, ‘False claims about WHO pandemic accord resurface online’ AFP (27 February 2023) <<https://factcheck.afp.com/doc.afp.com.339W4CQ>> accessed 13 July 2023

*the US could be an important benefit. Politically it makes perfect sense for countries to ask for a lot more to be put into the IHR.”*

*(Professor Suerie Moon, Co-Director at the Global Health Centre and Professor of Practice for the Interdisciplinary Programmes, Graduate Institute)*

---

These concerns may be mitigated in the long term by a potential replication of what occurred with the Framework Convention on Tobacco Control (FCTC). While the US has never ratified the FCTC, it was a strong political signal that saw reforms occur all over the world – including in the US. The political signal sent by an accord may lead to a similar domino effect. The argument that the Accord would send a stronger political signal was also echoed by a Global South negotiator:

---

*“The value of the pandemic instrument is that it has to be ratified by Member States. Once it is ratified, while both are legally binding, one is going to be worth more than the other. [Ratification] means that there will be strong internal discussion in a national capacity to ratify it. That will make each commandment stronger than any commandment that is in the IHR. Secondly, it’s about the signal that you send internationally – I don’t think amendments in the IHR are a strong enough signal to a Member State to say we understand how we’ll deal with this. It is a stronger signal to the world, to our congress, to our media, that we’re signing an instrument and we’re going to do things differently. With a pandemic instrument, like with the FCTC, we can meet periodically in a COP and see how implementation is going. And I think that’s what’s missing in the IHR.”*  
*(Global South Negotiator 3, interviewed 19 May 2023)*

---

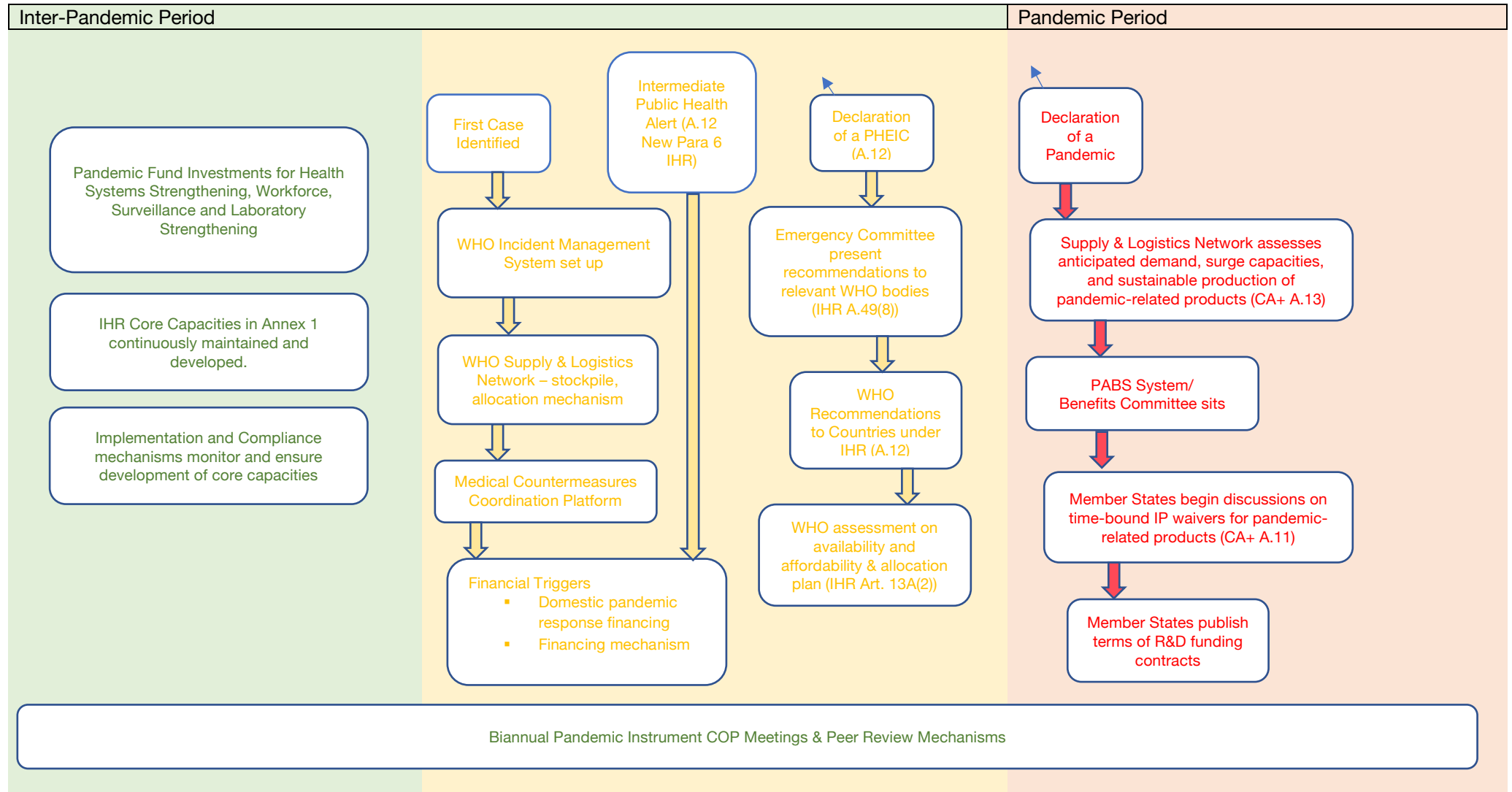
Based on the above, Figure 1 sets out the key legal and constitutional characteristics of Article 21 regulations such as the IHR versus Article 19 INB’s CA+.

Conventions/Treaties (Pandemic Accord)	Regulations (IHR Amendments)
<ul style="list-style-type: none"><li>• Political signal of priority</li><li>• For issues where universal adherence will take time</li><li>• To facilitate multilateral cooperation where domestic law and other policy have failed</li></ul>	<ul style="list-style-type: none"><li>• First line of defence against health emergencies</li><li>• Pertaining to competencies, nomenclature, temporary recommendations, prevention</li><li>• Not designed for the mobilization of financial and human resources.</li></ul>

Figure 1: Legal characteristics of the Pandemic Accord versus the IHR amendments.

# Pandemic Instruments, Mechanisms and Provisions: An Illustration of their Real-Time Application

**Note:** This diagram serves as an illustration of selected provisions in the CA+ and IHR in operation. Due to space and the evolving nature of negotiations, it is not meant to comprehensively represent all sections under negotiation, but to serve as a visual aide.



# Findings

## *Declaration of Pandemics versus Public Health Emergencies of International Concern (PHEICs)*

**Introduction.** Declarations are inextricably linked to what they trigger – whether this is financing, benefit sharing, coordination, advice to countries, or a multitude of different actions. For example, the declaration of a PHEIC in the IHR triggers several existing actions, such as consultations with the Emergency Committee and the issuance of temporary recommendations to countries.<sup>35</sup>

By contrast, there are numerous other efforts that occur without needing a declaration as a trigger or they occur in the inter-pandemic period. This includes ongoing work to develop IHR core capacities such as laboratory strengthening, collaborative surveillance networks, and socio-culturally appropriate information dissemination and risk management.

**Objective of Instrument Provisions.** To establish clear procedures and triggers at the onset of health emergencies and pandemics for the mobilisation of resources for response.

### **Relevant Provisions** (selected).

CA+ Pandemic Accord Article 15(2)	No provision on pandemic declaration. [Option 15.A]  Recognises WHO's central role as directing and coordinating authority on international health work, WHO Director-General shall determine whether to declare a pandemic. [Option 15.B]
IHR Amendments Article 12	Based on an assessment under IHR, followed by consultation with States Parties where the event is occurring, and the views of an Emergency Committee established under Article 48, the Director-General of WHO shall notify all States Parties of a Public Health Emergency of International Concern (PHEIC).
IHR Amendments Article 12(4bis)	The PHEIC declaration is not designed to mobilise funds in the case of an emergency event. The Director-General should use other mechanisms for this purpose.
IHR Amendments Article 12 (New Para 6)	Where an event does not meet the criteria for a PHEIC, but the WHO DG determined it requires heightened international awareness and a potential international public health response, the DG may issue an <b>intermediate public health alert/World Alert and Response Notice/communication notifying potential to develop into a PHEIC/regional PHEIC</b> to States Parties.
IHR Amendments Article 49(8)	After the PHEIC declaration, the Emergency Committee should present its recommendations to relevant WHO bodies dealing with health emergencies, including the Standing Committee on Health Emergency Prevention, Preparedness and Response.

### **Areas of Concern**

1. What should declarations trigger? Should explicit linkages be limited only to financing and to coordination mechanisms, or should these extend to supply-related mechanisms and assessments?
2. Could a definition and mechanism for declaration of a pandemic be included in the IHR so that a declaration both (a) applies to all States Parties and (b) triggers provisions within the Pandemic Accord?
3. Would the inclusion of a pandemic definition and mechanism for declaration in the IHR prevent regional health bodies from declaring regional public health emergencies?
4. Is a PHEIC too late of an alert for financing of pandemic response? Should financing and response be triggered by an intermediate public health alert (Article 12(New Para 6) IHR Amendments)?

<sup>35</sup> International Health Regulations, Article 12



### Areas of Concern

6. As the scope and governance of a medical countermeasures platform (MCP) have yet to be defined, is it necessary at this stage to discuss which declaration triggers its operation?
7. Would the inclusion of multiple explicit linkages between declarations and responses and actions introduce unnecessary rigidity, when pandemic responses need flexibility and agility?
8. Can new definitions such as the pandemic definition legally reference the PHEIC terminology?

**Cross-references and incompatibilities.** Between the two instruments, there are three declarations: the PHEIC declaration (Article 12(2) IHR Amendments), the Intermediate Health Alert/World Alert and Response Notice (Article 12(New Para 6) IHR Amendments), and the Pandemic Declaration (CA+ Article 15(2) Option 15.B).

There is no official guidance or regulations on the order of the PHEIC and pandemic declarations. According to the WHO COVID-19 Technical Lead, Maria van Kerkhove, a PHEIC declaration is to “coordinate immediate action before that event becomes even bigger, and potentially becomes a pandemic”.<sup>36</sup> This is consistent with what happened during COVID-19 – a PHEIC was declared in January 2020 and the pandemic declaration followed in March 2020. Based on this the order would be Intermediate Health Alert/World Alert and Response Notice → PHEIC declaration → pandemic declaration.

The CA+ Bureau’s Text proposes a definition of a pandemic composed of several elements, including the need for “sustained and high transmissibility from person to person” and “causing social and economic disruptions”.<sup>37</sup> However, it does not link to the PHEIC or Intermediate Health Alert definitions and declarations.

Declarations are inextricably linked to what they trigger, discussed in detail in the analysis section below. G20 discussions suggest that the declaration of a PHEIC for COVID-19 was too late for resource mobilization to support initial control efforts<sup>38</sup> and that there should be an intermediate alert to ensure more timely responses. However, the Intermediate Public Health Alert as proposed in the IHR Amendments is not explicitly linked to the proposed Financial Mechanism. Linkages between alerts and financial triggers may only be able to be finalized when Financial Mechanism negotiations are concluded.

**Opportunities for Consensus.** A PHEIC declaration is a response-related measure contained in the IHR and was deemed appropriate when included in the 2005 round of IHR amendments. Hence the inclusion of an Intermediate Public Health Alert remains within the purview and scope of the IHR. Some questions remain as to whether a declaration of a pandemic should therefore be included in the IHR with all the other declarations or whether a pandemic declaration is needed at all. Member State discussions at the joint INB-WGIHR meeting in July 2023 illustrate that Member States may be inclined to include the pandemic definition and declaration within the IHR so as to link to the PHEIC provisions therein.

The IHR provisions also detail several events that occur after a PHEIC has been declared. These include consultation between the WHO Director-General and the WHO Emergency Committee, recommendations to countries, assessments on availability and affordability of health products, and the development of an allocation plan for health products. What the Intermediate Health Alert and the pandemic declaration would trigger have yet to be discussed in detail. The preceding section of this report provides a visual illustration of some potential scenarios. Negotiators cautioned that too many explicit linkages to the declarations could reduce flexibility, but agreed that the Financial Mechanism should be explicitly linked to a trigger.

### Analysis.

A PHEIC is the strongest global alert the WHO can formally make and, when it is declared, countries have a legal duty to respond quickly. For a pandemic declaration, by contrast, there is no formally established decision-making process,

<sup>36</sup> WHO, ‘What’s the difference between Public Health Emergency of International Concern (PHEIC) and pandemic?’ *YouTube* (26 February 2023) <<https://www.youtube.com/watch?v=GAfZlnbtioY>> accessed 11 May 2023

<sup>37</sup> Intergovernmental Negotiating Body, ‘Bureau’s text of the WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (WHO CA+)’ (2 June 2023) A/INB/5/6 <[https://apps.who.int/gb/inb/pdf\\_files/inb5/AINB56-en.pdf](https://apps.who.int/gb/inb/pdf_files/inb5/AINB56-en.pdf)> accessed 18 July 2023

<sup>38</sup> WHO, for the G20 Joint Finance – Health Task Force, ‘Surge financing for the coordinated international response to a pandemic through multilateral implementing agencies: An overview of the scale & speed of requirements’ (20 March 2023), p. 10



agreed criteria, or agreement of what countries need to do in response.<sup>39</sup> For COVID-19, a PHEIC was declared on 30 January 2020.<sup>40</sup> On 11 March 2020, the WHO Director-General declared the COVID-19 outbreak to be a pandemic, but that statement did not fall under the IHR 2005.<sup>41</sup> The CA+ attempts to remedy this anomaly by including a placeholder on the declaration of a pandemic. These definitions are important because they determine what is triggered, such as financing and resource mobilization, and benefit sharing agreements. There are also additional considerations. As Pedro Villareal, Senior Research Fellow at the Max Planck Institute for Comparative Public Law stated in an April 2023 Graduate Institute seminar: “Not all Public Health Emergencies of International Concern will be pandemics,”<sup>42</sup> and therefore careful consideration is needed to decide the implications of declarations. As discussed elsewhere in this section, intermediate alerts have been introduced into the IHR text to ensure flexibility and speediness with declaration-related triggers, and said careful consideration on implications and triggers should be deployed here as well.

At time of writing, there is no agreed/endorsed definition of what constitutes a pandemic, although the CA+ draft text proposes the following definition:

⋮ ⋮ ⋮

*“pandemic” means the global spread of a pathogen or variant that infects human populations **with limited or no immunity through sustained and high transmissibility from person to person**, overwhelming health systems with severe morbidity and high mortality, **and causing social and economic disruptions**, all of which require effective national and global collaboration and coordination for its control.*<sup>43</sup>

— *Bureau’s text of the WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (WHO CA+) (2 June 2023)*

This definition was discussed in a joint INB and IHR session in late July 2023. Crucially, in an article in Geneva Health Files, Dr Mike Ryan, Executive Director at the Health Emergencies Programme at WHO, highlighted the difficulties around getting a pandemic definition right because so many aspects of an outbreak are unclear at its earliest stages:

⋮ ⋮ ⋮

*The definition that’s in the CA+ ... looks great. But then you recognise that much of the determination is post-factual. We have to remember, in a rapidly developing event, we don’t know the extent (of) spread, (sic) we don’t often have diagnostics, we don’t understand the severity, that’s changing in different places. And the severity may be different. The intensity may be different. So, you’re dealing with a moving object.*<sup>44</sup>

— *Dr Mike Ryan, Executive Director, Health Emergencies Programme, WHO, quoted in Geneva Health Files (26 July 2023)*<sup>45</sup>

---

<sup>39</sup> Emma Ross, ‘What is the difference between a pandemic and a PHEIC?’ Chatham House (20 October 2022) <<https://www.chathamhouse.org/2022/10/what-difference-between-pandemic-and-pheic>> accessed 10 May 2023

<sup>40</sup> WHO, ‘COVID-19 Public Health Emergency of International Concern (PHEIC) Global research and innovation forum’ (12 February 2020) <[https://www.who.int/publications/m/item/covid-19-public-health-emergency-of-international-concern-\(pheic\)-global-research-and-innovation-forum](https://www.who.int/publications/m/item/covid-19-public-health-emergency-of-international-concern-(pheic)-global-research-and-innovation-forum)> accessed 11 May 2023

<sup>41</sup> Gian Luca Burci, ‘The Legal Response to Pandemics: The Strengths and Weaknesses of the International Health Regulations’ (2020) *Journal of International Humanitarian Legal Studies* 11, 204-217, 205

<sup>42</sup> Pedro Villareal, in Graduate Institute seminar, ‘Averting A Collision Course? Beyond The Pandemic Instrument and The International Health Regulations’ (26 April 2023) <<https://www.graduateinstitute.ch/communications/events/pandemic-instrument-and-ihr-event>> accessed 11 May 2023

<sup>43</sup> Intergovernmental Negotiating Body, ‘Bureau’s text of the WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (WHO CA+)’ (2 June 2023) A/INB/5/6 <[https://apps.who.int/gb/inb/pdf\\_files/inb5/AINB56-en.pdf](https://apps.who.int/gb/inb/pdf_files/inb5/AINB56-en.pdf)> accessed 18 July 2023, Article 1(1)(b)

<sup>44</sup> Intergovernmental Negotiating Body, ‘Bureau’s text of the WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (WHO CA+)’ (2 June 2023) A/INB/5/6 <[https://apps.who.int/gb/inb/pdf\\_files/inb5/AINB56-en.pdf](https://apps.who.int/gb/inb/pdf_files/inb5/AINB56-en.pdf)> accessed 18 July 2023, Article 1(1)(b)

<sup>45</sup> Priti Patnaik, Nishant Sirohi, and Tessa Jager, ‘Decisive Discussions on Definition, Declaration of a Pandemic; Developed Countries’ Push to Park Access to Countermeasures in the INB?’ *Geneva Health Files* (26 July 2023) <[https://genevahealthfiles.substack.com/p/decisive-discussions-on-definition?utm\\_source=post-email-title&publicationid=79396&postid=135396019&isFreemail=false&utm\\_medium=email](https://genevahealthfiles.substack.com/p/decisive-discussions-on-definition?utm_source=post-email-title&publicationid=79396&postid=135396019&isFreemail=false&utm_medium=email)> accessed 4 August 2023

Furthermore, Ryan also pointed out that mpox and polio were never declared as pandemics but could have fit within the Bureau Text definition,<sup>46</sup> and argued that it was important for Member States to discuss potential scenarios.

Country interventions during this joint session were varied. Australia stated that both the PHEIC and pandemic definitions were “key to triggering major obligations in the respective instruments” and that the pandemic declaration should be included in the IHR.<sup>47</sup> India presented an opposing view, arguing that, because of the significant economic, traffic and trade disruptions, that it was inappropriate for the pandemic definition to be included in the IHR.<sup>48</sup> The European Union, while not commenting on the placement of the provision within either the IHR or CA+, suggested a less stringent definition to account for gaps in knowledge in a potential pandemic situation, including language such as ‘is likely to spread over a wide geographical area’ and ‘is likely to create a severe social disruption and economic loss.’<sup>49</sup> Questions also arose whether the term PHEIC should be included in the definition of a pandemic, perhaps to illustrate progression between the two. As Steve Solomon, WHO’s Principal Legal Officer described, cross-referencing terms is often done in other agreements and there would be no obstacle to doing so with the pandemic definition:

⋮ ⋮ ⋮

*With respect to the question of including the term PHEIC in a definition of a pandemic. This is also possible.....you can see (that) Member States have done this with definitions in a range of areas where they have defined a term and then use the understanding for that defined term in other defined terms. It’s a building block approach to language and it is helpful both from an implementation perspective and an interpretation perspective.”<sup>50</sup>*

— Steve Solomon, Principal Legal Officer, WHO, quoted in Geneva Health Files (26 July 2023)<sup>51</sup>

On cross-referencing of the two definitions (PHEIC and pandemic), there seems to be no legal obstacle to the pandemic definition (and therefore declaration) being included in the IHR alongside the PHEIC definition and to trigger provisions in the Pandemic Accord.

In terms of what each declaration (i.e. pandemic and PHEIC) would trigger, one legal expert suggested that a pandemic should trigger benefit-sharing measures and mechanisms for equitable distribution of key medical supplies:

---

*“The idea is that in terms of what it [the pandemic declaration] will trigger different from a PHEIC, the answer is it will at a minimum trigger the acute benefit sharing aspects of a pandemic declaration and there will be there will be continuous benefit sharing for pathogens with pandemic potential and GSD [genome sequence data]. But at the onset of a pandemic, it will be vitally important, as we saw from COVID-19, that pandemic-related products, i.e., the whole suite of medical and care countermeasures and said safeguards, including PPE and diagnostic kits, be available to WHO in real time and with the declaration of a pandemic be released for allocation based on a WHO evidence-based process.”<sup>52</sup>*

---

<sup>46</sup> Priti Patnaik, Nishant Sirohi, and Tessa Jager, ‘Decisive Discussions on Definition, Declaration of a Pandemic; Developed Countries’ Push to Park Access to Countermeasures in the INB?’ Geneva Health Files (26 July 2023) < [https://genevahealthfiles.substack.com/p/decisive-discussions-on-definition?utm\\_source=post-email-title&publicationid=79396&postid=135396019&isFreemail=false&utm\\_medium=email](https://genevahealthfiles.substack.com/p/decisive-discussions-on-definition?utm_source=post-email-title&publicationid=79396&postid=135396019&isFreemail=false&utm_medium=email) > accessed 26 July 2023

<sup>47</sup> Ibid

<sup>48</sup> Ibid

<sup>49</sup> Priti Patnaik, Nishant Sirohi, and Tessa Jager, ‘Decisive Discussions on Definition, Declaration of a Pandemic; Developed Countries’ Push to Park Access to Countermeasures in the INB?’ Geneva Health Files (26 July 2023) < [https://genevahealthfiles.substack.com/p/decisive-discussions-on-definition?utm\\_source=post-email-title&publicationid=79396&postid=135396019&isFreemail=false&utm\\_medium=email](https://genevahealthfiles.substack.com/p/decisive-discussions-on-definition?utm_source=post-email-title&publicationid=79396&postid=135396019&isFreemail=false&utm_medium=email) > accessed 4 August 2023

<sup>50</sup> Steve Solomon, Principal Legal Officer, WHO, quoted in Priti Patnaik, Nishant Sirohi, and Tessa Jager, ‘Decisive Discussions on Definition, Declaration of a Pandemic; Developed Countries’ Push to Park Access to Countermeasures in the INB?’ Geneva Health Files (26 July 2023) < [https://genevahealthfiles.substack.com/p/decisive-discussions-on-definition?utm\\_source=post-email-title&publicationid=79396&postid=135396019&isFreemail=false&utm\\_medium=email](https://genevahealthfiles.substack.com/p/decisive-discussions-on-definition?utm_source=post-email-title&publicationid=79396&postid=135396019&isFreemail=false&utm_medium=email) > accessed 4 August 2023

<sup>51</sup> Priti Patnaik, Nishant Sirohi, and Tessa Jager, ‘Decisive Discussions on Definition, Declaration of a Pandemic; Developed Countries’ Push to Park Access to Countermeasures in the INB?’ Geneva Health Files (26 July 2023) < [https://genevahealthfiles.substack.com/p/decisive-discussions-on-definition?utm\\_source=post-email-title&publicationid=79396&postid=135396019&isFreemail=false&utm\\_medium=email](https://genevahealthfiles.substack.com/p/decisive-discussions-on-definition?utm_source=post-email-title&publicationid=79396&postid=135396019&isFreemail=false&utm_medium=email) > accessed 4 August 2023

<sup>52</sup> Legal expert (interviewed 4 May 2023)

*(legal expert, interviewed 4 May 2023)*

---

The IHR 2005 state that a PHEIC declaration shall enable the WHO Director-General, with the advice of the WHO Emergency Committee, to notify and advise countries on “appropriate temporary recommendations”.<sup>53</sup> The proposed IHR amendments state that the “PHEIC declaration is not designed to mobilize funds in the case of an emergency event. The Director-General should use other mechanisms for this purpose.”<sup>54</sup> (See [section on new Financial Mechanisms](#).)

A new addition to the IHR is the notion of an Intermediate Public Health Alert to remedy criticisms of how responses triggered by the COVID-19 PHEIC declaration unfolded. Professor Gian Luca Burci from the Graduate Institute noted in a 2020 journal article the drawbacks of having a single trigger point:

⋮ ⋮ ⋮

*“The IHR 2005 establishes an unrealistic binary alert system, without any formal level of alert below a PHEIC. This approach is inconsistent with the complex progress of a disease outbreak and may preempt earlier guidance before an event reaches the threshold of a PHEIC.”<sup>55</sup>*

– Gian Luca Burci, *The Legal Response to Pandemics, 2020*

As discussed above, G20 countries considered that a PHEIC declaration was too late for resource mobilization for COVID-19.<sup>56</sup> A report of the G20 [Joint Finance–Health Task Force meeting](#) stated:

⋮ ⋮ ⋮

*During the COVID-19 crisis, the majority of multilateral financing was committed more than 6 months after the declaration of the Public Health Emergency of International Concern (PHEIC), long after the initial surge of cases and the implementation of stringent public health and social measures, such as lockdowns.<sup>57</sup>*

– G20 Joint Finance–Health Task Force: *Surge financing for the coordinated international response to a pandemic through multilateral implementing agencies: An overview of the scale & speed of requirements (March 2023)*

The question remains then whether the Intermediate Health Alert should explicitly be linked to the Financial Mechanism in Article 44A IHR Amendments or the Financial Mechanism in Article 19 of the CA+. In addition, implications for the ‘surge financing’ mechanism being discussed by the G20 Joint Finance–Health Ministers Task Force (JFHTF) need to be considered. The G20 document further states that surge financing “is essential to complement the Pandemic Fund” and that ‘it is needed at the onset of a new pandemic’.<sup>58</sup> Furthermore, the document asks how the surge financing work of the JFHTF can be integrated with the G20 Health Working Group’s work on the design of a new coordination platform for medical countermeasures, emphasizing the need to consider how declarations, financing and are connected.

Negotiators are undecided on whether an intermediate alert level should be created, let alone what it should trigger. In the case of one negotiator from a small country, an intermediate alert could be useful not necessarily to trigger a global response but rather to trigger domestic preparations:

---

*“On the possibility of having an intermediate [alert] – what does this mean? We don’t have a 100% set position on this, but our initial thought is that it’s not such a bad idea to have [an] intermediate*

---

<sup>53</sup> IHR 2005, Article 12(2)

<sup>54</sup> WHO, ‘Article-by-Article Compilation of Proposed Amendments to the International Health Regulations (2005) submitted in accordance with decision WHA75(9)’ (2022) <[https://apps.who.int/gb/wgihp/pdf\\_files/wgihp1/WGIHRCCompilation-en.pdf](https://apps.who.int/gb/wgihp/pdf_files/wgihp1/WGIHRCCompilation-en.pdf)> accessed 11 May 2023, Article 12(4bis)

<sup>55</sup> Gian Luca Burci, ‘The Legal Response to Pandemics: The Strengths and Weaknesses of the International Health Regulations’ (2020) *Journal of International Humanitarian Legal Studies* 11, 204-217, 212

<sup>56</sup> WHO, for the G20 Joint Finance – Health Task Force, ‘*Surge financing for the coordinated international response to a pandemic through multilateral implementing agencies: An overview of the scale & speed of requirements*’ (20 March 2023), p. 10

<sup>57</sup> *Ibid*

<sup>58</sup> *Ibid* p. 2

*public health or regional health alert or prior indication that a Public Health Emergency of International Concern [is coming]. Although [presumably] certain provisions would start to take effect only with the PHEIC? I think that an [intermediate alert] basically to help countries to understand that there might be something coming and predominantly trigger certain things within their [national] system but not necessarily to start a full-fledged global response to anything.”*

*(Global South negotiator, interviewed 4 July 2023)*

---

Another negotiator stated that an intermediate alert could trigger a financing mechanism, but that their country was still studying scenarios and options and would not be deciding on triggers until later in the negotiations:

*“The financing part is more complex. We are still studying questions related to the declaration of emergencies [PHEIC declaration] and some countries have proposed an intermediate level trigger. We are studying that. We know that the decision has to be understood in the larger context of the IHR and INB negotiation.”*

*(Global South negotiator, interviewed 5 July 2023)*

---

Dr Sultani Hadley Matendecheo, the Deputy Director-General of the Kenyan Ministry of Health and Vice Chair of the WGIHR felt that specifying what should happen subsequent to an intermediate public health alert was unnecessary due to existing systems within regions that were already operating and simply need to be optimised. In Dr Matendecheo’s own words:

*“An intermediate public health alert is neither here nor there. We don’t have to provide for this in the IHR or Pandemic Treaty. For instance, we generally experience frequent disease outbreaks in the African region; do we want to have them all declared as intermediate Public Health Emergencies of International Concern? In my considered opinion, members states should continue to strengthen their own processes, even as we encourage and provide within the IHR, for closer collaboration with other countries. This provision can be discretionary or left to the countries involved, to determine how they would wish to react to it. Otherwise, to load everything onto the IHR will most likely lead to loss of focus.”*

*(Dr Sultani Hadley Matendecheo, Deputy Director General for Health, Ministry of Health Kenya, and Vice Chair of the WHO Working Group on Amendments to the International Health Regulations 2005 (WGIHR), interviewed 29 August 2023), interviewed 29 August 2023)*

---

Another question to consider is what declarations trigger with regard to supply and logistics of pandemic-related products. However, as Paul Molinaro, Chief of Operations, Supply and Logistics at WHO suggests, this area may already be covered by established staging protocols:

*“We had [supply and logistics systems set up] before PHEIC is ever declared. During COVID-19, we already had an incident management team set up the night we got the first confirmation on New Year’s Day [2020], i.e., a decision to create an Incident Management System. Then at some point fairly soon after, an internal WHO grading call that allows us to start mobilizing well before the PHEIC is declared. The alarm bells of my technical colleagues were going off way before a PHEIC. And it was on that basis that throughout that month [January 2020], we had the first call with the pandemic supply chain network, logistics cluster partners, the first bilaterals with UNICEF, and the first bilaterals with WFP (World Food Programme) [on supply].”*

*(Paul Molinaro, Chief of Operations Supply and Logistics, WHO, interviewed 18 May 2023)*

---

A question that then arises is whether additional supply and logistics-related activities triggered by pandemic and PHEIC declarations are needed for other reasons, such as flexibility or to avoid overregulation. According to one Global South negotiator, exchange of information about supplies that countries have in stockpiles should occur as part of a 'constant flow of information' under the WHO Global Pandemic Supply Chain and Logistics Network established in the Pandemic Accord rather than initiated as a result of a declaration:

---

*"It will be really important that we have a commitment among the signatories [of the Pandemic Accord] that they are going to be transparent and that they will share information about what they have in stockpile. We don't need a trigger for it because it will be [part of] a constant flow of information. And if we have a pandemic, we will already have that information. If we wait for a trigger to begin collecting that information, it is going to be too late... Not everything in the pandemic instrument will need a trigger."<sup>59</sup>*

*(Global South negotiator, interviewed 19 May 2023)*

---

As discussed in the [Supply section](#) of this report, the CA+ Bureau Text and IHR proposed amendments contain provisions on different supply-related assessments, such as on demand/affordability/availability of products (Article 13A(2) IHR) and "costs and logistics for establishing and maintaining strategic stockpiles"<sup>60</sup> in the CA+, and "anticipated demand" for raw materials for sustainable production of pandemic-related products<sup>61</sup> in the CA+. These assessments would then inform an allocation plan, referred to in both instruments.

It is likely that some of these assessments (particularly on stockpiles of PPE) would be conducted regularly in the interpandemic period. Others may be triggered by declarations and may be relied on by Member States in both domestic pandemic response and in holding other Member States accountable through compliance mechanisms. Furthermore, Paul Molinaro, WHO's Chief of Operations Supply and Logistics, noted that additional work was being conducted within the Health Emergency Preparedness, Response, and Resilience (HEPR) framework to establish different stages and 'drawdown envelopes'.<sup>62</sup> If developed, these could also be useful for defining trigger points.

**Summation.** There is no legal obstacle to the pandemic declaration being contained in the IHR and triggering provisions in the Pandemic Accord. Furthermore, it would be feasible for the pandemic definition to build on the PHEIC definition to indicate progression of an emergency. Inclusion of pandemic declaration in the IHR would ensure that all Member States (even non-ratifiers of a Pandemic Accord) would be alerted to a pandemic situation and be able to take internal protection measures.

Discussions around what different declarations trigger are preliminary, although financing may be an area where explicit linkages are seen as necessary.

Multiple issues need to be considered with regard to declarations of intermediate alerts, PHEICs and pandemics:

1. How can a pandemic definition be established that is flexible, inclusive and sufficiently comprehensive to cover relevant pandemic scenarios?
2. Is an intermediate health alert needed? Should it only trigger national preparedness?
3. What is the appropriate location of provisions related to definitions and declarations? How should definitions and terms be cross-referenced?
4. What should the various declarations trigger? To what extent should financing, supply and other sections be explicitly triggered by declarations?
5. Should a medical countermeasures platform be established, what should trigger this and what governance mechanisms are needed?

Figure 2 below serves as a starting point for discussion and further elucidation of declarations and requisite triggers. See also the [visual mapping](#) earlier in this report.

---

<sup>59</sup> Interview with Global South negotiator 3, interviewed 19<sup>th</sup> May 2023

<sup>60</sup> Intergovernmental Negotiating Body, 'Bureau's text of the WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (WHO CA+)' (2 June 2023) A/INB/5/6 < [https://apps.who.int/gb/inb/pdf\\_files/inb5/AINB56-en.pdf](https://apps.who.int/gb/inb/pdf_files/inb5/AINB56-en.pdf) > accessed 18 July 2023, Article 13A(2bis)

<sup>61</sup> Ibid, Article 6(3)(b)

<sup>62</sup> Interview with Paul Molinaro, Chief, Operations Support & Logistics, WHO (via Zoom, 18 May 2023)



## Declarations and Triggers

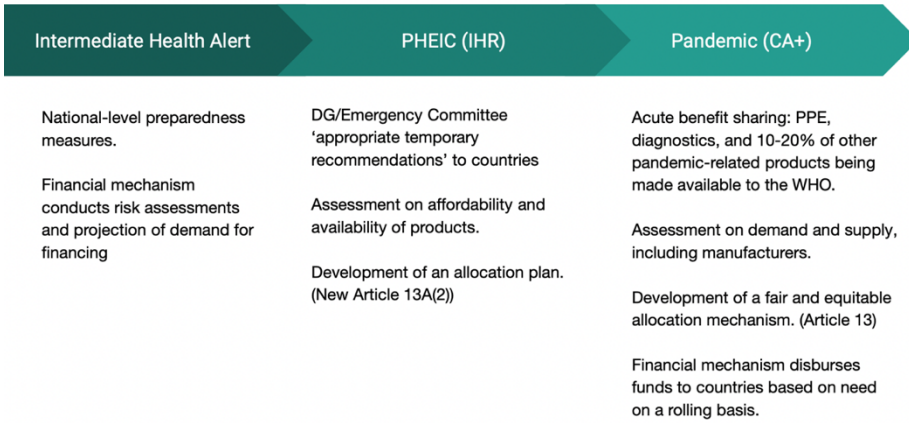


Figure 2: What could declarations and alerts in IHR and CA+ trigger?

## Common but Differentiated Responsibilities (CBDR)

**Introduction.** CBDR is a principle originating in global climate change law and regulations. It is based on the argument that there is shared moral responsibility across different countries to address global climate change,<sup>63</sup> but that developed nations should bear primary responsibility due to historical contributions to carbon dioxide emissions and differential capacities.<sup>64</sup> Its use in the pandemic instruments is rooted in the notion that Global North countries have historically manufactured medical countermeasures, house intellectual property for these medical countermeasures, and have more resources to be able to develop IHR capacities and finance pandemic response. The validity of extending the CBDR principle from climate change to pandemic preparedness is not universally accepted. Some countries argue that reference to 'differentiated responsibilities' should be maintained, while others are open to alternative terminology consistent with the same principle. Within the group of countries that support CBDR inclusion, there are divergences between those who have hard positions on the terminology of 'differentiated responsibilities' versus those who are open to different terminology that espouses the same principles.

**Objective of Instrument Provisions.** To establish and institutionalize the principle that countries with greater social and economic development (access to resources) during a pandemic or public health emergency have greater (differentiated) responsibilities towards ensuring global health security than those that have less access to resources.

### Relevant Provisions (selected).

CA+ Pandemic Accord Article 3

Option 7A. **Common but differentiated responsibilities and respective capabilities.** Parties that hold more capacities and resources relevant to pandemics should bear a commensurate degree of differentiated responsibility

Option 7B. **Common responsibilities and different capabilities.** And unequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger.

Option 7C. Not to include as a principle.

CA+ Pandemic Accord Article 17

All Parties shall fully implement the WHO CA+ recognising their different levels of development, with specific needs/special circumstances of developing country Parties to be full consideration for financial and technical assistance, technology transfer, and support for sustainable capacity building, and where a developing country lacks capacity to implement specific provisions of the CA+, that the Parties shall work together to identify the most relevant partner(s) that can support development of such capacities. [Option 17.A]

Specific needs and special circumstances of developing country Parties, especially those that are particularly vulnerable to the adverse effects of pandemics and other PHEICs and would have to bear a disproportionate or abnormal burden to be given full consideration, and financial assistance, technology transfer, technical assistance, and support for capacity to be provided by developed country Parties to implement CA+. Where a developing country Party lacks necessary capacity, implementation of the provision(s) concerned will not be required until implementation capacity has been acquired. [Option 17.B]

Not to include Article 17 [Option 17.C]

---

<sup>63</sup> Yan Zhu Zhang and Chao Zhang, 'Thirty years with common but differentiated responsibility, why do we need it ever more today?' Blavatnik School of Government (4 May 2022) <<https://www.bsg.ox.ac.uk/blog/thirty-years-common-differentiated-responsibility-why-do-we-need-it-ever-more-today>> accessed 11 May 2023

<sup>64</sup> Yuli Chen, 'Reconciling common but differentiated responsibilities principle and no more favourable treatment principle in regulating greenhouse gas emissions from international shipping' (2021) *Marine Policy* Volume 123, 104317; Pauw, Pieter; Brandi, Clara; Richerzhagen, Carmen; Bauer, Steffen; Schmole, Hanna (2014) : Different perspectives on differentiated responsibilities: a state-of-the-art review of the notion of common but differentiated responsibilities in international negotiations, Discussion Paper, No. 6/2014, ISBN 978-3-88985-596-1, Deutsches Institut für Entwicklungspolitik (DIE), Bonn <<https://www.econstor.eu/bitstream/10419/199419/1/die-dp-2014-06.pdf>> accessed 11 May 2023



IHR Amendments Article 3(1)

That the implementation of the Regulations shall be with full respect for dignity, human rights, and fundamental freedoms of persons... in accordance with common but differentiated responsibilities of States Parties, taking into consideration their social and economic development.

IHR Amendments Article 5(1)

Developed State Parties and WHO to offer assistance to developing State Parties to develop, strengthen, and maintain surveillance capacities, depending on availability of finance, technology, and know-how – and this capacity will be periodically reviewed through the Universal Health Periodic Review Mechanism.

### Areas of Concern

1. Is the CBDR principle transferable from a climate change to a pandemic prevention and response context?
2. Would loss of specific reference to 'differentiated responsibilities' lead to a dilution of the principle and risk a repeat of the inequities seen in the COVID-19 pandemic?
3. Might inclusion of CBDR disincentivize countries with limited capacity and resources from developing core competencies?

**Cross-References/Incompatibilities.** Both instruments contain language on CBDR.

**Opportunities for Consensus.** This is an area where countries hold strong positions; concessions in other areas are likely to be required before the CBDR issue is resolved. Broadly speaking, negotiating countries seem to be divided in three loose groups: a group of countries that argue that CBDR does not belong in health emergencies/pandemic preparedness and response; a group that considers the CBDR principle necessary with no language/terminology changes that may dilute its meaning; and a group that considers the CBDR principle necessary but is open to redrafting of language to avoid direct reference to CBDR. Within these two latter groups is a subgroup of countries that link CBDR specifically to PABS and One Health capacities, i.e., that countries with more resources, and where there is more manufacturing capacity, should have additional responsibility for ensuring that WHO has sufficient pandemic products to distribute to countries in need, for promoting transfer of know-how and technology, and for supporting development of One Health capacities in less developed countries i

Negotiations may need to consider these questions:

1. Can equivalence be drawn between differential country contributions to greenhouse gas emissions and differential access to pandemic tools? To what degree can equivalencies be drawn between industrialization and practices of industrialized countries, and pandemic inequities?
2. To what extent has CBDR in treaties been effective at mobilizing action? To what extent have other principles such as equity and human rights been relevant to mobilize action in other treaties? Are these relevant considerations for inclusion or non-inclusion of CBDR in one or other instrument?
3. What practically does CBDR mean financially for countries? Does it mean that countries with more resources should universally and voluntarily provide resources for countries with fewer resources?
4. Would CBDR risk undermining compliance and accountability mechanisms designed to ensure that countries develop core capacities and keep their IHR obligations?
5. Can countries fulfil proposed One Health obligations without the CBDR principle?

## Analysis

At the centre of the arguments for CBDR is an acknowledgment that principles of solidarity<sup>65</sup> did not deliver equitable and timely access to pandemic-related products. It is a principle rooted in equity and distributive justice,<sup>66</sup> and in the historical contributions and respective capabilities in a particular area. It is also one of the most contested topics in the pandemic legislative arena. Some countries argue that, while CBDR is applicable in the specific climate change context, it is not needed to address equitable access, which “is already covered under the principles of equity and international solidarity”.<sup>67</sup> It has also been argued that CBDR “will not be applicable in the context of pandemic governance”<sup>68</sup> and that consensus will be difficult to achieve.<sup>69</sup> Some countries also believe that CBDR will be used as a disincentive or excuse by less-developed countries unwilling to invest in the development of core capacities without external resourcing.. A negotiator from a high-income country has expressed opposition to inclusion of CBDR in the Pandemic Accord on the grounds of its lack of relevance:

⋮ ⋮ ⋮

*We do not support “common but differentiated responsibilities and capabilities.” This concept is not appropriate in the context of pandemic PPR. We look forward to seeking common ground to best ensure universal application while also ensuring capacities are strengthened so that countries can meet their obligations.*<sup>70</sup>

– Ambassador Pamela Hamamoto, US Negotiator for the Pandemic Accord

Japan stated in a March 2023 INB session: “CBDR has no place in the context of pandemic PPR. Was not COVID-19 a reminder to the whole world to work together?”<sup>71</sup> In addition, the United States has further stated that CBDR is a concept that has not proven effective at mobilising action.<sup>72</sup>

Appropriateness requires teasing out the key commonalities with developments in climate change. International climate change lawyer Lavanya Rajamani described how up to the United Nations Conference on Environment and Development held in Rio de Janeiro in 1992, there was growing acknowledgment of industrial country contributions to the global environmental crisis, leading to the CBDR principle.<sup>73</sup> Notably, Rajamani stated that “enhanced capabilities are a direct result of industrialization, which in turn resulted in the spike of GHG [greenhouse gas] emissions that is causing climate change.”<sup>74</sup>

An argument made by Global South countries is that industrialization has resulted in increased purchasing power and the ability to secure large amounts of pandemic products to the exclusion of the Global South, causing pandemic inequity. Industrialization also means an increased ability to develop core capacities. This argument also relies on an uncomfortable notion of causality – and some may argue that there is a difference between ‘causing pandemic inequity’ and ‘causing pandemics’, hence the non-appropriateness for the pandemic space. It could also be argued that the economic benefits enjoyed by the Global North have, at least to some degree, been at the expense of the Global South. This would argue that there is some moral obligation of behalf the Global North to make a greater contribution to a

---

<sup>65</sup> Emmanuel Macron, Angela Merkel, and others, ‘Covid is the greatest test of global solidarity in decades – we have to work with, not against, each other’ Independent (3 February 2021) <<https://www.independent.co.uk/voices/covid-vaccines-macron-merkel-von-der-leyen-b1796793.html>> accessed 11 July 2023

<sup>66</sup> Hamrouni, Maïa-Oumeïma and Canal Forgues Alter, Eric (2022). Equity, International Cooperation, and Global Public Health: Use of the Common but Differentiated Responsibilities Principle in the Fight against COVID-19. *Journal of International Women's Studies*, 23(3), 106-121.

Available at: <https://vc.bridgew.edu/jiws/vol23/iss3/8>

<sup>67</sup> <<https://genevahealthfiles.substack.com/p/is-there-a-case-for-common-but-differentiated?nthPub=3>> accessed 19 April 2023

<sup>68</sup> Government of Monaco, cited in Nithin Ramakrishnan, ‘WHO: Developed countries oppose CBDR inclusion in new pandemic instrument’ *Third World Network* (29 July 2022) <<https://www.twn.my/title2/health.info/2022/hi220702.htm>> accessed 11 July 2023

<sup>69</sup> Nithin Ramakrishnan, ‘WHO: Developed countries oppose CBDR inclusion in new pandemic instrument’ *Third World Network* (29 July 2022) <<https://www.twn.my/title2/health.info/2022/hi220702.htm>> accessed 11 July 2023

<sup>70</sup> U.S. Department of State, ‘Statement by Ambassador Pamela Hamamoto World Health Organization (WHO) Fourth Meeting of the Intergovernmental Negotiating Body (INB)’ (27 February 2023) <<https://www.state.gov/statement-by-ambassador-hamamoto-who-fourth-meeting-of-the-inb/>> accessed 11 July 2023

<sup>71</sup> Priti Patnaik & Shoa Moosavi, ‘Pandemic Accord Negotiations: Away from Public Glare, but Center of Attention’ *Geneva Health Files* (3 March 2023) <<https://genevahealthfiles.substack.com/p/pandemic-accord-negotiations-away>> accessed 11 May 2023

<sup>72</sup> Nithin Ramakrishnan, ‘WHO: Developed countries oppose CBDR inclusion in new pandemic instrument’ *Third World Network* (29 July 2022) <<https://www.twn.my/title2/health.info/2022/hi220702.htm>> accessed 11 May 2023

<sup>73</sup> Lavanya Rajamani, ‘The reach and limits of the principle of common but differentiated responsibilities and respective capabilities in the climate change regime’ in Navroz Dubash (editor), *Handbook of Climate Change and India: Development, Politics and Governance* (Routledge 2012), p. 121

<sup>74</sup> Ibid

global challenge such as pandemic preparedness and response. However, it is difficult to argue that the Global North holds greater responsibility for the origins of pandemics, marking a significant difference to the climate change context. An alternative argument would be that the Global North, in the climate change context, have contributed to climate change inequity, and thus extrapolating these arguments to pandemic inequity.

Another scholar analysing the applicability of CBDR to pandemic preparedness and response makes the point that in climate, 'some states contributed more to environmental problems, placed greater pressure on resources, and overall had a higher capacity to adopt protection measures, which in turn demanded stricter obligations.'<sup>75</sup> CBDR is also being discussed in the context of the negotiation of a treaty to end plastic pollution, taking into account the complex interactions and supply chain of plastics on a global scale.<sup>76</sup> Given supply chain implications in pandemics – such as hoarding and increased market access for HICs, this may also be a relevant comparison. COVID-19 saw the stockpiling of doses by Global North countries by much more than they needed, with one example illustrating that the G7 and European Union having 769.8 million vaccines to spare in 2021, even if 75% of their populations were vaccinated and 20% getting boosters.<sup>77</sup>

Meanwhile, Bangladesh, in making the case for CBDR in the CA+ stated that One Health and the widely varied capabilities on animal/plant/human surveillance between countries was a prime example of why CBDR was important.<sup>78</sup> Others raised CBDR in relation to surveillance obligations. One Global South negotiator stated that CBDR was necessary for inclusion in the IHR to ensure support was provided for core capacity development:

---

*“Developed countries place so much emphasis on surveillance and reporting obligations... What we are saying as developing countries is that we need the resources to implement these surveillance obligations and the only way to achieve this is through CBDR – a binding obligation on developed countries to provide the financial and other necessary support to develop and maintain the capacities required under the IHR... Article 44 on Collaboration and Assistance has not worked. We need a higher standard and that’s CBDR.”<sup>79</sup>*

*(Global South negotiator, interviewed 12 July 2023)*

---

Some Global South countries stated that inclusion of the principle in both the IHR and CA+ was non-negotiable, but that they were flexible on language:

---

*“It’s the principle that matters – that there is a common responsibility, but that countries are at different stages to implement those responsibilities. For us it’s a red line in the sense that the principle needs to be reflected, but whether it needs to be amended in its name, we’re flexible. We understand the historical background of the principle in climate change and there are issues with equivalence [of the two]. Having said that, our position remains that it is an important point that needs to be reflected.”<sup>80</sup>*

*(Global South negotiator, interviewed 9 May 2023)*

---

However, other Global South countries stated that any amendment of the language would dilute the intention of the provision. As one negotiator illustrated:

---

<sup>75</sup> Abhinav Verma, 'Adapting Common But Differentiated Responsibility to the Global Cooperation for COVID-19 Response' *Journal of International Affairs* (26 April 2020) <<https://ia.sipa.columbia.edu/online-articles/adapting-common-differentiated-responsibility-global-cooperation-covid-19-response>> accessed 11 July 2023

<sup>76</sup> Aleke Stöfen-O'Brien, "Chapter 23 Common but Differentiated Responsibilities as a Guiding Principle towards a Potential International Treaty on Plastic". In *Peaceful Maritime Engagement in East Asia and the Pacific Region*, (Leiden, The Netherlands: Brill | Nijhoff, 2022) doi: <https://doi.org/10.1163/9789004518629024>

<sup>77</sup> Olivia Goldhill, 'We have enough Covid vaccines for most of the world. But rich countries are stockpiling more than they need for boosters' *STAT* (13 December 2021) <<https://www.statnews.com/2021/12/13/we-have-enough-covid-vaccines-for-most-of-world-but-rich-countries-stockpiling-more-than-they-need/>> accessed 11 May 2023

<sup>78</sup> *Ibid*

<sup>79</sup> Global South negotiator (via Whatsapp, 12 July 2023)

<sup>80</sup> Interview with Global South negotiator (via Zoom, interviewed 9 May 2023)

---

*“[High-income countries] should take into account that the realities are completely different. And those that have more capacity should bear commensurate responsibility. We think it’s very important that this concept be kept as it is. Some countries have suggested diluting it such as ‘common responsibilities but different capacities’ or something like that. But that doesn’t translate what the concept is. The concept is that their responsibilities are differentiated.”<sup>81</sup>*

*(Global South negotiator, interviewed 5 July 2023)*

---

A Nigerian government official stated that the principle shouldn’t just be CBDR but rather CBDR-RC (common but differentiated responsibilities and respective capabilities) and that this would distinguish it from the climate agreement where source of emissions was the determining factor of why certain countries have differentiated responsibilities. In their own words:

---

*“We are favourable to CBDR-RC as opposed to just CBDR or CBRC. We have listened to the arguments from other countries about why pandemics are different from the climate situation, but we have also consulted with our legal team here which confirmed that there would be no legal implications from including and transferring the principle. Furthermore, we are aware that the CBDR-RC principle has evolved from the Convention for the Establishment of an Inter-American Tropical Tuna Commission and the United Nations Convention on the Law of the Sea and now to the climate context and maybe, the upcoming plastics treaty. Recognising that these relate to the environment predominantly, we don’t think that there’s anything that stops us from adapting and transferring these concepts from climate to global health security. We have thus proposed guiding definitions to this effect. That’s the Nigerian position.”*

*(Dr Chukwuma Anyaike; Director of Public Health, Nigeria and Chair to Nigeria’s Technical Committee for the Pandemic Treaty and IHR Amendments, interviewed 5 October 2023)*

---

Addressing the concern that CBDR could be used by countries to neglect fulfilment of core capacity obligations under the IHR, this same negotiator stated that “CBDR will empower countries to be able to reach their obligations by ensuring support for countries to reach the same level of capabilities”.<sup>82</sup>

A negotiator from a small country rebutted the notion that countries want to shirk their responsibilities on developing core capacities through the inclusion of CBDR. Like the negotiator quoted above, this negotiator saw CBDR as essential to develop equivalent capacities across the globe, which would benefit all countries:

---

*“Creation of capacities is not a request from developing world to developed countries. It is in the interest of everyone to have [CBDR] provisions in both instruments, to strengthen laboratories and surveillance, but also to strengthen response side of things. And if this point is not [understood] then there is no point to having either document and we can have a WHO resolution instead. This is about having more capacities worldwide to respond to pandemics and that’s why we need common but differentiated responsibilities.”*

*(Global South negotiator, interviewed 4 July 2023)*

---

In addition, it can be argued that the principle of CBDR does not nullify the role of compliance and accountability bodies that will continue to hold countries responsible for fulfilling their obligations.

---

<sup>81</sup> Global South negotiator (via Zoom, interviewed 5 July 2023)

<sup>82</sup> Ibid

A concern among high-income countries is that CBDR will continue to result in high-income countries having to financially support core capacity development in less developed countries, rather than countries continuing to incrementally improve and develop IHR capacities based on their financial capabilities. Countries from all development levels will need to consider implications of CBDR in the context of the new financial mechanisms in both documents as well – in that whether the donor model in the past pandemic was appropriate or whether a fair share model (where countries provide a percentage of funds based on GDP) is preferred.

**Summation.** The firm positions held on CBDR indicate that this area will likely remain unresolved until the last stages of negotiations. While there are no constitutional reasons why CBDR should not be in one or both instruments, appropriateness and feasibility will depend on a combination of political realism and whether countries move on ideology.

These questions remain relevant in negotiator considerations:

1. Can equivalence be drawn between increased contribution to greenhouse gas emissions and increased contribution to pandemic tools scarcity?
2. To what extent have CBDR principles in treaties been effective at mobilizing action? Is the degree of efficacy at mobilizing action relevant for CBDR inclusion/non-inclusion within pandemic-related instruments?
3. What practically would CBDR mean financially for both Global North and Global South countries?
4. Would CBDR interfere with compliance and accountability mechanisms designed to ensure that countries develop core capacities and meet their Accord obligations?

## Research and Development (R&D)

**Introduction.** Several COVID-19 vaccines were funded largely with public funding, with 97% of research and development (R&D) for the Oxford/AstraZeneca vaccine funded by the UK Government or by charitable trusts,<sup>83</sup> US\$6 billion of public funding provided for R&D of the Moderna vaccine,<sup>84</sup> and the United States Biomedical Research and Development Authority (BARDA) alone spending US\$19.3 billion on COVID-19 vaccine R&D.<sup>85</sup> These sizeable public investments did not always correlate with access and affordability; as some scholars commented: “Public funders bore significant financial risks while private companies controlled access to the largely publicly funded knowledge needed to make the resulting products”.<sup>86</sup>

In addition, manufacturers applied tiered pricing standards that often did not correspond to the income levels of countries – a claim that is off-quoted by industry as a fair and equitable approach to access.<sup>87</sup> For example, South Africa and Uganda reportedly paid US\$5.25 and US\$7.00 per dose, respectively, for the AstraZeneca vaccine, while European countries were charged US\$3.00.<sup>88</sup> Similarly, Moderna offered its vaccine to South Africa at US\$30–42 per dose while higher income countries paid US\$32–37 for the same vaccine.<sup>89</sup> Purchase agreements are typically confidential, however, meaning that a comprehensive assessment of price differences cannot be made.

Vaccines were also predominantly manufactured in high-income countries and funded by high-income country institutions/donors, spurring conversations across the Global South about R&D investment and manufacturing capacities. The African continent, for example, invests only 0.42% of GDP into R&D, compared to the global average of 1.7%, despite targets set in 2006 that African member states would increase investments to 1% of GDP.<sup>90</sup> COVID-19 inequity spurred several investment initiatives in the Global South, including the African Pharmaceutical Technology Foundation, established by the African Development Bank,<sup>91</sup> investments in Indonesia to develop mRNA vaccine technology,<sup>92</sup> and the mRNA Vaccine Technology Transfer Programme.<sup>93</sup> However, both capacity and resource gaps remain.

**Objective of Instrument Provisions.** To ensure the efficient development of health tools and equitable access to resulting products, to diversify R&D and production sources of pandemic-related products, to provide clarity to countries and developers in advance of a crisis through conditions attached to public funding of R&D, to promote open science and transparent knowledge-sharing approaches, and to increase R&D capacities.

### Relevant Provisions.

CA+ Pandemic Accord Article 9(1)

That the Parties shall cooperate to build, strengthen, and sustain capacities and institutions for R&D for pandemic-related products, particularly in developing countries, including for clinical trials and open science approaches.

CA+ Pandemic Accord Article 9(2)

Each Party, in accordance with national laws, when providing public funding for R&D and taking into account the extent of public funding,

---

<sup>83</sup> Samuel Cross, Rho Y, Reddy H, *et al*, ‘Who funded the research behind the Oxford–AstraZeneca COVID-19 vaccine?’ *BMJ Global Health* 2021;**6**: e007321.

<sup>84</sup> Hussein S Lalani, Avorn J, Kesselheim AS. US Taxpayers Heavily Funded the Discovery of COVID-19 Vaccines. *Clin Pharmacol Ther.* 2022 Mar;**111**(3):542–544. doi: 10.1002/cpt.2344. Epub 2021 Jul 9. PMID: 34243221; PMCID: PMC8426978.

<sup>85</sup> Congressional Budget Office, ‘Research and Development in the Pharmaceutical Industry’ (April 2021) <<https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf>> accessed 24 July 2023

<sup>86</sup> Katrina Perhudoff, Ellen ‘t Hoen, Kaitlin Mara, and others, ‘A pandemic treaty for equitable global access to medical countermeasures: seven recommendations for sharing intellectual property, know-how and technology’ *BMJ Global Health* 2022;**7**:e009709. doi:10.1136/bmjgh-2022-009709

<sup>87</sup> European Federation of Pharmaceutical Industries and Associations, ‘A shared approach to supporting Equity Based Tiered Pricing’ <<https://www.efpia.eu/media/636825/a-shared-approach-to-supporting-equity-based-tiered-pricing.pdf>> accessed 25 July 2023; Moon, S., Jambert, E., Childs, M. *et al*. A win-win solution?: A critical analysis of tiered pricing to improve access to medicines in developing countries. *Global Health* **7**, 39 (2011). <https://doi.org/10.1186/1744-8603-7-39>

<sup>88</sup> Darcy Jimenez, ‘Covid-19: vaccine pricing varies wildly by country and company’ *Pharmaceutical Technology* (26 October 2021) <<https://www.pharmaceutical-technology.com/features/covid-19-vaccine-pricing-varies-country-company/>> accessed 24 July 2023

<sup>89</sup> *Ibid*

<sup>90</sup> Paul Adepoju, ‘Africa’s future depends on government-funded R&D’ *Nature Africa* (25 September 2022) <<https://www.nature.com/articles/d44148-022-00134-4>> accessed 24 July 2023

<sup>91</sup> *Ibid*

<sup>92</sup> Andree Surlanta, ‘Indonesia’s slow path to vaccine self-sufficiency’ *East Asia Forum* (22 November 2022) <<https://www.eastasiaforum.org/2022/11/22/indonesias-slow-path-to-vaccine-self-sufficiency/>> accessed 25 July 2023

<sup>93</sup> Georgia Bisbas, ‘mRNA Technology Transfer Programme’ *The Lancet Microbe* (4 July 2023) DOI: [https://doi.org/10.1016/S2666-5247\(23\)00183-0](https://doi.org/10.1016/S2666-5247(23)00183-0)



shall promote public dissemination of results of government-funded research for the development of pandemic-related products and publish the terms of government-funded R&D agreements for pandemic related products, including research inputs, processes, and outputs, pricing/pricing policies for end products, licensing for manufacturing in developing countries, and equitable access/affordability terms.

CA+ Pandemic Accord Article 9(3)

Parties shall increase transparency of information about R&D for pandemic related products by sharing information on research agendas and national R&D priorities during pandemic emergencies (as appropriate) and sharing information about plans to strengthen R&D capacities including R&D workforce.

IHR Amendments Article 44(1)(c) (new)

States parties to collaborate and assist other states parties (especially developing countries) in strengthening capacity to identify health threats including through surveillance, research and development cooperation, technological and information sharing.

IHR Amendments New Annex 10 Article 2(b)(ix)

WHO and States Parties collaborating and assisting each other shall carry out research and building capabilities for implementation of the regulations including product development.

#### Areas of Concern

1. Do provisions in the Bureau Text allow for a too high degree of discretion on conditions for R&D and publication of terms of government-funded R&D agreements through text such as ‘as appropriate’ and ‘in accordance with national laws’?
2. Has the Bureau’s text been weakened by removal of the specific obligation to attach access conditions to public funding, and does it focus too much on transparency (publication of terms) rather than inclusion of access conditions in R&D funding agreements?
3. Will countries be able to compel manufacturers to share prices of products and pricing policies?

**Cross-References/Incompatibilities.** Article 9(1) CA+ overlaps with Articles 44(1)(c) and Annex 10’s Article 2(b)(ix) in the IHR, in that they all discuss the strengthening and building of R&D capacities, although the CA+ Article specifically references R&D for ‘pandemic-related products’. Retaining these overlapping provisions could result in complexity in compliance, as two separate compliance mechanisms would convene separately to discuss R&D.

**Opportunities for Consensus.** The addition of ‘as appropriate’ and ‘in accordance with national laws’ signals sensitivity around concrete commitments on transparency on R&D funding agreements. Furthermore, the Bureau’s text removes the requirement for Member States to attach conditionalities to R&D funding agreements and conflates provisions on transparency and the use of conditions as leverage on provision of R&D funding which was more clearly demarcated in the Zero Draft. In April 2023, the European Commission adopted a proposal for a new Directive and Regulation that would require pharmaceutical companies to publish information on all direct financial support for R&D of medicines received from public authorities or publicly funded bodies.<sup>94</sup> This provision relies on self-reporting by industry. The CA+ provision states that Member States, in accordance with national laws, should publish the terms of government-funded R&D agreements, including pricing and pricing policies. European pharmaceutical industry has specifically stated that ‘procuring entities and Member States should respect pricing confidentiality’.<sup>95</sup> Publication of R&D agreements, and disclosure of pricing information in particular, will therefore likely remain contentious.

<sup>94</sup> European Commission, ‘Proposal for a Directive Of The European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC’ (26 April 2023) < [https://eur-lex.europa.eu/resource.html?uri=cellar:bfc9e00-e437-11ed-a05c-01aa75ed71a1.0001.02/DOC\\_1&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:bfc9e00-e437-11ed-a05c-01aa75ed71a1.0001.02/DOC_1&format=PDF)> accessed 6 August 2023

<sup>95</sup> European Federation of Pharmaceutical Industries and Associations (EFPIA), ‘White Paper: On the Effectiveness of Public Procurement of Medicines In The EU’ (February 2022) < [https://www.efpia.eu/media/636671/efpia\\_white\\_paper\\_public\\_procurement.pdf](https://www.efpia.eu/media/636671/efpia_white_paper_public_procurement.pdf)> accessed 6 August 2023

The IHR focus on prevention and the development of capacities for public health emergencies. Hence the two proposed new provisions on R&D are constitutionally appropriate. However, discussions will need to be had on whether the proposed Article 9(1) in the CA+ would be more appropriately placed in the IHR, given its focus on competencies and potential for duplication if R&D capacity-building is included in both the IHR and CA+.

**Analysis.** Proposed R&D-related provisions in the CA+ Bureau's Text centre predominantly on the attachment of conditions to publicly funded R&D funding agreements and the obligations of Member States to publish the terms of these agreements, including provisions for pricing and pricing policies for end-products and equity/accessibility terms. These provisions speak to the notion that publicly funded R&D should result in products that are 'public goods' and, in the context of pandemics, 'global public goods'.<sup>96</sup> In addition, providing public funds creates leverage for a Member State to negotiate conditions in support of the public good.

Companies developing COVID-19 vaccines received large amounts of government funding without having any conditions imposed on product availability or pricing in less-developed countries.<sup>97</sup> Given these and other issues around public funding of pandemic products and accessibility, negotiators are seeking legal provisions in the CA+ that will increase R&D transparency and improve the leverage of governments providing public funding:

---

*"Article 9(2)(b) is a reaction to government-funded R&D like Operation Warp Speed... Americans were vaccinated at least 6 months before citizens of my country. We're not opposed to the pharmaceutical industry making lots of money. But when their profits are coming out of government-funded research and, more importantly, impacts the global allocation of countermeasures, this has to be tempered with provisions that increase transparency in R&D and increase the likelihood of equitable distribution."*

*(Global South negotiator, interviewed 23 June 2023)*

---

Another negotiator stated that including provisions on pricing transparency was essential to both their negotiations in both the R&D and supply section of the CA+, and that pricing transparency should be included as part of R&D funding conditionalities:

---

*"Having transparent pricing was one of the big issues for many countries who were not able to negotiate in the same way that high-income countries can. When you have many companies selling [the product] in the market, you get prices that are fair. When you have one company [with a] monopoly selling it, it is a different story. Price transparency for us is crucial."*

*(Global South negotiator, interviewed 4 July 2023)*

---

Another negotiator pointed out that HICs should agree to price transparency in R&D agreements especially given that some Global South negotiators are 'increasingly flexible and pragmatic' on time-bound waivers in Article 11 of the Bureau's text. In their own words:

---

*"(Price transparency) is an important element. Thing is, we need an Accord now – and we have learned that we need to come to a middle ground. And on TRIPS flexibilities and the waivers, we in (region) need to discuss because there is no point. The essence of multilateralism requires that we make (concessions) and if we don't, we miss the opportunity of making things better."*

---

<sup>96</sup> Peacock, S.J. Vaccine nationalism will persist: global public goods need effective engagement of global citizens. *Global Health* **18**, 14 (2022). <https://doi.org/10.1186/s12992-022-00802-y>

<sup>97</sup> European Federation of Pharmaceutical Industries and Associations, 'A shared approach to supporting Equity Based Tiered Pricing' <<https://www.efpia.eu/media/636825/a-shared-approach-to-supporting-equity-based-tiered-pricing.pdf>> accessed 25 July 2023; Moon, S., Jambert, E., Childs, M. *et al.* A win-win solution?: A critical analysis of tiered pricing to improve access to medicines in developing countries. *Global Health* **7**, 39 (2011). <https://doi.org/10.1186/1744-8603-7-39>

*(Global South negotiator, interviewed 29 August 2023)*

---

Dr Sultani Matendecheo, Deputy Director-General of the Ministry of Health in Kenya told us that their country was open to negotiations on pricing transparency provided other provisions in the Accord would facilitate access to pandemic tools. In his own words:

---

*“I see where they (states parties in the Global North) are coming from. Health products and technologies are part of the business chain. Sharing certain business secrets can be tantamount to jeopardizing the very business in question. What we need to ask ourselves is ‘why do we want this transparency’? If it is ostensibly to enable access to the relevant pandemic-related products and countermeasures, are there other (less controversial) strategies available? For instance, if we have sufficient resources, availed through a clear and predictable global financing mechanism, can we consider short-term purchases, directly from producers in the Global North, even as we concomitantly pursue longer-term strategies, like prioritizing capacity-building initiatives for research, innovation, and local production, which would then gradually upset the global balance? If this is a viable alternative strategy, the Global South would not really need to pursue concessions around patent waivers and forfeiture of Intellectual Property rights, or R&D transparency. Long-term, this would not only boost local capacity to produce medical countermeasures for pandemic prevention, preparedness, and response, but also health products and technologies for all our other public health needs.”*

*(Dr Sultani Hadley Matendecheo, Deputy Director General for Health, Ministry of Health Kenya, and Vice Chair of the WHO Working Group on Amendments to the International Health Regulations 2005 (WGIHR), interviewed 29 August 2023)*

---

The question remains, therefore, whether a viable alternative strategy exists should no agreement be reached on price transparency in R&D agreements for pandemic-related products nor time-bound patent waivers. Pricing transparency was stated by high-income negotiators as being the biggest sticking point in the R&D provisions. It was felt unlikely that industry, which will not be Parties to the Pandemic Accord, could be compelled to share prices of end products and pricing policies, particularly at the stage of negotiation/finalization of R&D funding agreements. Instead of these conditions, the EU has proposed a tiered pricing approach integrated into the Pandemic Accord<sup>98</sup> for the supply of scarce countermeasures. It also suggests that high-income countries should take coordinated action to ensure that ‘availability and affordability commitments’, namely allocation and tiered pricing policies, are set out in purchase agreements and in agreements for R&D relating to new pandemic countermeasures.<sup>99</sup>

The EU Commission in April 2023 adopted a proposal for a new Directive and Regulation which would require pharmaceutical companies to publish information on all direct financial support for the R&D of medicines received from public authorities or publicly funded bodies.<sup>100</sup> According to Rachael Crockett, Senior Policy Advocacy Manager at the Drugs for Neglected Diseases initiative (DNDi), this is essentially a question about where Member States use their leverage with industry, with the EU “choosing to use their leverage as a funder at a later stage rather than earlier during development [of a pandemic-related product]”.<sup>101</sup> These sentiments were echoed by one country negotiator who stated that conditionalities in procurement contracts (as opposed to R&D funding contracts) were too late:

---

<sup>98</sup> European Union, ‘European Union *Initial* Textual Proposals For An Agreement On Pandemic Prevention, Preparedness And Response’ (28 March 2023)

<<https://www.eeas.europa.eu/sites/default/files/documents/2023/EU%20proposals%20integrated%20into%20the%20ZD%2028%20March.pdf>> accessed 24 July 2023, p. 18

<sup>99</sup> *Ibid.*, p. 16

<sup>100</sup> European Commission, ‘Proposal for a Directive Of The European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC’ (26 April 2023) < [https://eur-lex.europa.eu/resource.html?uri=cellar:bfc9e00-e437-11ed-a05c-01aa75ed71a1.0001.02/DOC\\_1&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:bfc9e00-e437-11ed-a05c-01aa75ed71a1.0001.02/DOC_1&format=PDF)> accessed 6 August 2023

<sup>101</sup> Rachael Crockett, Senior Policy Advocacy Manager, Drugs for Neglected Diseases initiative (via email, 1 August 2023)

---

*“The EU's proposal moves towards leaving it to the end and agreeing on a tiered pricing approach once you sign a procurement contract with the supplier, which is quite late. At that time, there's growing demand and scarcity. I don't know whether their proposal will be helpful at that later stage. This is why [conditionalities] should be attached at the R&D stage, so you have multiple levers.”*

*(Global South negotiator, interviewed 31 July 2023)*

---

According to Professor Suerie Moon, access conditions are needed for both procurement and R&D funding agreements, not just one. Furthermore, Moon argues that it is vital for governments to regulate companies within their territories so that they act in the public interest, and that the Accord should ensure both transparency of public funding agreements for R&D and conditionalities attached to that R&D funding:

---

*“Generally, in public international law, you have governments and countries that are Parties [to agreements] and not private entities. And it is governments who have the obligation to regulate private entities operating in their territory to respect human rights. So, from a legal point of view, it is up to governments to do everything they can to regulate private firms to act in the public interest and to respect, protect, and fulfil human rights. And that's why I think that's one of the reasons for calling on government to put conditions on their funding of R&D and on their procurement. The EU has been putting more emphasis on conditions in their procurement contracts, which is interesting because many of us [academics and activists working on access to medicines] have been emphasizing conditions on upfront push funding of R&D. What would make sense is to have conditions on both. Ultimately is this all public money, and while transparency is important, the Bureau's text is already strong on it. Where it is weak is on conditions for public funding of R&D.”*

*(Professor Suerie Moon, Co-Director at the Global Health Centre and Professor of Practice for the Interdisciplinary Programmes, Graduate Institute)*

---

The ‘weakness’ Moon refers to is related to the shifts between the earlier Zero Draft of the CA+ and the Bureau’s text released in May 2023. The Zero Draft stated that Parties shall ‘establish appropriate conditions for publicly funded research and development, including on distributed manufacturing, licensing, technology transfer and pricing policies’.<sup>102</sup> The Bureau’s text removes this provision and instead asks Member States to publish the terms of R&D contracts, as appropriate and in accordance with national laws, providing Member States with the ability to disregard the requirement for publication should it be inconsistent with national laws.

■ ■ ■ ■

*“(There is) more reliance on voluntary measures. There are a lot more references to ‘as appropriate’ – I think the phrase is used some 47 times.”<sup>103</sup>*

*– Professor Suerie Moon, cited in Health Policy Watch (24 May 2023)*

The shift between the Zero Draft and the Bureau’s Text signals the sensitivity around including terms and conditions, including pricing transparency, in agreements for funding of R&D, and enables countries to forgo certain provisions based on whether they deem the measure appropriate or otherwise. This would most likely occur when countries are prioritizing doses for their own countries – the ‘vaccine nationalism’ seen during the COVID-19 pandemic.

---

<sup>102</sup> INB, ‘Zero draft of the WHO CA+ for the consideration of the Intergovernmental Negotiating Body at its fourth meeting’ (1 February 2023) <[https://apps.who.int/gb/inb/pdf\\_files/inb4/AINB43-en.pdf](https://apps.who.int/gb/inb/pdf_files/inb4/AINB43-en.pdf)> accessed 25 July 2023, Article 9(2)(e)

<sup>103</sup> Elaine Ruth Fletcher, ‘Exclusive: Updated Pandemic Accord Draft Sees Watered Down Text on Publicly-Funded R&D; Pathogen Access and ‘Benefit Sharing’ Linkage Remain’ Health Policy Watch (24 May 2023) <<https://healthpolicy-watch.news/exclusive-updated-pandemic-accord-draft-sees-watered-down-text-on-publicly-funded-r-pathogen-access-and-benefit-sharing-linkage-remain/>> accessed 24 July 2023

In addition, the Bureau's text seems to conflate two obligations previously included in the Zero Draft on including conditions on public funding and publishing R&D contract terms. In other words, access conditions linked to funding of R&D is separate from transparency of those agreements. Additionally, an obligation to publish contract terms does not ensure that public R&D funders use their leverage to attach pro-access conditions to their funding, nor ensure that recipients of funding enact or establish pro-access activities and approaches.

According to Rachael Crockett, the shifts made the Bureau's text 'significantly weaker' than the Zero Draft. Crockett further argued that provisions on R&D funding conditionalities should be included in both the IHR and CA+ so that health products for emergencies could also be subject to conditions for access-based pricing and transparency.

Both the CA+ and IHR contain provisions referring to the need for Parties to collaborate on and assist developing countries with the development of R&D capacities, including the R&D workforce. There is an evolving global R&D landscape, including the establishment of the African Union Partnerships for African Vaccine Manufacturing (PAVM) and the Indonesian National Research and Innovation Agency (BRIN) in 2021, the Japanese Strategic Centre of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA) in 2022, investments in Indonesia to develop mRNA vaccine technology,<sup>104</sup> and the mRNA Vaccine Technology Transfer Programme,<sup>105</sup> signalling key opportunities for increased collaboration, coordination and capacity development.<sup>106</sup>

However, overlapping provisions on capacity development for R&D in both the CA+ and IHR could result in complexity for compliance bodies. It is currently unclear whether there will be two separate Implementation and Compliance Committees, joint compliance committees, or an overarching Universal Health and Preparedness Review (UHPR)<sup>107</sup> that would operate as a peer mechanism like the Universal Periodic Review (UPR) on human rights.

An additional question is whether these compliance mechanisms would discuss R&D capacity development conducted specifically for pandemic-related products or also that related to product development in the inter-pandemic period. Given the focus of the IHR on capacities and competencies, it may be appropriate to shift Article 9(1) to the IHR. However, one negotiator expressed concern that the IHR compliance mechanisms would be too weak to increase accountability on this provision, and that it was only through a Conference of Parties (COP) that adequate oversight over increasing R&D capacities could occur. While stronger compliance mechanisms are planned for the IHR, as discussed in the [Compliance section](#), ultimately this may come down to the practicalities of monitoring R&D capacity building.

According to one negotiator, it was a strategic decision to include R&D capacities in both documents because of the possibility that fewer Parties would initially ratify the Pandemic Accord. However, the duplication could be retained and addressed jointly under one governance mechanism such as the COP.<sup>108</sup>

**Summation.** Sensitivities exist predominantly around conditions to be included in publicly funded R&D agreements with manufacturers, particularly in regard to prices of end-products or pricing policies, and ensuring greater transparency on these agreements. Furthermore, the Bureau's text does not distinguish between two separate issues of R&D funding agreements – transparency and leverage to ensure access conditions are included in funding agreements. The Bureau's text also provides more leeway for countries that would prefer to forgo solid commitments on such conditionalities, through the use of the phrases 'as appropriate' and 'in accordance with national laws'.

In addition, the IHR and CA+ both contain overlapping provisions on States Parties collaborating with each other to increase R&D capacities. This could raise compliance challenges, but overlapping provisions may be necessary due to the perceived strengths of the COP compared with IHR compliance mechanisms. Based on these issues, key questions for negotiator consideration include:

1. What examples exist of affordable pricing and price transparency provisions in government-funded R&D contracts? How have these worked in practice?

---

<sup>104</sup> Andree Surlanta, 'Indonesia's slow path to vaccine self-sufficiency' *East Asia Forum* (22 November 2022)

<<https://www.eastasiaforum.org/2022/11/22/indonesias-slow-path-to-vaccine-self-sufficiency/>> accessed 25 July 2023

<sup>105</sup> Georgia Bisbas, 'mRNA Technology Transfer Programme' *The Lancet Microbe* (4 July 2023) DOI: [https://doi.org/10.1016/S2666-5247\(23\)00183-0](https://doi.org/10.1016/S2666-5247(23)00183-0)

<sup>106</sup> Suerie Moon, in Graduate Institute Workshop 'Pandemic Product R&D: Insights from Practice and Implications for Pandemic Rulemaking' (10 July 2023)

<sup>107</sup> Gian Luca Burci and others, 'Implementation and Compliance In International Law: Implications For Pandemic Rulemaking' (upcoming 2023) p.

17

<sup>108</sup> Interview with Global South negotiator (via Zoom, 31 July 2023)

2. At what stage of research, development and procurement can conditions be applied to ensure efficient development of health tools and equitable access to such tools? What type of product or disease area could this apply to in the context of the IHR vs WHO CA+?
3. What is the best mechanism for monitoring R&D capacities? Are two separate mechanisms ideal for these purposes?



## Pathogen Access and Benefit Sharing (PABS)

**Introduction.** In practice, scientists, researchers and governments regularly share genome sequence data and pathogen samples with each other. However, this does not always result in a sharing of the benefits of scientific advances based on those samples or data. Benefit sharing related to pathogens of pandemic potential can occur in a range of ways, ranging from academic benefits such as scientific collaboration and acknowledgment of source, economic benefits such as joint ownership of intellectual property or preferential terms, and/or access to newly developed products via donation.<sup>109</sup>

This is an area which is complex and has resulted in controversy. For example, in 2007, Indonesia temporarily suspended international sharing of samples of H5N1 influenza<sup>110</sup> over concerns about being able to access vaccines developed from their use, citing the Convention on Biological Diversity's (CBD's) principle of sovereignty over biological resources, and catalysing the negotiation of the Pandemic Influenza Preparedness (PIP) Framework.<sup>111</sup> Both the CA+ and IHR amendments texts contain proposals relating to access and benefit sharing, as illustrated below, set amongst a wider patchwork of rules pertaining to benefits.

As the Graduate Institute elaborated in a 2022 document: '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.'<sup>112</sup> This section of the report unpacks the main contested points on PABS, informed by desk review and key informant interviews.

**Objective of Instrument Provisions.** To ensure fair and equitable treatment of countries sharing genetic sequence data and pathogens, and equitable distribution of scientific products for contribution to science during pandemics.

### Relevant Provisions.

CA+ Pandemic Instrument Article 12	Option 12A States that a PABS system shall be developed through COP proceedings. Option 12B that the Parties in the CA+ shall establish the PABS system and that sharing of biological materials shall occur through an 'established WHO coordinated laboratory network, subject to conclusion of a Standard Material Transfer Agreement'. In addition, multilateral sharing shall occur via a WHO allocation mechanism as follows: 10% as a donation and 10% at affordable prices to WHO, or collaboration with manufacturers from developing countries and WHO initiatives to transfer technology and know-how.
IHR Amendments Article 2, New 3.	States that PABS provision will be subject to progress in discussions on the Pandemic Instrument.

### Areas of Concern

1. With PABS provisions, would pathogens and genome sequence data only be shared in a 'transactional' manner (i.e. only if there are guarantees on donations of products or technology transfer).
2. Without PABS, would Global South countries who contribute to scientific progress be slow to receive the resulting benefits, as happened during the COVID-19 pandemic?
3. Would a transactional (as opposed to multilateral) PABS system result in significant additional costs associated with compliance checks?
4. Within a PABS system, would companies opt only for donations and not technology transfer?
5. Would a Benefits Sharing Expert Committee adjudicating benefits on a case-by-case basis reduce certainty and visibility on benefits?
6. How feasible would it be to compel/incentivize industry to transfer technology through standard material transfer agreements?

<sup>109</sup> Anthony Rizk, Adam Strobeyko, Gian Luca Burci, Suerie Moon, 'What Are the Options? Pathogen-, GSD- And Benefit- Sharing In An International Instrument' (2022) <<https://repository.graduateinstitute.ch/record/301010>> accessed 3 May 2023, p. 9

<sup>110</sup> Reuters, 'Indonesia to stop sharing bird flu samples' 6 February 2007) < <https://www.reuters.com/article/us-birdflu-indonesia-baxter-s-idUSJAK17040720070206>> accessed 30 June 2023

<sup>111</sup> Rizk, Strobeyko, and others (supra note 122), p. 6

<sup>112</sup> Ibid, p. 14

### Areas of Concern (continued)

6. How exactly would a Benefits Committee and PABS System operate in practice?
7. Might countries where many manufacturers are based not ratify the Pandemic Accord, significantly weakening the PABS system.

**Cross-References/Incompatibilities.** Article 10(3)(c) of the CA+ text refers to the use of a ‘Standard Material Transfer Agreement, developed for the purposes of the PABS System’ after which ‘access shall be accorded expeditiously’ by the relevant laboratory possessing the genome sequence data (GSD) or pathogens. A proposed amendment in the IHR to Regulation 6(3) states that there shall be no sharing of GSD or information until an effective and transparent PABS system with SMTAs is agreed to by WHO Member States. The IHR Amendments are dependent on a PABS system being agreed upon in the CA+ text. Central to considerations is that the IHR have established signatories and will likely have more signatories than the Pandemic Accord, at least initially, so would have wider applicability.

**Opportunities for Consensus.** Some interviewees (both high-income country delegations and non-state actors) suggested that it would be impossible to compel companies (who are not party to the Pandemic Accord) to transfer know-how and technology, and to provide benefits through donation of products. However, this could arguably be done through: (1) conditionalities in government research and development contracts to developers; and (2) offering companies ‘something of value’, as in the influenza model, where industry participates and receives biological material and provides 10% of influenza vaccines to the WHO allocation mechanism in return. The WHO International Pathogen Surveillance Network (IPSN) could operate in tandem with the CA+ PABS system in a similar fashion that the Global Influenza Surveillance and Response System (GISRS) operates for influenza.

Those opposing the PABS system argue that introducing a PABS systems could interfere with the routine sharing of data and samples, and thereby slow down the development of new products. In addition, it is suggested that the costs of compliance could potentially double the costs of compliance with the Nagoya Protocol.<sup>113</sup> This analysis neglects to account for Article 4(4) of the Nagoya Protocol which states that where a specialized instrument on ABS is developed, the Nagoya protocol would no longer apply.

The *realpolitik* of the negotiations indicates that it may be difficult to build in commitments to technology transfer, despite available WHO mechanisms such as the WHO COVID-19 Technology Access Pool (C-TAP).

The European Union has questioned how accountability would be written into PABS mechanisms. Provisions would need to be established to deal with situations such as SMTAs being breached and to address questions of which adjudication body would mediate or apply legally enforceable accountability mechanisms. Further detail is needed in the Pandemic Accord text on how the PABS System and Benefits Expert Committee would be operationalized, particularly in comparison to existing or planned mechanisms, such as the GISRS, the BioHub, the IPSN, and other similar networks, as country negotiators (from both the North and South) stated that they were unclear on what their obligations would be.

Detailed provisions on a PABS system being established could occur via the Pandemic Accord. However, cross-references and alignment with the IHR would be necessary, and consideration needs to be given to the legally binding nature of the system (i.e. whether it is an ‘opt-out’ mechanism under Article 21 or ‘opt-in’ under Article 19). Given the IHR’s focus on core capacities, and the role of the emergency committee and WHO Director-General with regard to declaration of a PHEIC, cross-referencing should make clear when the PABS system would be triggered (e.g. after a pandemic declaration) and what competencies would need to be engaged and/or developed for optimal PABS during an imminent pandemic.

### Analysis

The central question surrounding PABS is summed up by the scholars from the Graduate Institute: “How can benefits be negotiated, secured, and distributed in an expeditious, fair, equitable, and multilateral manner?”<sup>114</sup> Informing this

---

<sup>113</sup> Covington, ‘The Impact of the Nagoya Protocol on Global Pathogen-Sharing’ (January 2023)

<sup>114</sup> Anthony Rizk, Adam Strobeyko, Gian Luca Burci, Suerie Moon, ‘What Are the Options? Pathogen-, GSD- And Benefit- Sharing In An International Instrument’ (2022) <<https://repository.graduateinstitute.ch/record/301010>> accessed 3 May 2023, p. 18

are several ancillary questions. Some of these are illustrated by country negotiators, speaking at the INB intersessional on PABS in March 2023:<sup>115</sup>

---

*“From a technical point of view, do you think it’s possible to plan for transitional measures in the text we are currently negotiating [such as] a specific instrument that would deal with PABS. States may be reluctant to share any information where we would end up in the same system again.”*  
(Badibalaki Wembie, Second Counsellor, Geneva Mission for Togo)

*On a PABS System: “What kind of enabling environment factors can be created in order to make sure that this kind of multilateral mechanism can work? ...What are the pros and cons for us [of this coming] under Article 19 or 21?”*  
(Pieter Vermaerke, Counsellor: Health Matters and Environment, Belgium)

*“On incentives, access to technology, capacity for research countermeasures financing... how does the bureau intend to link the GISAID system, the BioHub, and others? How can all of these be brought together?”<sup>116</sup>*  
(Botswana)

---

Overall, countries seem to be divided into two camps, with some Global North countries not in favour of a ‘transactional’, barter-style mechanism guaranteeing access to benefits (such as intellectual property related to newly developed vaccines or technology transfer) if information on pathogens is shared, while for developing countries “this is a key negotiating chip to guarantee fair access to not only countermeasures, but also to deliberate on issues of sovereignty and agency”.<sup>117</sup> Going one step further, one Global South negotiator spoke about the importance of PABS for the agreement: “For African countries, everything hinges on PABS, or African countries will consider the CA+ to be a failure.”

Professor Suerie Moon, Co-Director, Global Health Centre, Graduate Institute Geneva, echoed this point:

---

*“ABS is at the heart of the political bargain that has to be struck.”*

---

The factors account for the importance given to PABS in the CA+: the COVID-19 experience, where countries in the Global South provided pathogens and sequence data but did not receive adequate vaccine supplies; and the fact that, in the influenza model, technology transfer has never been selected as an option in exchange for access to influenza viruses and biological material. As Professor Suerie Moon describes:

---

*“The PIP framework is a very useful and important agreement. But one of the big weaknesses is that they have laid out in the SMTA a list of options for benefits and that is up to the user to select in most cases, i.e., that the pharmaceutical industry chooses which benefits they want to provide from the list. And this has meant that technology transfer or the sharing of IP is never chosen. And that’s a big weakness that has to be addressed in the text of the Pandemic Accord and/or the IHR.”*  
(Professor Suerie Moon, Co-Director, Global Health Centre, Graduate Institute Geneva)

---

Negotiators from high-income countries interviewed for this report raised the costs of compliance with a potential PABS system, including the costs of compliance ‘checking’ of countries with widely differing ABS laws and regulations,

---

<sup>115</sup> < <https://who.zoom.us/rec/play/ucbabs9-qx5Kq9TAbJQloTsPx4weGkUTxo0ZIH9VMUvMEUKBqAgYts5W-F2aEYUJiA9tBCJldiCo4Xx.q1wvEYLQfolzng11?canPlayFromShare=true&from=sharerecordingdetail&continueMode=true&componentName=rec-play&originRequestUrl=https%3A%2F%2Fwho.zoom.us%2Frec%2Fshare%2Fd1WtRrpNExi6nQqE4ifPmK3ENzcgFBWiKdG9UnPMYLqA1GiEY50141eM3NJ1GgK.xeC2yPwYYMVkqJJY>> accessed 4 May 2023

<sup>116</sup> Ibid, timestamp 01:20

<sup>117</sup> Priti Patnaik and Nishant Sirohi, ‘Pathogen Access and Benefits Sharing: The Fulcrum On Which Equity Objectives Rest?’ Geneva Health Files (28 April 2023) <<https://genevahealthfiles.substack.com/p/pathogen-access-and-benefits-sharing>> accessed 4 May 2023

as significant and cumbersome. They also suggested that there would not be a way for the pharmaceutical industry to be compelled to share a percentage of products with the WHO or to transfer technology given that the pharmaceutical industry is not a party to the CA+.

These arguments echo those in a January 2023 Covington report commissioned by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA):

⋮ ⋮ ⋮

*On the for-profit side, of the dozen or so companies we spoke with, all were deeply familiar with the Nagoya Protocol and ABS rules. They all had extensive IT systems, dedicated personnel, and standard operating procedures in place to comply with ABS laws. One interviewee shared that in his/her company, the cost of compliance amounted to about 4 to 5 million USD a year for compliance checks around the world, for physical materials only. **The interviewee predicted that if this were to extend to genetic sequence data as well, the cost would double.***

– Covington, ‘The Impact of the Nagoya Protocol on Global Pathogen-Sharing’ (January 2023), page 25

Companies reading of these cost implications would no doubt disagree with a bilateral system, described as being ‘imposed’ on them by the Nagoya Protocol.<sup>118</sup> It should be noted that because of the legal character of the protocol and indeed its contents, a bilateral system is not imposed upon them; the Protocol also provides a multilateral approach to achieve its objectives. This multilateral approach, which would involve cooperative action to mitigate public health risks, is not featured in the Covington report – and should be considered in-depth by negotiators. According to Article 4.4 of the Nagoya Protocol:

⋮ ⋮ ⋮

*Where a specialized international access and benefit-sharing instrument applies that is consistent with and does not run counter to the objectives of the Convention and this Protocol, **this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.***<sup>119</sup>

– Nagoya Protocol, Article 4(4)

This means that, if a PABS system were included in the CA+, compliance with the Nagoya Protocol would no longer apply, and would only need to be operationalized with regard to PABS provisions within the CA+. However, non-applicability would need to be governed by a defined set of genetic resources subject to PABS, for example a WHO-developed list of pathogens of pandemic potential.

It has also been argued that PABS provisions within the Bureau’s Text could not realistically be operationalised as “the pharmaceutical industry are not signatories to the agreement. Member states are – and we cannot compel industry to comply.”<sup>120</sup> One legal expert stated that compliance is advanced by industry receiving something that is valuable to them in return.<sup>121</sup> An example of this is the GISRS platform, which comprises institutions in 126 WHO Member States and shares influenza viruses, data and benefits. It enables industry to access valuable GISRS information and materials, including samples of influenza virus of pandemic potential. As a condition of use of GISRS, industry provides 10% of annual influenza doses to the WHO per the PIP Framework.<sup>122</sup> According to one legal expert, the CA+ PABS system could operate in a similar manner, but linked to a WHO network or system (such as the IPSN) that provided similarly valuable information and materials regarding potentially pandemic pathogenic threats:

---

*“The IPSN could be the model to bring industry to the table, and 10% of products committed to WHO is an easier sell because they’ve never objected to it in the PIP Framework. They use GISRS because it is cheaper for them rather than having to track down countries bilaterally for virus*

---

<sup>118</sup> Covington, ‘The Impact of the Nagoya Protocol on Global Pathogen-Sharing’ (January 2023)

<sup>119</sup> Nagoya Protocol. Article 4(4)

<sup>120</sup> Global North country negotiator,

<sup>121</sup> Legal expert (interviewed in person, 23<sup>rd</sup> June 2023)

<sup>122</sup> WHO, ‘Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits’ (2021) <<https://apps.who.int/iris/rest/bitstreams/1351857/retrieve>> accessed 26 June 2023

*sharing. They make a partnership contribution of US\$28 million a year but it still works out with them in the end as they have an over US\$5 billion profit margin on flu vaccines.”*

*(Legal expert, interviewed 23 June 2023)*

---

Agreement on the PABS system as laid out in Option 12B of the Bureau’s Text would also increase legal certainty on what obligations industry would commit to in return for use of the data. On this, one Global South negotiator stated:

*“While some may be concerned about the ‘transactional’ nature of this – we don’t want a repeat of what happened during COVID-19. This is an understandable African group position. The controversy around this illustrates how long manufacturers in high-income countries have been using data and biological material without sharing the benefits. For African countries, everything hinges on PABS, or African countries will consider the CA+ to be a failure.”*

*(Global South negotiator, interviewed 23 June 2023)*

---

The PABS system as contained in the current CA+ draft states that pathogens can be shared via an SMTA developed specifically for the PABS system and that Parties should sustain it in inter-pandemic times through appropriate governance mechanisms. The CA+ draft also states that some of the text currently present in the CA+ draft on the PABS system ‘could be adopted under Article 21 of the WHO Constitution’, whether in the IHR amendments or under separate pandemic-related regulations. One legal expert discussed the potential to use the Article 21 mechanism:

*“It is certainly possible, in principle, to put an ABS system in IHR (2005), but it might not be considered a ‘targeted amendment’, and, more substantively, there may be questions about how doing so might affect the integrity and focus of the current IHR (2005). There are also questions about the ‘elephant in the room’, i.e. how to ensure that all countries will be legally bound to an ABS system where universality is critical. After all, if even just a few countries aren’t sharing pathogens and certain key countries aren’t sharing benefits, the whole system becomes weaker. One possible answer to this question is to consider using Article 21 again, which is to say, using Article 21 to establish a new, supplementary regulation dealing with ABS specifically. Such a regulation, a ‘Global Health Regulation 2024’, for example, could, in theory, be a vehicle for Member States to forge an ABS system that would likely apply to all countries (noting that so far no country has opted out of any Article 21 regulation), and would dovetail with both IHR (2005) and the CA+.”*

---

A Global South legal expert and observer to the negotiations separately cautioned about high levels of fragmentation caused by multiple instruments and processes. However, this legal expert agreed that, to ensure the widest possible adoption, the PABS system should be contained in both the Pandemic Accord and the IHR amendments, suggesting that this would help prevent the “drain of genetic resources from developing countries to developed countries”. Furthermore, ensuring that the PABS system was in both instruments would ensure that most countries adopted the provisions:

*“[We want] to ensure that there is a legal guarantee that diversification of production happens. For this to happen, it is important that the ABS should be connected not necessarily just to the INB, but also to the IHR 2005... We want the benefit-sharing mechanism applicable to both instruments. If it is under Article 19, I have a fair hunch or feeling that US may not ratify the new instrument, just like the Swiss won’t – as they both did with the FCTC. This would mean that the Biohub as well as American manufacturers to be out of the ambit of pandemic treaty... I don’t think Article 19 alone is a solution, because Article 19 would create obligations on certain countries, and no obligations on other countries. This would be very dangerous.”*

---



This was echoed by Larry Gostin, Professor of Global Health Law at O'Neill Institute at Georgetown University:

---

*“The great advantage of about putting ABS in the IHR as opposed to the pandemic instrument is that you have 196 States Parties in the IHR – you're not going to get that level of agreement to a pandemic treaty that has any kind of robust norms.”*

---

Another proposal is that a ‘Benefits Committee’ be established and mandated to convene quickly during a potential emergency and “*secure what it considers to be fair and equitable benefits*”.<sup>123</sup> Agreements resulting from Benefits Committee adjudication would be published upon execution and transparent to the general public. The proposal for a Benefits Committee is based on the fact that a fixed approach to benefit sharing cannot be established as the precise characteristics of future pandemics cannot be predicted, so fair and equitable benefit sharing for pathogen samples and genome sequence data will vary on a case-by-case basis.<sup>124</sup> As the Graduate Institute (2022) points out:

---

*“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.”*<sup>125</sup>

---

This point was reiterated by one of the co-authors of the report, Professor Suerie Moon, in an interview:

---

*“It is very difficult to get away from the need to adapt the response to the specificities of a pathogen, an outbreak, and a set of technologies that may or may not exist, may have been developed by one or several different entities. For example, if a product needed for an outbreak is already available worldwide as a low-cost generic (imagine if ivermectin had been shown to be effective for COVID-19), the most important benefits to secure may not be product donations or technology transfer, because lots of producers already know how to make it. But for COVID-19 vaccines, clearly technology transfer was insufficient and would be an important benefit to secure in future similar situations. But in yet another scenario, like mpox and the smallpox vaccine where there is an urgent need and very limited supply from one company, and we are seeing relatively small and sporadic clusters of cases (meaning it's a risky market that other companies may not wish to enter), the most important benefit may indeed be a donation in the short-term, and perhaps a commitment from the single producer to supply a minimum volume to an international stockpile. We cannot decide all of that in advance and we need some governance mechanisms to deal with that complexity in real time.”*

---

A Benefits Committee (or Access and Benefits Committee) could address weaknesses that exist in the PIP Framework, where pharmaceutical companies were contractually obliged to donate products and fulfilled those obligations, but have chosen not to share intellectual property, technology and know-how about those products.<sup>126</sup> As has been suggested, however, strengths of the PIP Framework, such as how pathogen sharing is placed on an equal footing with benefit sharing, and the mechanisms to implement those principles, for example through SMTAs and channelling of benefits through WHO, can be adapted for non-influenza pathogens.<sup>127</sup> Both the IHR and the CA+, therefore, offer

---

<sup>123</sup> Anthony Rizk, Adam Strobeyko, Gian Luca Burci, Suerie Moon, ‘What Are the Options? Pathogen-, GSD- And Benefit- Sharing In An International Instrument’ (2022) <<https://repository.graduateinstitute.ch/record/301010>> accessed 3 May 2023, p. 18

<sup>124</sup> Ibid, p. 9

<sup>125</sup> Ibid, p. 18

<sup>126</sup> Priti Patnaik and Nishant Sirohi, ‘Pathogen Access and Benefits Sharing: The Fulcrum on Which Equity Objectives Rest?’ Geneva Health Files (28 April 2023) <<https://genevahealthfiles.substack.com/p/pathogen-access-and-benefits-sharing>> accessed 4 May 2023

<sup>127</sup> Anthony Rizk, Adam Strobeyko, Gian Luca Burci, Suerie Moon, ‘What Are the Options? Pathogen-, GSD- And Benefit- Sharing In An International Instrument’ (2022) <<https://repository.graduateinstitute.ch/record/301010>> accessed 3 May 2023, p. 12



an opportunity for codification of these norms – whether in the body of text, as annexes, or as separate regulations under Article 21.<sup>128</sup>

However, the Graduate Institute emphasizes that the Benefits Committee in the Bureau’s Text is different from what it proposes in its report, It suggests that the Committee should be composed of country representatives rather than experts. In the words of Professor Suerie Moon:

---

*“In the Bureau’s Text, it is called an expert committee, and, in our paper, we don’t emphasize the expert nature, meaning that it’s very important that Member States are there. You need political weight in that committee because the decisions the committee would make or would be very closely involved with making are, at the end of the day, decisions for which countries need to take political responsibility. I would rely less on expertise than what we’ve seen in the Bureau’s draft, and more on political responsibility of governments in such a committee.”*

---

In an interview, one Global South negotiator stated that his region would not support the idea of a Benefits Committee deciding benefits on a case-by-case basis. This negotiator argued that there was a false equivalence being made between where the Benefits Committee originated (in the High Seas treaty) and pandemic-related benefits sharing:

---

*“We want a comprehensive access and benefit sharing mechanism [and] we want this to be created immediately as part of the INB negotiations. The comparisons [between a pandemic benefits committee and a marine biodiversity benefits committee] are misplaced in the sense that you’re dealing with resources beyond national jurisdictions in the High Seas treaty. In the case of the pandemic accord and the IHR, you will primarily deal with resources that fall within the jurisdiction of Member States. I don’t understand why other people should take credit on our natural resources. Whereas in the BBNJ [the High Seas treaty], you’re dealing with resources that are the common heritage of mankind.”<sup>129</sup>*

---

Based on interviews with negotiators and documented tensions relating to application of the PIP Framework, Global South negotiators would like to see the weaknesses of the PIP Framework remedied in the Pandemic Accord. As Frederick Abbott, Professor of International Law, explains:

---

*“A major issue in the PIP framework negotiations was what the developing countries side wanted – development and manufacturing capacity. They did not really want donations [of products] to WHO. They wanted to be able to build themselves up to make their own stuff and make it available. And that would entail transfer of technology and how that was going to be carried out and so forth. And the ultimate compromise at the end [of the PIP framework negotiations] was that the companies were given two choices. They could transfer technology, or they could provide products [and] they all opted for option B. And so there have been no technology transfer initiatives under the PIP framework.”*

---

Another Global South negotiator reiterated this point, stating that voluntary approaches of technology transfer in the PIP framework have not been taken up by industry and for that reason they were looking for binding commitments in the Pandemic Accord:

---

*“We have looked at the implementation of the [PIP] framework and the option of technology transfer has not been taken up basically because it’s a voluntary option that is presented to manufacturing companies. Based on this, we want binding commitments on benefit sharing. Our approach is that there should be upfront commitment to benefit sharing from manufacturers and*

---

<sup>128</sup> Priti Patnaik and Nishant Sirohi, ‘Pathogen Access and Benefits Sharing: The Fulcrum On Which Equity Objectives Rest?’ Geneva Health Files (28 April 2023) <<https://genevahealthfiles.substack.com/p/pathogen-access-and-benefits-sharing>> accessed 4 May 2023

<sup>129</sup> Global South Negotiator 1, interviewed 9 May 2023

*those that seek access to pathogens in genetic sequence data. There must be a clear commitment upfront to benefit sharing [and] some of the options are [building on] what is in the PIP framework such as donation of productions to the WHO of not 10% but higher than that, but we also want technology transfer and capacity building – all of which should be brought under the Pandemic Accord. From my perspective, they have to be legally binding, and they must also [have] commitment from Member States themselves that they will not prevent the sharing of benefits on the grounds of public policy assumptions or the use of the General Agreement on Tariffs and Trade to say that big pharmaceutical companies cannot transfer benefits. And that’s something that we will also try to close.”<sup>130</sup>*

---

Given that the Pandemic Accord is a Member State agreement, the practicality and workability of compelling manufacturers to share technology is debatable and would be complex. However, some experts state that this could be engineered not as a function of a direct order from Member States to manufacturers upon the sharing of pathogens and sequence data (which would be unrealistic) but rather as a function of creating an infrastructure that facilitates technology transfer, for example, through direct encouragement to deposit digital sequence information in public databases, as elaborated by Kathryn Garforth, Secretariat for the Convention on Biological Diversity.<sup>131</sup>

James Love, Director at Knowledge Ecology International (KEI), stated that a workable model could be based on an ‘open-source dividend’ mechanism. A KEI document states that the basic idea would involve the setting aside of a ‘portion of the commercial rewards from a medical product to be shared with persons or communities that openly shared knowledge, data, materials, and technology on a royalty-free and non-discriminatory basis’,<sup>132</sup> and that this would involve appointment of a temporary expert jury, when a new product enters the market. This group of experts, focusing on just one product, would collect and evaluate the evidence supporting nominations from the public, regarding persons or organizations that openly shared the knowledge, data, materials or technology that was useful in the development (or manufacturing) of that specific product.<sup>133</sup>

According to Love, this approach would enable manufacturers from anywhere in the world to access the technology:

*“The bigger the Open-Source Dividend is, the more people will choose the open-source technologies because it would be more profitable. Rather than picking winners and losers and trying to have ad hoc proprietary agreements with people. Because you open source it, you’ll let anyone in the planet play around your technology and speed up [innovation] with no transaction costs and no licensing.”*

---

It is unclear, however, whether this approach has any Member State backing, and how it would apply in pandemic/crisis scenarios.

An industry body, the IFPMA, has criticized a ‘transactional approach’ to PABS,<sup>134</sup> i.e. that sharing of GSD or pathogen data is dependent on guarantees of technology transfer, risking that countries withhold essential data needed until guarantees on tech transfer are established. KEI proposes that technology transfer could be better achieved by focusing on conditions related to government-funded R&D and through specific incentives to companies:

*“I wouldn’t want tech transfer to rise or fall on whether or not somebody shares a virus. The low hanging fruit on tech transfer would be [conditions on] government-funded R&D. If people can figure out how to create an incentive for companies to agree to share the know-how, IP rights,*

---

<sup>130</sup> Global South negotiator 2, interviewed 9 May 2023

<sup>131</sup> INB Intersessional, Pathogen Access and Benefit Sharing, 2023

<sup>132</sup> Knowledge Ecology International, ‘Additional written comments by Knowledge Ecology International to the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response’ (24 June 2022) < <https://www.keionline.org/wp-content/uploads/Open-Source-Dividend-INB-24June2022.pdf> > accessed 21 May 2023

<sup>133</sup> Ibid

<sup>134</sup> Kerry Cullinan, ‘“Transactional’ Pathogen Sharing Undermines Global Health Security’ Health Policy Watch (17 January 2023) < <https://healthpolicy-watch.news/transactional-pathogen-sharing-undermines-global-health-security/> > accessed 21 May 2023

*trade secrets, and the whole set of rights that you would attach to a government-funded thing cross-border – this would make more sense.”*

---

By contrast, Sangeeta Shashikant from Third World Network rejected the notion of predetermined benefits being transactional because no bilateral exchange would be involved, but rather that the benefits would be shared widely:

*“It is not transactional because we are not looking at bilateral benefits. This is cooperation at the multilateral level. Once we have a system of ABS, it is saying that countries are going to be sharing the biological material and sequences at the multilateral level, overseen by the World Health Assembly and who as an institution is subject to guidelines, and that Member States are going to be developing [products] with respect to access considerations and that this would be subject to certain terms and conditions on its use.”*

---

### **Summation**

Negotiators and experts believe PABS to be at the centre of the political bargain in the CA+, indicating its central importance to the Global South. The opposition to a PABS system seems to be rooted in questions about feasibility of such a system, costs of compliance attributed to the Nagoya Protocol, that Nagoya protocol interferes with product development, and other additional benefit-sharing mechanisms. Given that there is a benefits-sharing system in place via the PIP framework for influenza and GISRS, and the possibility of establishing new GISRS-like networks or systems, the question about feasibility seems addressable. In addition, given Article 4(4) of the Nagoya Protocol states that the Protocol shall not apply where a ‘specialized international access and benefit-sharing instrument’ has been developed, multilateral approaches that are cooperative in nature can offer legal certainty for both access and benefit sharing, as well as incentives for industry.

## One Health

**Introduction.** According to the WHO, One Health is an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems, and crucially recognizes that human and animal health are connected to the wider environment.<sup>135</sup> While COVID-19 origins work continues, the first peer-reviewed article from Chinese swabs indicate that animal DNA was present in samples that tested positive for SARS-CoV-2.<sup>136</sup> Given that over the past three decades 75% of newly detected human pathogens have originated in non-human animals<sup>137</sup>, and increasing recognition of the role of the environment and climate change in aggravating zoonoses,<sup>138</sup> there is a recognition that there needs to be better coordination across these fields.

As outlined by the Quadripartite<sup>139</sup> (the WHO, Food and Agriculture Organization of the United Nations, United Nations Environment Programme and World Organization for Animal Health), One Health has a strong focus on prevention and early detection of cross-species transfer of pathogens of pandemic potential.

The Bureau's Text for the Pandemic Accord presents two options, one that places various One Health obligations upon parties and one that proposes removal of the One Health section, implying that it belongs in a separate treaty process or in regulations. The key issue in this area is that One Health provisions would place additional obligations, for example relating to surveillance, upon countries that already have limited financing and technical capacity for human surveillance, without making clear what additional funding or technical assistance would be available. In addition, some parties are concerned that these obligations would divert essential resources away from human health. This suggests that financing and technical assistance questions will need to be addressed before less-developed countries take on additional obligations.

**Objective of Instrument Provisions.** To ensure greater coordination, surveillance, accountability, and investments around the health of people, animals, and ecosystems.

### Relevant Provisions.

CA+ Pandemic Instrument Article 5

Parties to regularly assess One Health capacities and to, inter alia, develop and implement a national One Health action plan on antimicrobial resistance in humans and animals, and to promote or establish One Health joint training and education plans for human, animal, and environmental health workforces. Option 5B is 'not to include the article'.

IHR Amendments Annex 1, Article New 5

That state parties should build capacities on collaborative surveillance networks to quickly detect public health events at 'human-animal-environmental interface including zoonotic spills and Anti-Microbial resistance'.

### Areas of Concern

1. Would One Health obligations as included in the Bureau's Text require significant financial, operational and technical trade-offs with regard to human health?
2. Do all countries appreciate the importance of greater coordination on One Health and are they aware of all initiatives occurring at the human-animal-environment interface?
3. Have One Health norms been developed by the Quadripartite with insufficient Member State consultation?
4. Does One Health belong in a separate accord/instrument/process, so that it does not divert resources away from human health?

<sup>135</sup> WHO, 'One Health' <<https://www.who.int/health-topics/one-health#tab=tab1>> accessed 5 June 2023

<sup>136</sup> Liu, W.J., Liu, P., Lei, W. *et al.* Surveillance of SARS-CoV-2 at the Huanan Seafood Market. *Nature* (2023). <https://doi.org/10.1038/s41586-023-06043-2>

<sup>137</sup> Jeremy Brice, Rossella Soldi, Pablo Alarcon-Lopez, Javier Guitian, Julian Drewe, [Daniela Baeza Breinbauer](#), [Francisca Torres-Cortés](#) and Katie Wheeler, 'The Relation Between Different Zoonotic Pandemics and the Livestock Sector' (November 2021) <<https://www.lse.ac.uk/business/consulting/reports/the-relation-between-different-zoonotic-pandemics-and-the-livestock-sector>> accessed 5 June 2023

<sup>138</sup> Camilo Mora and others, 'Over half of known human pathogenic diseases can be aggravated by climate change' *Nat. Clim. Chang.* 12, 869–875 (2022). <https://doi.org/10.1038/s41558-022-01426-1>

<sup>139</sup> WHO, 'Quadripartite call to action for One Health for a safer world' (27 March 2023) <<https://www.who.int/news/item/27-03-2023-quadripartite-call-to-action-for-one-health-for-a-safer-world>> accessed 21 August 2023

### Areas of Concern (continued)

5. Would exclusion of One Health commitments in the Pandemic Accord be a lost opportunity to make significant progress on One Health?

**Cross-References/Incompatibilities.** Both documents refer to the need to build capacities at the ‘human–animal–environmental interface’. The Pandemic Accord, however, is more detailed and points to multiple new commitments for Member States, including national action plans, training and the implementation of One Health surveillance mechanisms.

**Opportunities for Consensus.** Some countries have suggested that do not have the financial and technical capacity to enact and operationalize comprehensive action plans on One Health. On this, several governments that are in favour of One Health provisions in the CA+ and IHR acknowledged that the question of resourcing has yet to be resolved. Some countries have had longstanding domestic initiatives that promote collaboration across human and animal health but do not necessarily call these ‘One Health’, and there may need to be more work done on identifying and mapping existing initiatives. In addition, there may be a need to establish a high-level coordination mechanism on One Health to build upon existing work, whether as a subsidiary body to the COP or as a separate mechanism.

Others believe that One Health does not belong in the Pandemic Accord as it could divert resources away from human health. In addition, some are concerned that One Health norms have been thus far advanced through the Quadripartite<sup>140</sup> group of agencies without adequate Member State deliberation and accountability – and that this needs to occur as a separate process rather than through inclusion in the INB and IHR processes. Negotiators from ministries of health suggested that they did not have the mandate from other ministries necessary for One Health negotiations and that a separate process or agreement was necessary for One Health before it could be linked to a Pandemic Accord. There is also the perception that, while prevention of zoonotic spillover is important, pragmatically it will be difficult to achieve commitments on One Health without significant trade-offs on access to countermeasures and financing. The multiple overlapping concerns highlight the need for in-depth multilateral conversations and decisions specific to One Health that cover both ideological and financial issues.

The IHR amendments propose building capacities on collaborative surveillance networks to detect public health events at the human–animal–environmental interface. The amendments do not explicitly refer to One Health terminology, and therefore may be more palatable given that many countries are already collaborating on human and animal health but may not identify these specifically as One Health initiatives. Furthermore, the provision is loosely phrased and enables countries to make gains on collaborative surveillance at the human–animal–environmental interface according to their own capacities. However, this may still be dependent on whether a financial mechanism is successfully established within the IHR, as many low- and middle-income countries will have insufficient resources to build these networks. Furthermore, Member States will need to consider whether it is appropriate to insert provisions focused on this interface in regulations targeted predominantly at human health. Given that training is capacities-related, this area may be more suitable for inclusion in the IHR rather than the Pandemic Accord.

### Analysis.

Central to One Health discussions in these two processes are questions about financial and technical capabilities and the nature of the two processes (with an Article 19 CA+ process being more political and IHR more technical and capacities-focused). There is strong recognition that progress needs to occur on One Health, with the ‘Friends of One Health’ group of countries (including Denmark, Kenya, Fiji, Switzerland and the EU), as well as Iran, Paraguay, Colombia, and Saudi Arabia speaking in favour of One Health provisions in the CA+ in March 2023 INB discussions.<sup>141</sup> Legal experts have spoken in favour of it, with Professor Lawrence Gostin emphasizing:

---

<sup>140</sup> WHO, ‘Quadripartite Memorandum of Understanding (MoU) signed for a new era of One Health collaboration’ (29 April 2022) <[https://www.who.int/news/item/29-04-2022-quadripartite-memorandum-of-understanding-\(mou\)-signed-for-a-new-era-of-one-health-collaboration](https://www.who.int/news/item/29-04-2022-quadripartite-memorandum-of-understanding-(mou)-signed-for-a-new-era-of-one-health-collaboration)> accessed 7 June 2023

<sup>141</sup> Priti Patnaik & Shoa Moosavi, ‘Pandemic Accord Negotiations: Away from Public Glare, but Center of Attention’ *Geneva Health Files* (3 March 2023) <<https://genevahealthfiles.substack.com/p/pandemic-accord-negotiations-away>> accessed 11 May 2023

---

*“I am a passionate believer in One Health. Everyone who is honest understands that human and animal health, and the environment are crucial to human flourishing. We need to get it done, and the Pandemic Accord is our best and probably last shot.”*

*(Professor Lawrence Gostin, via email communication, 2 June 2023)*

---

Negotiators from the European Union emphasized the high likelihood of the next pandemic originating from zoonotic spillover, arguing strongly for a One Health approach:

---

*“If you don’t apply any One Health approaches, that is counterintuitive and makes no sense as you cannot improve prevention. The likelihood of any new pandemic [originating] from zoonotic spillover is over 70%.”*

*(European Union negotiator, interviewed via Zoom, 1 June 2023)*

---

A representative from the Africa Centres for Disease Control and Prevention (Africa CDC) detailed how there has been ‘remarkable progress’<sup>142</sup> on One Health in African Union Member States, including One Health approaches in the Africa common position on antimicrobial resistance. While the document does not explicitly refer to ‘One Health’, the document recommends that African Union Member States ‘establish and strengthen national task forces that represent human, animal, plants, and environmental agencies’, and that regional economic communities should ‘harmonize regulation of antimicrobial agents used in animals and humans.’<sup>143</sup> There are also technical taskforces at the African Union on zoonotic diseases that resemble the One Health Quadripartite. In the words of Dr Yewande Alimi, Antimicrobial Resistance and One Health Program Coordinator at Africa CDC:

---

*“The African Union has mechanisms that are able to push strong political momentum on issues such as One Health. We are leveraging our strength as a technical institution by looking at zoonotic diseases and similarly, the African Union also has a mechanism for coordination for zoonotic diseases, where you have public health agencies, agriculture-focused agencies, climate change, and food safety agencies in a multisectoral task force like the Quadripartite, just at the regional or African Union level.”*

*(Dr Yewande Alimi, Antimicrobial Resistance and One Health Program Coordinator, Africa CDC)<sup>144</sup>*

---

One negotiator pointed to ongoing efforts on One Health in their region, and national government efforts that were supportive of One Health approaches. However, this negotiator stated that One Health was a multi-ministry effort and given that the Pandemic Accord was predominantly with the realm of health officials, a separate protocol or agreement on One Health was more appropriate:

---

*“We actually have One Health action plans with [regional body] and we’ve been doing this voluntarily. Now they want to put One Health as an obligation. There’s a lot of things [about One Health] that we haven’t yet done nor understood. For example, when they mention integrated surveillance, what does this mean? We ask and no one really tells us, although we know it means to monitor all your animals and plants etc, but how can you put this in the Pandemic Accord because it involves other ministries, and it’s not MOH per se that we’ll be doing this. Therefore, putting it in a Pandemic Accord we think it’s a bit too much, even though we are doing some One*

---

<sup>142</sup> Interview with Yewande Alimi, Antimicrobial Resistance & One Health Program Coordinator, Africa CDC (via Zoom, 15 June 2023)

<sup>143</sup> African Union, Africa Common Position on Antimicrobial Resistance (July 2019)

<<https://au.int/sites/default/files/newsevents/workingdocuments/36768-wd-sa24481eoriginalafricacommonpositiononantimicrobialresistance.pdf>> accessed 4 July 2023

<sup>144</sup> Interview with Yewande Alimi, Antimicrobial Resistance & One Health Program Coordinator, Africa CDC (via Zoom, 15 June 2023)



*Health approaches. One Health is a big area. Some say that perhaps you should have something else first, not place into a treaty, but some kind of small-scale agreement on One Health before linking it to the Pandemic Accord.”*

*(Global South negotiator, interviewed 31 July 2023)*

---

While there is an acknowledgment that One Health is important, and indeed countries said that they were already doing work along the human-animal-environment interface (without necessarily calling it One Health), some country negotiators stated that they do not have the financial or technical capacity to take on One Health obligations as proposed in the Bureau’s Text, including action plans, surveillance and training. In the words of one Global South negotiator:

*“We have not even reached the capacity we need to on human surveillance much less animal surveillance.”*

*(Global South negotiator, interviewed 5 June 2023)*

---

Some countries are examining options for opt-in or opt-out of mandatory One Health commitments given these concerns. This includes making reservations when ‘signing, ratifying, formally confirming, accepting, approving, or acceding to a treaty’.<sup>145</sup>

The issue of financing for One Health implementation was deemed critical. Drawing a comparison with antimicrobial resistance (AMR) targets, Africa CDC suggested that One Health targets without requisite financing would hamstring meaningful progress:

*“For example, in 2015 countries were mandated to develop [AMR] national action plans. What we saw with lower middle-income countries and a lot of African countries is that we all went into the global action plan on AMR with the template we developed for national action plans. When it was time to implement, there were no financial resources provided, so countries just did not cost it. We just adapted based on the global context and global recommendations, but when it was time to implement, we struggled all around. We don’t have the resources.”*

*(Dr Yewande Alimi, Antimicrobial Resistance and One Health Program Coordinator, Africa CDC)*

---

These tensions are well-recognized. In a Graduate Institute seminar in April 2023, Professor H el ene de Pooter acknowledged that these commitments could be overwhelming to Member States and that “to facilitate consensus, states could decide that the national plans and contributions [to One Health] could be defined progressively and reinforced with time.”<sup>146</sup> In follow-up correspondence, Professor de Pooter stated that it was concerning that One Health was presented as a mere option in Article 5 of the May 2023 Bureau’s Text,<sup>147</sup> reflecting “some states’ feelings that One Health is not a priority and is too costly.”<sup>148</sup>

On the issue of progressive contribution as mentioned by Professor de Pooter, one delegation from a high-income country stated that they would be open to the notion of transition periods for implementation. Should this become a

---

<sup>145</sup> United Nations, ‘Guide to Practice on Reservations to Treaties’ (2011), Article 1.1.1 <[https://legal.un.org/ilc/texts/instruments/english/draft\\_articles/1\\_8\\_2011.pdf](https://legal.un.org/ilc/texts/instruments/english/draft_articles/1_8_2011.pdf)> accessed 7 August 2023

<sup>146</sup> H el ene de Pooter in Graduate Institute seminar, ‘Averting A Collision Course? Beyond The Pandemic Instrument and The International Health Regulations’ (26 April 2023) <<https://www.graduateinstitute.ch/communications/events/pandemic-instrument-and-IHR-event>> accessed 11 May 2023

<sup>147</sup> ‘Draft Bureau’s Text of the WHO CA+’ (22 May 2023) < <https://healthpolicy-watch.news/wp-content/uploads/2023/05/DRAFTINBBureau-text22-May.pdf>> accessed 8 June 2023

<sup>148</sup> Interview with H el ene de Pooter (via email correspondence, 2 June 2023)

common position of all Member States supportive of One Health being in the Pandemic Accord, concrete discussions would still be required on levels of financing, both external and domestic.

There are also questions about where is the ‘natural home’ of One Health – in a Pandemic Accord or the IHR amendments. The current IHR amendments document refers to building capacities of the State Parties at community/intermediate level on collaborative surveillance networks at the human–animal–environment interface, including zoonotic spills and AMR within the territory of the State Party. Central to this question is the nature of the IHR 2005. As Gian Luca Burci describes:

⋮ ⋮ ⋮

*“The IHR is not an operational instrument for the mobilization of financial and human resources, and neither does it purport to regulate the domestic response to outbreaks except with regard to national ‘core capacities’”<sup>149</sup>*

– Gian Luca Burci, *The Legal Response to Pandemics*, 2020

When interviewed, Burci argued that the purpose of the IHR should remain largely unchanged, but they should have additional enforceability and strength, with a more robust process complementing or replacing the currently voluntary mechanism of Joint External Evaluation<sup>150</sup>:

---

*“IHR should continue to do largely what it is already doing but strengthened and given more teeth. Presently, it is all based on self-assessment [of capacities] with some guidance from WHO, but that to me is not enough to deter some states from what they did during COVID, i.e., basically going on their own and undermining the very idea of the IHR as an instrument for coordination, for uniformity, for harmonization, and so on and so forth. Fundamentally, IHR is limited to preparedness, early detection, and containment. There are many different views on the rationale for the two instruments [CA+ and IHR] and what their competitive advantages are, but in my very modest view, the IHR should continue to do what it does, and more regulatory, transactional, and political issues such as One Health and equity should in principle be negotiated in either in a treaty or in a separate instrument.”*

*(Gian Luca Burci, interviewed via Zoom, 5 May 2023)*

---

On the question of which legal instrument One Health belongs in, a legal expert from Third World Network argued that inclusion of One Health in the IHR 2005 and WHO CA+ would not advance the One Health agenda nor benefit pandemic prevention, preparedness and response. One Health, it was suggested, is a broad multidisciplinary scientific concept that goes far beyond the scope of health emergency preparedness and response. In addition, the same expert argued that:

---

*“Investments needed for One Health surveillance could burden and constrain developing countries policy space to develop and invest in health systems such as primary health care and hospital care facilities.”*

*(Nithin Ramakrishnan, Developing Country Observer, Third World Network)*

---

Ramakrishnan also highlighted how countries have made substantial progress in IHR surveillance scores in contrast to response capacities. In his own words:

---

<sup>149</sup> Gian Luca Burci, ‘The Legal Response to Pandemics: The Strengths and Weaknesses of the International Health Regulations’ (2020) *Journal of International Humanitarian Legal Studies* 11, 204-217, 207

<sup>150</sup> WHO, ‘Joint External Evaluation’ < [https://www.who.int/emergencies/operations/international-health-regulations-monitoring-evaluation-framework/joint-external-evaluations#:~:text=Joint%20External%20Evaluations&text=A%20Joint%20External%20Evaluation%20\(JEE,to%20deliberate%20or%20accidental%20events](https://www.who.int/emergencies/operations/international-health-regulations-monitoring-evaluation-framework/joint-external-evaluations#:~:text=Joint%20External%20Evaluations&text=A%20Joint%20External%20Evaluation%20(JEE,to%20deliberate%20or%20accidental%20events)> accessed 21 August 2023

*"The most significant gap in the present law is equitable access to health products, technologies and services. This corresponds to current IHR capacity scores level, which shows substantial progress in achieving surveillance capacities rather than response capacities. Countries need to spend negotiating energy on this. Many aspects of pandemic prevention are already addressed by FAO, OIE, and UNFCCC. If these organizations are adequately resourced and they fulfil their mandate, pandemic prevention would naturally be aided and organized. Investing in prevention, although [an] appealing concept, we have to be realistic that infections and spillovers are not fully avoidable, and adequate primary care and hospital care facilities are important to stop it from spreading on a pandemic scale."*

*(Nithin Ramakrishnan, Developing Country Observer, Third World Network)*

---

Questions about the 'natural home' of One Health also seem to be rooted in more fundamental questions about who 'created' and defined One Health, and whether this definition had the democratic weight of Member States behind it. In the words of one negotiator:

*"The concern of developing member state diplomats pertains to efforts to institutionalize One Health through prominent inclusion in the WHO CA+. Clearly there's a benefit from having an integrated approach, and in fact our health officials like One Health. But there is no single agreed definition and standards on One Health except for those developed by the Quadripartite – standards which have not been agreed to by Member States. We are cautious because it seems to us like they want to institutionalize these standards without Member State deliberation. The insistence on One Health in the pandemic instrument is a really big deal for them but the question is why exactly? This for me is still missing – and when that it is clarified then we can perhaps make progress in the negotiations."*

*(Global South negotiator, interviewed 23 June 2023)*

---

The realpolitik lands, therefore, at the nexus of necessity, resources, procedure and trade-offs, including with respect to resourcing and actions in the agricultural sector in developing member states. Professor Suerie Moon stated that without these trade-offs, there would unlikely be an agreement on One Health:

*"It does make sense to put in place long-term measures to prevent spillover. But the question of how high a priority is that for many of the developing countries and what applies in terms of potentially significant economic costs and changes to people's livelihoods and practices in agricultural sectors – these are potentially very, very profound changes. It's a big ask. And if the big ask comes without trade-offs either on countermeasures or trade-offs on financing, then I don't see how there will be agreement reached on it."*

*(Professor Suerie Moon, Co-Director at the Global Health Centre and Professor of Practice for the Interdisciplinary Programmes, Graduate Institute, interviewed 23 June 2023)*

---

One academic suggested that the Pandemic Accord text can help to drive One Health-related activities and approaches. Professor de Pooter was supportive of the Bureau Text, and in particular Option 5.A.3 (The Parties will identify and integrate into relevant pandemic prevention and preparedness plans interventions that address the drivers of the emergence and re-emergence of disease at the human-animal-environment interface, including but not limited to climate change, land use change, wildlife trade, desertification and antimicrobial resistance). However, she suggested that One Health for prevention purposes should be more explicitly mentioned in other sections, such as Option 4B (Parties to periodically update and review comprehensive multisectoral national infection prevention and control measures, plans and programmes) and Article 6.4.E (reinforce public health functions for cross-sectoral prevention of zoonoses).

De Pooter was concerned that there was no reference to mainstreaming One Health into trade law such as General Agreement on Tariffs and Trade (GATT) Article XX and the Sanitary and Phytosanitary (SPS) Measures Agreement. On this point, De Pooter and Burci's 2022 White Paper proposed several possible scenarios, such as states refusing to import animals or food products that are produced inconsistently with the One Health perspective.<sup>151</sup> This suggests that further discussions, whether through intersessional meetings or other formal meetings, are needed on how One Health provisions could be integrated into other relevant treaties and instruments in international law.

The cost issue remains critical for countries with overstretched budgets and with insufficient technical capacity, and has been acknowledged by funders such as the World Bank, which stated that "an investment framework for prevention needs to include the health of humans, animals, and ecosystems... It needs to guarantee that there are no missing links in the complex risk management chain spanning prevention, preparedness, response, and recovery that brings together disparate public agencies unaccustomed to collaborating and coordinating."<sup>152</sup> The World Bank has proposed several options, including international grants or high concessional loans, to enable states to achieve at least minimum standards on pandemic management and One Health, with grants also available to low-income livestock herders/farmers who may not be able to afford relevant health and veterinary services.<sup>153</sup>

There is some acknowledgment by high-income country negotiators of the need to resolve financing and capacities questions before Parties agree to extensive One Health provisions in the Pandemic Accord. In the words of one European government legal expert:

---

*"On One Health, all of us completely agree that it is super important. You need to have One Health surveillance if you want to be able to have a full overview on what's happening. Of course, we are very much aware that if you don't have capacities, you cannot do surveillance. That's going to have to be a discussion. This is not something we've fully discussed yet."*

*(European government legal expert, interviewed 6 June 2023)*

---

Infectious diseases epidemiologist and public health expert Dr Ngozi Erundu from the Global Institute for Disease Elimination (GLIDE) suggests that there are pragmatic ways of making One Health provisions less onerous for countries, for example by mapping initiatives and budget lines that already exist in countries. Rather than creating a financial mechanism, Erundu suggested that the Pandemic Accord should establish a coordination mechanism for 'health in all policies':

---

*"Something that I've heard a lot from countries like Ethiopia, Sudan, Kenya, is that they've been working alongside each other on human and animal health before it was called One Health. We need to pull out strategies that already exist and support countries in creating those budget lines – that is one way to make it not too laborious or overwhelming. I would hesitate to suggest we need a separate financing mechanism for One Health when these countries have already been thinking about health in all policies. It's more about incorporating and recognizing those budget lines and ensuring that there is some kind of high-level coordination mechanism."*

*(Dr Ngozi Erundu, Technical Director, GLIDE, interviewed 6 June 2023)*

---

**Summation.** There are several key issues that will need to be discussed by Member States before agreement can be reached on One Health, including:

---

<sup>151</sup> De Pooter and Burci (coord.), 'White Paper 22: One Health' <<https://www.ilaparis2023.org/wp-content/uploads/2022/12/SANTE-EN.pdf>> accessed 6 June 2023, p. 99

<sup>152</sup> World Bank, 'Putting Pandemics Behind Us: Investing in One Health to Reduce Risks of Emerging Infectious Diseases' (2022) <<https://openknowledge.worldbank.org/server/api/core/bitstreams/956a58be-ddd8-572f-8aac-df5ab453d7b2/content>> accessed 5 June 2023, p. 35

<sup>153</sup> World Bank, 'Putting Pandemics Behind Us: Investing in One Health to Reduce Risks of Emerging Infectious Diseases' (2022) <<https://openknowledge.worldbank.org/server/api/core/bitstreams/956a58be-ddd8-572f-8aac-df5ab453d7b2/content>> accessed 5 June 2023, p. 36

1. Is there a common understanding of the One Health approach, and are Member States comfortable with the norms developed by the Quadripartite?
2. What financial and technical assistance would need to be provided to ensure One Health obligations were met in less-developed countries?
3. Would One Health initiatives/approaches in the CA+ divert resources away from human health be mitigated?
4. What mapping has been done on existing initiatives (and budget lines) at the human-animal-environment interface within countries?
5. What appetite is there for a separate One Health instrument? And would one be feasible?

To facilitate an agreement on One Health that addresses zoonosis prevention without being financially and technically overwhelming for less-developed countries, mapping of existing initiatives and domestic budget lines on animal and human health could identify current resourcing and capacity gaps. This would provide the World Bank and other multilateral development banks, as well as climate and agriculture funders, with an indication of the likely resourcing needs.

Negotiators could explore the feasibility of a high-level One Health coordination mechanism to be integrated into the Pandemic Accord to coordinate existing efforts occurring at the human-animal-environment interface, perhaps as a subsidiary body to the COP, rather than creating extensive additional obligations without guarantee of financial and technical capacities. To facilitate progress, use of opt-in or opt-out of mandatory One Health commitments could enable countries some flexibility in achieving One Health obligations over the short term. Countries are entitled to express reservations when 'signing, ratifying, formally confirming, accepting, approving, or acceding to a treaty'.<sup>154</sup>

---

<sup>154</sup> United Nations, 'Guide to Practice on Reservations to Treaties' (2011), Article 1.1.1  
<[https://legal.un.org/ilc/texts/instruments/english/draft\\_articles/1\\_8\\_2011.pdf](https://legal.un.org/ilc/texts/instruments/english/draft_articles/1_8_2011.pdf)> accessed 7 August 2023

## Supply Chain and Logistics

**Introduction.** The COVID-19 pandemic was marked by supply constraints of essential products, stockpiling of products beyond national needs by some countries, and an overall lack of transparency on national stockpiles. In addition, while the ACT-Accelerator delivered 1.9 billion doses of vaccines through the COVAX mechanism, and nearly 180 million tests through the diagnostics pillar, these were delivered much later and in smaller quantities than in the Global North. Behind the scenes, there were many logistical challenges to transporting pandemic products given global reductions in air traffic, with WHO logistics teams requiring many ad hoc and transactional interactions with countries to obtain overflight clearances, landing permits in countries, and waivers during export bans.

Recognizing this, in May 2023 the WHO Director-General identified the need to focus on 'end-to-end health emergency supply chains'<sup>155</sup> and a medical countermeasures (MCM) coordination platform to 'harness and align (sic) the collective capabilities'<sup>156</sup> of various actors. This is perhaps what 'a partnership' in Option 13C refers to in the Bureau Text. However, as the World Health Assembly wrapped up in May 2023, it was evident that Member States wanted a radical reform away from the ACT-Accelerator model and from any parallel processes that involve Member States.<sup>157</sup>

**Objective of Instrument Provisions.** To ensure greater coordination and greater equity around supply and logistics, including through efficient multilateral and regional purchasing mechanisms, and to promote transparency in cost and pricing of pandemic-related tools.

### Relevant Provisions.

CA+ Pandemic Accord Article 13(2)	Options to create a Supply & Logistics Network that would inter alia promote transparency, identify the most efficient multilateral and regional purchasing mechanisms, map distribution options, and assess anticipated demand for pandemic-related products [Option 13A]
	Not establish a Supply & Logistics Network, but rather the Parties shall conduct all specified functions, including developing a mechanism to ensure the fair and equitable allocation of pandemic-related products. [Option 13B]
	That WHO will establish a Partnership to collaborate with relevant agencies within the UN system, regional organisations, and other relevant organisations to, inter alia, determine equitable allocation and advance purchase commitments. [Option 13C]
CA+ Pandemic Accord Article 13(3)	That Parties shall make publicly available online the terms of government-funded purchase agreements for pandemic-related products.
IHR Amendments Article 13(5)	Upon request by WHO, States Parties to provide support to WHO-coordinated activities including supply of health products and technologies for effective response to a PHEIC in another State Parties' jurisdiction and to provide reasons to WHO if unable to do so.
IHR Amendments Article 13A	During the international response to a PHEIC declaration, WHO shall carry out an assessment on the availability and affordability of health products such as Dx, Tx, Vx, PPE and other tools. In addition, WHO shall, in its allocation plan for health products, identify and prioritise recipients of health products.

---

<sup>155</sup> World Health Organization, 'Strengthening WHO preparedness for and response to health emergencies: Strengthening the global architecture for health emergency preparedness, response and resilience: Report by the Director-General' A76/10 (19 May 2023) p. 8 <[https://apps.who.int/gb/ebwha/pdf\\_files/WHA76/A7610-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA76/A7610-en.pdf)> accessed 20 May 2023

<sup>156</sup> Ibid, p. 7

<sup>157</sup> Priti Patnaik, 'The Remaking of WHO Finances: WHO Could Become the First UN Agency to go the Replenishment Way; Countries Assert Their Role In Defining Health Emergencies Architecture' Geneva Health Files (26 May 2023) < <https://genevahealthfiles.substack.com/p/the-remaking-of-who-finances-who>> accessed 4 July 2023



IHR Amendments Article 18

In making recommendations vis-à-vis international travel and trade, WHO to consult ICAO, IMO, WTO to avoid unnecessary interference. That Parties ensure that there are contingency plans in place to facilitate health care worker movement and supply chains are facilitated in a PHEIC.

IHR Amendments Annex 1

That State Parties leverage digital technology for (inter alia) forecasting and supply chain management. (Article 6(d))

#### Areas of Concern

1. Would new mechanisms create an 'ACT-Accelerator 2.0', without addressing oversight, governance and operational shortcomings of the ACT-Accelerator model?
2. Would a 'network' be sufficiently collaborative with other agencies outside WHO, and could a Partnership in Option 13C better facilitate involvement of other actors?
3. How can sufficient country oversight and influence be ensured in any allocation mechanism established, whether part of the proposed Supply & Logistics Network or Partnership or elsewhere in the CA+ text?
4. Would a mechanism on supply be able to address equitable access without linkages to production?

**Cross-References/Incompatibilities.** Both CA+ and the IHR amendments refer to supply-related assessments. In the CA+, this refers to an assessment of the anticipated demand for pandemic-related products, sources (manufacturers and suppliers) of pandemic-related products, and the IHR amendments refer to an assessment of the availability and affordability of health products required for responding to a PHEIC.<sup>158</sup> Not all PHEICs will become pandemics, but both assessments would arguably be useful in either a PHEIC or pandemic scenario. Hence it may be useful for language to be streamlined for consistency across both instruments. Assessments of demand, availability and affordability could be triggered upon declaration of a PHEIC, with updating of these assessments by the Supply & Logistics Network in consultation with Member States and informed by relevant publicly available purchase agreements should the PHEIC progress to a pandemic.

In addition, both CA+ and the IHR amendments refer to an allocation plan or mechanism. In the case of PHEICs that progress to pandemics, it will need to be made clear whether this allocation plan will be brought under the purview of the CA+ and relevant bodies, and whether it would be subject to more inclusive governance.

**Opportunities for Consensus.** Many countries criticized the ACT-Accelerator (ACT-A) model for its lack of accountability. ACT-A supply mechanisms were perceived as being flawed, opaque, insufficiently inclusive and not led by the needs of the Global South. Hence many countries expressed concern about proposals for a Medical Countermeasures Platform (MCP) that might replicate ACT-A, especially if certain regions of the world overrepresented in its decision-making structures. Many countries see Section 13 CA+ as a way to remedy these deficiencies.

Some form of a Supply & Logistics Network/Partnership is felt to be necessary, but it would have to be supported by Member States to minimize issues related to practicalities such as uncoordinated overflight permissions, landing permits, and the implementation of export bans. This is referred to implicitly in IHR Article 18 but is not explicitly linked to the operation of the Network in the CA+.

Allocation mechanisms without inclusive governance could jeopardize equitable distribution of supplies. Furthermore, countries would need to be more transparent about volumes purchased, to discourage hoarding of supplies that are needed in other regions. Such an allocation mechanism could be set up with a governance structure that includes an advisory board with Pandemic Accord and IHR focal points, as well as civil society and independent experts.

The IHR are intended to be part of the first line of defence in health emergencies, are related to competencies, nomenclature and temporary recommendations, and do not relate to the mobilization of financial and human resources. Most suggested amendments to the IHR, including the recommendation for use of digital technology and efficient management of supply chains, therefore seem appropriately placed. However, the suggested amendments do not specify how the assessments and allocation plans conducted after the declaration of a PHEIC evolve in the case of a pandemic being declared.

---

<sup>158</sup> WHO, Article-by-Article Compilation of Proposed Amendments to the International Health Regulations (2005) submitted in accordance with decision WHA75(9) (2022), Article 13A(2)

Moving closer to consensus will require consideration of the following questions:

1. How can countries be equitably represented in decision-making of an allocation/supply mechanism?
2. How could the MCP address the shortcomings of the ACT-Accelerator and the supply issues seen in the COVID-19 response?
3. How should Article 13 be linked to production, and what concrete production-related obligations could be placed on Member States with manufacturing capacity?

## Analysis.

Discussions with negotiators revealed the need for clarity on the purpose of a Supply & Logistics Network. An interview with WHO's Chief of Operational Support & Logistics, Paul Molinaro, found that supply and logistics work during the COVID-19 pandemic was complicated by issues such as ad hoc engagements with countries, multiple overflight clearance arrangements, coordination with military authorities, and arrangement of landing permits. Having an established Network could help to streamline work across borders:

---

*"[During the COVID-19 pandemic] we put together the supply and logistics system primarily among the UN agencies and this was shepherded in when we had the UN Secretary-General request the creation of a task force for the COVID-19 Supply Chain system. From that, a number of NGOs and partners like the Global Fund, UNITAID and CHAI came in. However, one of the criticisms or shortcomings that we saw was that it was very difficult to engage with regional bodies and some Member States beyond a purely transactional relationship – i.e. states telling us we need something, us sourcing it, and in moving it [across borders] having to address individual states to transport [the products]. In order to put the plan together, we need several overflight clearances and landing permit in a third country which were difficult to get. We would address each country on an individual basis in order to get all the ducks in a row. This was a very ad hoc and transactional relationship with many of the states. When you hear that one country has put an export ban, you write to them asking for clarification, and we get a waiver, etc. This was one of the key considerations in proposing a Supply & Logistics Network."*

*Paul Molinaro, Chief of Operational Support & Logistics, WHO (via Zoom, 18 May 2023)*

---

One negotiating Member State, however, stated that the Bureau Text was insufficiently clear as to the obligations of the Member States towards such a Network. They argued that, as a Member State agreement, the text should be reworded to reflect this more appropriately – for example, so that it states that Member States should facilitate overflight and other logistical clearances, and that they should provide transparency to the Network on availability of commodities and purchases. According to Molinaro, a Supply & Logistics Network empowered through a Pandemic Accord would ensure there were legally binding commitments on better coordination and greater transparency on commodities supply:

---

*"Where possible, we should at least get commitments on sharing information in a transparent way. This doesn't necessarily mean giving up commercially sensitive data, but [rather], to know who's buying what, and who's delivering where, which provides a sense of where the gap is. That kind of coordination and information exchange should be embedded in the response. If someone (like the Supply & Logistics Network) is asking '(Which agencies/bodies) should be strengthened to optimise the response, the supply chain and coordination (of the response)'" - This is important because as the disease evolves and moves and shifts, and different populations start to take on more of a burden, it is important to be able to get those signals and provide that to a number of different parties [involved in procurement and supply] to say, 'right now, the critical area to supply is here'."*

*(Paul Molinaro, Chief of Operational Support & Logistics, WHO (interviewed via Zoom, 18 May 2023)*

---

Article 13 also places the design of an allocation mechanism firmly within the purview of the Supply & Logistics Network in the CA+. However, IHR amendments in Article 13A state that, after an assessment of affordability and availability, WHO will create an allocation plan. While not all PHEICs will become pandemics, when a PHEIC does become a pandemic, there will be a need to clarify whether the allocation plan developed after a PHEIC declaration will then be transferred to the Supply & Logistics Network for updating. There is also a need to consider *when* an allocation plan or mechanism can realistically be designed. Therapeutics, vaccines and some diagnostics may take time to develop, and thus an allocation plan or mechanism may only be feasible sometime after a pandemic declaration.

Discussion of the allocation plan provision in both CA+ and IHR texts led negotiators to reflect on the COVAX mechanism (within ACT-A) during the COVID-19 pandemic. Overall, negotiators from one region in particular noted the uneven and disproportionate allocation to one country in that region, raising the need for increased country involvement in the governance of any mechanism existing under Article 13 of the CA+. Negotiators from most regions repeated this latter point, highlighting what they felt were shortcomings in ACT-A governance style and poor transparency:

---

*“COVAX was something which was created and improvized last minute. I am not as critical of COVAX as some people are because it was simply created out of nothing. It was not planned; it was done in a rush and was an attempt to solve a problem. Things could have been done much better. We do need a more organized system within WHO to respond to pandemics and of great importance is that the governance of such a system should be much more transparent, with Member States having much more involvement.”*

*(Global South negotiator, interviewed via Zoom, 4 July 2023)*

---

Another negotiator echoed this point, but further stated that the EU proposal on medical countermeasures supply would not be accepted as it was not clear where Member States would have a vote:

---

*“We are not looking for what’s in the EU proposal, i.e. a platform that is independent where we don’t see any space where we as Member State can have a say and a vote. This does not work for us. It is really important for us that an allocation mechanism has a governance [mechanism] where we have a say and participate in what’s happening there. We need to see that in the Supply Network proposal.”*

*(Global South negotiator, interviewed 19 May 2023)*

---

Yet another negotiator made a similar point but linked this more explicitly to the ACT-A, and ongoing discussions around the proposed Medical Countermeasures Platform:

---

*“In the ACT-Accelerator, the donor countries had a stronger voice. They set up [the ACT-Accelerator] with other stakeholders such as philanthropic foundations and Member States didn’t have a strong voice. It wasn’t a very inclusive or transparent process at all. And actually, we [continue to be] concerned because right now discussions on the countermeasures platform is still being discussed among a small number of countries. I understand there are going to be consultations with WHO, but you cannot start like this again and having a restricted number of Member States involved.”*

*(Global South negotiator, interviewed 5 July 2023)*

---

In this vein, some negotiators stated that linking an allocation mechanism to production more explicitly was necessary to promote equity, arguing for “provisions that mandate more decentralized production” and for an allocation mechanism that involves regional procurement agencies more intimately.<sup>159</sup>

The Medical Countermeasures Platform has been criticized as being an ‘ACT-A 2.0’, “with more or less the same stakeholders and largely following the same overall ideas”.<sup>160</sup> This has been acknowledged by the Executive Director of the WHO Health Emergencies Programme, who stated at a World Health Assembly side event: “The real process is happening through the INB, the IHR revision process...These are the only agreements that existed and will exist internationally.... That is the mechanism through which any platform [will be] designed... There are many, many, members that are really frustrated right now because they can’t see into this process.”<sup>161</sup>

From these testimonials, it appears that negotiators expect some version of the medical countermeasures platform within Article 13 of the CA+. This will need to consider two main points:

- The multiple different medical countermeasures discussions in different forums<sup>162</sup> (G7 (Vision for Equitable Access to Medical Countermeasures), the Johannesburg process, and the G20 (Global Medical Countermeasures Coordination Platform)<sup>163</sup>.
- The scope of medical countermeasures that extends beyond supply and logistics, such as those related to R&D and community engagement

This suggests that medical countermeasures provisions will need to be placed elsewhere in the text and radically restructured to ensure inclusive governance while maintaining agility.

Civil society input to the Medical Countermeasures Prototype Working Group has suggested an advisory group be set up that includes IHR focal points and INB members, civil society and community representatives, and independent experts,<sup>164</sup> as well as thematic working groups that would ensure an end-to-end approach.<sup>165</sup> If adopted, these structures would bring the medical countermeasures platform outside the scope of Article 13 of the CA+.

The proposed IHR amendments related to supply remain predominantly focused on the need for Parties to provide support to WHO-coordinated activities (Article 13(5)) on supply of health products and that core capacities be developed as regards ‘effective management of emergency supply chains.’ (Annex 1, Article 5(vi)) One expert expressed concerns that this language remained passive – pointing perhaps to the need for robust compliance and accountability mechanisms in the IHR and a financial mechanism to ensure countries can be supported to facilitate delivery and maintain supply chains to ensure adequate response in an emergency. However, this could also reflect the legal character of the respective instruments, with the IHR intended to focus on capacities and competencies in preparedness and the CA+ a more appropriate location for political statements to facilitate supply and logistics.

**Summation.** Both instruments refer to an allocation plan or mechanism for products, but do not specify what would happen should a PHEIC develop into a pandemic. There are inconsistencies across the documents, with the CA+ text stating that the Supply & Logistics Network is responsible for the allocation plan while the IHR amendments text gives this role to the WHO more generally.

There is also a need to consider *when* an allocation plan or mechanism could be designed, given the potential need to develop new therapeutics, vaccines and diagnostics. For emergencies that remain as PHEICs, allocation plans are still required but, depending on the region affected, could be developed regionally in consultation with WHO.

---

<sup>159</sup> Interview with Global South negotiator (via Zoom, 5 July 2023)

<sup>160</sup> Els Torreele, Dr Joanne Liu, Michel Kazatchkine, ‘Opinion: Fighting epidemics takes equitable medical countermeasures’ Devex (13 June 2023) < <https://www.devex.com/news/opinion-fighting-epidemics-takes-equitable-medical-countermeasures-105676> > accessed 4 July 2023

<sup>161</sup> Mike Ryan, quoted in Priti Patnaik, Shoa Moosavi, Tessa Jager, ‘Countries Assert Their Role In Defining Health Emergencies Architecture’ Geneva Health Files (26 May 2023) < <https://genevahealthfiles.substack.com/p/the-remaking-of-who-finances-who> > accessed 17 July 2023

<sup>162</sup> Suerie Moon, ‘The ‘Countermeasures’ Jigsaw: Pluralism, Fragmentation, or just Chaos?’ Governing Pandemics Snapshot (July 2023) < <https://www.governingpandemics.org/gp-snapshot> > accessed 17 July 2023

<sup>164</sup> Rahman, Fifa and Kalama, Onesmus and Rick, Samantha and Lal, Arush and Baker, Brook K., A Medical Countermeasures Platform for Future Pandemics: Essential Elements for Equity (July 3, 2023). Available at SSRN: <https://ssrn.com/abstract=4498289>

<sup>165</sup> Defined as constituting upstream to downstream initiatives, from R&D and manufacturing through to patients receiving products. Torreele E, Kazatchkine M, Liu J, Dybul M, Cárdenas M, Singh S, Quigley HL, McNab C, Sirleaf EJ, Mazzucato M, Clark H. Stopping epidemics when and where they occur. *Lancet*. 2023 Feb 4;401(10374):324-328. doi: 10.1016/S0140-6736(23)00015-6. Epub 2023 Jan 12. PMID: 36642089; PMCID: PMC9836401.

To accommodate Member States' views on governance, additional text would need to be added to Article 13 CA+ for example to specify that the allocation mechanism would be determined in consultation with Member States in special emergency session of the COP.

The supply and logistics provisions in the IHR amendments seem appropriately focused on competencies. Points to clarify in the CA+ include relationships with the medical countermeasures platform, appropriate governance mechanisms, and linkages to production.

## Co-Development and Transfer of Technology and Know-How

**Introduction.** Inequities in supply of COVID-19 vaccines, therapeutics and diagnostics were well documented during the COVID-19 pandemic. This was the result of several factors, including the hoarding of vaccine supplies in high-income countries, and preferential supply to such countries, at times when the supply of vaccine was insufficient to meet global demand.

An intellectual property waiver combined with transfer of technology and know-how was seen by some to be an essential element for unlocking access for the Global South. According to the People's Vaccine Alliance, "The transfer of largely publicly funded vaccine technology and know-how from pharmaceutical corporations would fast track production to a matter of months."<sup>166</sup> However, Norway's global health ambassador John-Arne Røttingen said that waiving intellectual property rights could only aid in the production of small molecular weight substances but not in the setting up of biological production lines, such as those needed for vaccine manufacturing, urging more voluntary solutions to technology transfer.<sup>167</sup>

Activists and countries worked towards a TRIPS waiver, amidst pushback from industry and countries where vaccine manufacturers were based.<sup>168</sup> Eventually, a WTO Ministerial Decision on vaccines was adopted in June 2022 stating that "an eligible Member may authorize the use of the subject matter of a patent" through mechanisms such as emergency decrees or government use authorizations, whether or not a Member State had a compulsory licence regime in place.<sup>169</sup> This was not, however, a comprehensive TRIPS waiver – it did not include know-how for production and did not extend to diagnostics and therapeutics.<sup>170</sup> Meanwhile, in October 2022, an EU Council Regulation was promulgated stating that "the Commission should therefore be able to require the licensing" of intellectual property during public health emergencies.<sup>171</sup> Countries are seeking a more predictable regime via the CA+ Pandemic Accord and the IHR Amendments.

### Relevant Provisions (selected)

#### CA+ Pandemic Accord Article 11

The Parties working through the COP to strengthen and develop innovative multilateral mechanisms on the pooling of knowledge and intellectual property that promote relevant transfer of technology and know-how. In inter-pandemic times, parties to encourage entities (in particular those that receive significant public financing) to grant licenses to manufacturers to use their intellectual property, and in the event of a pandemic, parties to take appropriate measures **to support time-bound waivers of IP** that can accelerate or scale up manufacturing of pandemic-related products and apply the full use of the flexibilities provided in the TRIPS Agreement. [Option 11.A]

That transfer of technology and know-how for the manufacture of pandemic-related products shall be conducted in manner consistent with national and international laws, and that each Party shall, in accordance with national laws, make available non-exclusive licensing of government-owned technologies on mutually agreed terms, and promote the publication of the terms of voluntary licensing or technology transfer agreements. Option 11.B in turn has two options 5(e) on the suspension of intellectual property rights, or not to include 5(e). [Option 11.B]

---

<sup>166</sup> Calling For a People's Vaccine Against COVID-19 (March 2022) <<https://peoplesvaccine.org/wp-content/uploads/2022/03/Vaccine-Open-Letter-March-2022.pdf>> accessed 13 July 2023

<sup>167</sup> (21 February 2022) <<https://www.iiprd.com/the-wto-trips-waiver-a-panacea-to-the-covid-19-menace/>> accessed 13 July 2023

<sup>168</sup> Samuel Horti, Ashleigh Furlong, Sarah Anne Aarup, 'Who Killed the Vaccine Waiver?' *Bureau of Investigative Journalism* (10 November 2022) <<https://www.thebureauinvestigates.com/stories/2022-11-10/who-killed-the-vaccine-waiver>> accessed 13 July 2023

<sup>169</sup> World Trade Organization, 'Ministerial Decision on the TRIPS Agreement' (22 June 2022) WT/MIN(22)/30 <<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True>> accessed 13 July 2023

<sup>170</sup> Amalie Holmgaard Mersh, 'WTO ministerial conference delivers TRIPS waiver to criticism' *EurActiv* (17 June 2022) <<https://www.euractiv.com/section/health-consumers/news/wto-ministerial-conference-delivers-trips-waiver-to-criticism/>> accessed 13 July 2023; Third World Network, 'Trade: Decision on COVID-19 diagnostics & therapeutics doubtful by MC13?' (20 June 2023) <<https://www.twn.my/title2/wto.info/2023/ti230611.htm>> accessed 13 July 2023

<sup>171</sup> Official Journal of the European Union, 'COUNCIL REGULATION (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level' (24 October 2022) <<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R2372>> accessed 13 July 2023



IHR Amendments New Article 13A(3)	Subsequent to a PHEIC declaration, States Parties to provide in their intellectual property laws exemptions and limitations to exclusive rights of IP holders to facilitate manufacture, export, and import of required health products.
IHR Amendments New Article 13A(6)	WHO to develop and maintain a database containing details on ingredients, know-how, manufacturing process, or any other information required to facilitate manufacturing of health products.
IHR Amendments New Article 13A(7)	States Parties to take measures to ensure that the activities of non-state actors, especially the manufacturers and those claiming associated intellectual property rights, do not conflict with the right to the highest attainable standard of health, including to comply with WHO allocation mechanism, to donate a percentage of products to WHO, to share pricing policy transparently, and to share know-how.

### Areas of Concern

1. Would opposition to time-bound waivers inhibit development of regional manufacturing in future pandemics?
2. Would agreement on [PABS system](#) proposals require concessions on intellectual property provision?
3. Should intellectual property issues only be discussed in WIPO or WTO forums and treaties?
4. Is intellectual property only relevant to response and therefore not appropriate for inclusion in the IHR?
5. Would waiver/compulsory licensing measures stifle innovation and reduce pharmaceutical company investments?

**Cross-References/Incompatibilities.** Both CA+ and IHR refer to intellectual property (IP) waivers/exemptions in the context of pandemics and PHEICs, respectively. Only the CA+ refers to specific support towards time-bound waivers, whereas the IHR refers to countries ensuring that they have options for waivers/compulsory licencing in their domestic IP laws.

**Opportunities for Consensus.** Many high-income countries have IP waiver provisions in their domestic laws. Hence opposition to waiver provisions would be inconsistent with domestic policy. Domestic laws on waivers also often require authorization or initiation from a minister of health (or equivalent official), which is inconsistent with the notion that IP is solely the realm of WTO or WIPO. However, encouraging support for specific time-bound IP waivers during a pandemic is likely to remain controversial and may deadlock negotiations. One legal expert suggested that it would be difficult to obtain agreement on both a PABS system and time-bound waivers during a pandemic. Hence negotiators may seek trade-offs between PABS and IP provisions.

IHR provisions discuss waiver-related competencies at the national level. As outlined in [Figure 1](#), the IHR generally contain provisions that are intended to be part of the first line of defence in health emergencies, are related to competencies, nomenclature, temporary recommendations and prevention, and are not intended to mobilize financial and human resources. While IP is predominantly a function of response rather than prevention, PHEIC declarations are also a function of response and were introduced into the IHR in 2005 as a function of political realism. Hence, from a constitutional standpoint, there is no reason why IP could not be included in the IHR but are likely to relate to 'soft coordination' and 'first line of defence' function. The provisions proposed, such as the databases containing information about know-how and manufacturing processes,<sup>172</sup> and provisions relating to nation states ensuring that they establish exemptions/compulsory licence/waiver provisions in their domestic laws (competency-related), seem appropriate.

**Analysis.** While IP for COVID-19 vaccines was more frequently discussed in the recent pandemic, IP issues also arose with novel antivirals such as nirmatrelvir/ritonavir (Paxlovid) and to diagnostics such as the GeneXpert machines and cartridges. For example, the anticipated patent expiry date for GeneXpert cartridges is 11 December 2037,<sup>173</sup> and the

<sup>172</sup> These provisions were supported also by external civil society actors such as Knowledge Ecology International: Thiru Balasubramaniam, 'WGIHR 3: KEI statement on the consideration of proposed amendments' *Knowledge Ecology International* (18 April 2023) <<https://www.keionline.org/38650>> accessed 10 May 2023

<sup>173</sup> Carla Maria McDowell-Buchanan and Daniel Clemens, 'Integrated immuno-pcr and nucleic acid analysis in an automated reaction cartridge' (Filed 11 December 2017) <<https://patents.google.com/patent/EP3551766B1/en?q=Integrated+immuno-pcr+and+nucleic+acid+analysis+>

patents applying to the universal docking bays and data doors on the machines expire in September 2033.<sup>174</sup> Given that GeneXpert machines are widely available (40,000 GeneXpert systems have been installed in more than 180 countries)<sup>175</sup> and return results within 1–2 hours, they are a useful platform for quick and accurate PCR results. GeneXpert cartridges are expensive at US\$15 per cartridge, and many countries utilized manual PCR instead. For Paxlovid, countries purchased doses at industry-determined tiered pricing rates until manufacturers were granted licences to manufacture under a Medicines Patent Pool agreement.<sup>176</sup> It should be noted that in August 2022, many LMICs still did not have access to Paxlovid, whereas countries across the Global North obtained access as early as December 2021.<sup>177</sup> The reasons for this delay are multifactorial, potentially including supply constraints, cost barriers, and IP barriers.

Some countries claim that waiver/compulsory licensing measures will stifle innovation and reduce pharmaceutical industry investments. Many of these same countries, however, have waiver or compulsory licensing provisions in their own laws. For example, the United Kingdom allows for the use of an invention by a government department during any period of emergency, including for supplies “essential for the life of the community”.<sup>178</sup> United States law dictates that a patent owner is entitled to remedies and compensation for government use and manufacture of an invention.<sup>179</sup> French law states that failing an amicable agreement with the patent holder, the government may order a compulsory licence in the interests of public health for a drug, medical device, in vitro diagnostic or therapeutic.<sup>180</sup> Germany has similar laws applying in the case of an epidemic of national concern, with the Federal Ministry of Health being able to issue an order for use of an invention in the interest of public welfare or federal security.<sup>181</sup> A recently promulgated European Union regulation states that, especially where public authorities have provided financial support for production of medical countermeasures, the Commission should be able to require the licensing of IP rights.<sup>182</sup>

It is less clear whether IP belongs in the IHR. James Love, Director of Knowledge Ecology International, suggested that support for its inclusion is in part a response to concerns about the final text of the Accord:

---

*“We are supportive of what the African group and Bangladesh call for in a new article 13A [in the IHR]. But I think there are many other actors involved, including the United States and the European Union, who probably want a very pared down and trim IHR, and they would probably argue that this has no place in the IHR. One could see this as a guardrail or safeguard [by the African group and Bangladesh] basically to have it [in case it doesn’t make it into an] Article 19 type framed instrument.”*

*(James Love, Director of Knowledge Ecology International, interviewed 10 May 2023)*

---

Other interviewees made a similar point about the ‘guardrail’ referred to by Love, with inclusion in the IHR being a negotiating tactic by Global South countries given that some countries may not ratify any Pandemic Accord. It highlights the approach of getting ‘contentious’ topics in both instruments in case certain countries do not ratify the Accord. Negotiating tactic or otherwise, valid questions remain about the appropriateness of IP in the two instruments and complementarity if it is included in both.

---

in+an+automated+reaction+cartridge&oq=Integrated+immuno-pcr+and+nucleic+acid+analysis+in+an+automated+reaction+cartridge> accessed 30 September 2022

<sup>174</sup> Ron Chang and others, ‘Universal Docking Bay and Data Door in a Fluidic Analysis System’ (Filed 5 September 2013) <<https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2014039703>> accessed 30 September 2022

<sup>175</sup> Cepheid, ‘Cepheid and BioGX Announce Collaboration to Develop MPOX PCR Test for the GeneXpert® System’ (27 June 2022) <<http://cepheid.mediaroom.com/2022-06-27-Cepheid-and-BioGX-Announce-Collaboration-to-Develop-MPOX-PCR-Test-for-the-GeneXpert-R-System>> accessed 4 November 2022

<sup>176</sup> Pfizer, ‘Pfizer and The Medicines Patent Pool (MPP) Sign Licensing Agreement for COVID-19 Oral Antiviral Treatment Candidate to Expand Access in Low- and Middle-Income Countries’ (16 November 2021) <<https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-medicines-patent-pool-mpp-sign-licensing>> accessed 13 July 2023

<sup>177</sup> Matahari Global Solutions, ‘Mapping Access Gaps in COVID-19: Results from 14 Countries and Territories’ (August 2022) <<https://matahari.global/wp-content/uploads/2022/08/Mapping-Access-Gaps-in-COVID-19.pdf>> accessed 13 July 2023

<sup>178</sup> Patents Act 1977, Article 59 (United Kingdom)

<sup>179</sup> 28 U.S. Code § 1498 (United States)

<sup>180</sup> Code de la propriété intellectuelle, Article L613-16 (France)

<sup>181</sup> Gesetz zum Schutz der Bevölkerung in einer epidemischen Lage von nationaler Tragweite. Bundesgesetzblatt Jahrgang 2020 Teil I Nr. 14, ausgegeben zu Bonn am 27. März 2 (Germany)

<sup>182</sup> Official Journal of the European Union, ‘COUNCIL REGULATION (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level’ (24 October 2022) <<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R2372>> accessed 13 July 2023

Although there are some suggestions that IP should solely be the purview of WIPO and WTO, many nation states have domestic laws on waivers that involve an order or instructions from their ministries of health, recognizing that IP is both a trade and health issue. This is widely recognised in the Global South, with Brazil stating in earlier negotiations sessions:

■ ■ ■

*“Regarding technology transfer and intellectual property, we would like to emphasize that we need to be bold and put into place strong provisions that will improve production capacity to match demand during future pandemics. We would like to record that in accordance with its constitution, WHO can take all necessary action to attain the objective of the organization, which is the attainment by all peoples of the highest possible level of health. IP on health products cannot be restricted to a trade issue, and it’s essential that we have provisions on the future instrument.”<sup>183</sup>*

— *Brazilian negotiators, quoted in Geneva Health Files (3 March 2023)*

The discussion around feasibility of inclusion of IP provisions in the CA+ and IHR may therefore be less about the substantive/constitutional nature of IP provisions but rather the appropriateness of IP within each or either instrument. Given focus on competencies and technical issues in the IHR, it would make seem to make sense for countries to prepare for the next public health emergency by promulgating national laws on waivers and compulsory licensing. An additional salient question is whether IP waivers constitute provisions intended to prevent the international spread of disease. Professor Gian Luca Burci provides some insight on this:

---

*“The question [of whether IP and tech transfer belongs in the IHR] may be addressed from two perspectives: (1) do these issues fall within the scope of article 21(a) of the WHO Constitution that focuses on ‘prevention’; and (2) do these issues risk turning the IHR into a regulatory and transactional instrument and thus diluting and compromising the original function and scope of the IHR as a technical instrument focused on coordinating detection and containment of disease outbreaks? These may politicize the implementation of the IHR even more, may complicate the work of WHO and weaken the preparedness, detection and response functions that still seem crucial to most WHO member states. However, there is no constitutional obstacle to including IP and similar issues in the IHR.”*

*(Professor Gian Luca Burci, Adjunct Professor of International Law at the Graduate Institute of International and Development Studies, via email, 14 July 2023)*

---

On this point, Burci suggested that, while IP issues generally relate to response rather than prevention and preparedness, the inclusion of the PHEIC declaration in the IHR in 2005 meant that the IHR contained both preparedness and response provisions. Furthermore, Burci argued that “it is an accepted legal approach that the WHO Constitution as developed in 1946 could not be interpreted in the same way today”<sup>184</sup> and that in 2005 it was interpreted with flexibility and with political realism. Nevertheless, he suggested that the ‘soft’ coordination nature of the IHR should be preserved. On this note, there appears to be no constitutional barrier to the inclusion of IP in the IHR. The overall scope of IP provisions may be argued to be in line with the competencies nature of the IHR (incorporating waiver provisions into domestic IP laws, Article 13A(3)) and the soft coordination nature (maintaining databases containing know-how and manufacturing information, Article 13A(6)). However, this is likely to be contentious throughout negotiations.

This contentious nature is seen by some as detrimental to concluding negotiations by the deadline of May 2024. According to one negotiator:

---

<sup>183</sup> Priti Patnaik and Shoa Moosavi, ‘Pandemic Accord Negotiations: Away from Public Glare, but Center of Attention’ Geneva Health Files (3 March 2023) <<https://genevahealthfiles.substack.com/p/pandemic-accord-negotiations-away>> accessed 11 May 2023

<sup>184</sup> Interview with Gian Luca Burci, Adjunct Professor of International Law at the Graduate Institute of International and Development Studies (via Zoom, 17 July 2023)

---

*“We think that there is too much focus on IP waivers. We think that if we can tackle conditionalities on R&D and ensure that there is more transparency, this tackles problems that might not be resolved in other chapters (such as IP) without necessarily putting all your energy into this [IP] chapter. I feel like other chapters can give you the quick wins rather than concentrating on this and dealing with a lot of pushback from Member States that host manufacturers. This is just something that is very hard for us to be demanding on; it has been a fight for the last 10-20 years. Perhaps there will be a break where we can get a bit more, but I don’t know whether this is the time to push the envelope. We remain quite open, obviously, but we think it’s best to just cite the TRIPS agreement and Doha Declaration and ensure that countries have the right to do it [waive patents].”*

*(Global South negotiator, interviewed 31 July 2023)*

---

**Summation.** There are no constitutional reasons for why IP could not be included in both instruments. However, inclusion should be differentiated, and complementarity should be taken into account based on the legal character of each instrument. There is no constitutional reason to exclude IP from the IHR. Given that many countries already have health-related IP waiver provisions in domestic laws, proposing incorporation of uniform provisions can be deemed a competency-related provision.

The CA+ states in Article 11 that, in the case of a pandemic, the Parties shall support time-bound waivers of IP, to which the EU has stated it would object.<sup>185</sup> Some interviewees highlighted the political bargain that may have to be struck with either PABS or broad IP waivers – i.e. it was unlikely that there would be agreement to accept both. Some Global South countries considered exclusion of time-bound waivers from the CA+ as unacceptable, while others placed less emphasis on waivers versus a preference of stronger transparency in purchasing agreements (discussed in [Supply section](#)) and transparency in R&D agreements (in [R&D section](#)).

## *A New Financial Mechanism for Pandemic Preparedness and Response*

**Introduction.** From 2020 to 2022, the deployment of COVID-19 tools and shepherding of resources in the global response was channelled through agencies in the Access to COVID-19 Tools Accelerator (ACT-A), including Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI), the Global Fund, the Foundation for Innovative New Diagnostics (FINN), and the WHO. Donors predominantly came from the Global North and decisions about funding priorities were made by agencies. An ACT-A evaluation found that only 38.4% of respondents believed that the resource mobilization model should be replicated in future pandemics.<sup>186</sup>

---

<sup>185</sup> Rory O’Neill, ‘WHO text swerves hard IP restrictions in future pandemics’ *Managing Intellectual Property* (20 July 2023)

<<https://www.managingip.com/article/2by6m9h70y9sqpyvikagw/who-text-swerves-hard-ip-restrictions-in-future-pandemics#:~:text=Americo%20Zampetti%2C%20one%20of%20the,for%20a%20broad%20TRIPS%20waiver>> accessed 24 July 2023

<sup>186</sup> Open Consulting, ‘External Evaluation of the Access To COVID-19 Tools Accelerator (ACT-A)’ (10 October 2022), p. 10 <[https://www.who.int/publications/m/item/external-evaluation-of-the-access-to-covid-19-tools-accelerator-\(act-a\)](https://www.who.int/publications/m/item/external-evaluation-of-the-access-to-covid-19-tools-accelerator-(act-a))> accessed 19 July 2023

There have been many discussions on new financial mechanisms for pandemic preparedness and response. The World Bank's Pandemic Fund was established in September 2022, with the first round of applications focusing on (1) disease surveillance systems; (2) laboratory systems; and (3) strengthening public health workforce and community workforce capacity.<sup>187</sup> The WHO has proposed 10 reforms to the health emergency preparedness, response and resilience (HEPR) framework, including three on financing. These included establishing a coordinating mechanism for financing to promote domestic financing and gap-filling with international financing to strengthen HEPR (Proposal 7) and the expansion of the WHO Contingency Fund for Emergencies to allow direct financing of national responses (Proposal 9).<sup>188</sup> Meanwhile, the G20 have proposed a surge financing mechanism "for the onset of a new pandemic".<sup>189</sup> Both the CA+ and IHR amendments refer to financing mechanisms.

### Relevant Provisions.

CA+ Pandemic Accord Article 19(3)	The Parties agree to establish funding mechanisms to support implementation of the CA+, providing resources to assist Parties on capacity building, strengthening of health systems and laboratory capacities for PPPR, R&D for pandemic-related products, technology transfer, and the CA+ allocation mechanism. It shall be funded through, inter alia, annual contributions by Parties, contributions from product manufacturers, and voluntary contributions.
CA+ Pandemic Accord Article 19(6)	<p>The Parties shall establish 'debt swap' programmes that convert debt repayment into PPPR investments in health [Option 19.A]</p> <p>The Parties shall commit to expanding partnerships with development finance institutions to provide additional financing to developing countries through prioritised debt relief and debt restructuring. [Option 19.B]</p>
IHR Amendments Article 44A	A mechanism shall be established to provide the financial resources on a grant or concessional basis to developing countries, to build, develop, strengthen, maintain Annex 1 core capacities, to strengthen health systems, to build, develop, and maintain research, development, adaptation, production, distribution capacities in local or regional levels, and addressing health inequities existing both within and between States Parties.

### Areas of Concern

1. How feasible would it be to expand the CFE to support country response? Is it feasible for the WHO to take on expanded banking and financing functions?
2. What governance structures are needed to ensure transparency and accountability for a financial mechanism? Does the mechanism as proposed replicate the ACT-Accelerator financing model?

### Areas of Concern (continued)

3. Would a 'fair share' model, such as annual contributions, be adhered to by (be feasible for) all Member States?
4. How would inclusion of a financial mechanism within the IHR change how they are implemented?
5. How can debt swap arrangements be included where MDBs are not Party to the agreement?
6. What happens if negotiations are concluded on the IHR amendments but not the CA+?
7. Should certain alerts or declarations trigger response financing? What scenarios have been modelled that can help guide our decision?

<sup>187</sup> World Bank, 'The Pandemic Fund: First Call for Proposals' (February 2023) <<https://thedocs.worldbank.org/en/doc/eac1acfe37285a29942e9bb513a4fb43-0200022022/related/Pandemic-Fund-Cover-Note.pdf>> accessed 19 July 2023

<sup>188</sup> WHO, '10 proposals to build a safer world together: Strengthening the Global Architecture for Health Emergency Preparedness, Response and Resilience' (June 2022) <<https://cdn.who.int/media/docs/default-source/emergency-preparedness/whoheprjune30draftforconsult.pdf?sfvrsn=e6117d2c4&download=true>> accessed 19 July 2023

<sup>189</sup> WHO, for the G20 Joint Finance – Health Task Force, 'Surge financing for the coordinated international response to a pandemic through multilateral implementing agencies: An overview of the scale & speed of requirements' (20 March 2023), p. 2



**Cross-References/Incompatibilities.** Both instruments refer to a financing mechanism, with some overlapping objectives. In the IHR amendments, the financing mechanism is intended to develop core capacities and strengthen health systems, whereas the CA+ financing mechanism refers to funding to assist Parties on capacity building, strengthening of health systems and laboratory capacities for pandemic preparedness and response, R&D for pandemic-related products, technology transfer, and the CA+ allocation mechanism.

### **Opportunities for Consensus.**

The IHR was not originally designed for resource mobilization. One legal expert stated that the Article 44A proposal on financing therefore was a ‘non-starter’ and would dilute the original mandate of the IHR. One option to avoid this would be to establish the mechanism in the CA+ and to insert a cross-reference to the mechanism as a source of core capacities funding in the IHR. However, this could create problems as (1) not all countries would be party to the CA+ and thus may not be required to contribute into the fund and/or would not receive disbursements from the fund and (2) it is unclear what would happen to the financing mechanism if negotiations were concluded for the IHR but not for the CA+. Hence, while not technically constitutionally appropriate, a financing mechanism could be established in the IHR as a function of necessity and political realism. Notably, one public health expert stated that a more systematic approach to financing IHR competencies was necessary given the piecemeal approach to IHR competencies financing thus far.

An additional question relates to the centrality of a financing mechanism for IHR implementation and compliance: what would change with health emergency preparedness if the IHR included a financing mechanism? In theory, a robust financing mechanism could ensure that onsite visits could occur as part of a compliance mechanism, that there could be country oversight of disbursements and funding allocation for preparedness, and that finances would not be subject to control by independent agencies.<sup>190</sup>

Negotiators were reluctant to support the World Bank’s Pandemic Fund as the financing mechanism within either the CA+ or the IHR, owing to its ownership by an external agency and decision-making structures that do not include adequate oversight by Member States. Most supported a financing mechanism within the WHO, although some experts noted that WHO is not designed to operate as a bank. The Contingency Fund for Emergencies (CFE), which disbursed US\$88m for emergencies in 2022, is a counterpoint to this – but it is not clear that it could be expanded significantly to disburse funding to Member States and not just for WHO-led deployments.

Debt swaps are of particular importance for less-developed countries, but the Bureau’s text proposals currently create obligations for agencies and bodies that are not parties to the CA+. This could be redrafted to “Parties are encouraged to explore debt swap arrangements with appropriate organizations...” or it could be made more specific by restricting its applicability to bilateral/country lenders.

Consensus in this area is highly dependent on practical arrangements, the likelihood of the CA+ successfully being established, and the desire of Member States to have a financial mechanism with the widest possible membership.

## **Analysis**

The COVID-19 pandemic demonstrated that there are substantial financing gaps in countries’ pandemic prevention, preparedness, and response capacities. According to one estimate, an additional US\$15 billion needs to be invested by development partners annually, with national governments dedicating an additional 1% of their country’s GDP towards health, including surveillance capacities.<sup>191</sup> Others have argued that future pandemics require a better

---

<sup>190</sup> At time of writing, there is a surplus of unspent funding of \$2.7B held by Gavi, with the agency exploring three options for disbursement/investment of funds. Ann Danaiya Usher, ‘Gavi commits USD 1.65 billion for COVID vaccines though demand is ‘close to zero’’ *Development Today* (4 July 2023) <<https://www.development-today.com/archive/2023/dt-5--2023/gavi-donors-considering-three-options-for-unspent-covax-money>> accessed 7 August 2023

<sup>191</sup> [Global Burden of Disease 2021 Health Financing Collaborator Network](#), ‘Global investments in pandemic preparedness and COVID-19: development assistance and domestic spending on health between 1990 and 2026’ (2023) 11(3) *The Lancet Global Health* E385-E413



financing structure for community systems.<sup>192</sup> During the COVID-19 pandemic, many community-led organizations were conducting essential work within communities, but were not able to unlock funding from large donors spearheading financing for response.<sup>193</sup>

In addition, an ACT-Accelerator evaluation found that there was insufficient accountability and transparency in COVID-19 financing, with only 38.4% of respondents believed that the resource mobilization model should be replicated in future pandemics.<sup>194</sup> The evaluation also noted that vaccines received two-thirds of total financing, and suggested that diagnostics, therapeutics and health systems should have been resourced better.<sup>195</sup> A WHO document prepared for the G20 made a series of recommendations, including that a minimal threshold of US\$30 billion should be made available within days to weeks of the start of a major health emergency of pandemic potential and that standard operating procedures for triggering, managing and reporting surge financing should be developed.<sup>196</sup>

These findings suggest the following priorities:

1. Development of sustainable financing for pandemic preparedness and core capacities.
2. Development of sustainable financing for crisis/emergency situations (what the G7 and G20 are calling 'surge financing').
3. Establishing clear protocols, including triggers for financing for response.
4. Ensuring that financing mechanisms developed are more transparent, accountables and equitable.
5. Increasing domestic financing for pandemic preparedness, prevention and response.

Positions continue to evolve on the nature and governance of a financing mechanism for future pandemics. The main point of consensus seems to be that a financial mechanism should be incorporated in one of the two legal instruments rather than operating independently of Member State scrutiny. In the words of one negotiator:

---

*"The financial mechanism for pandemic response is very important. I agree with those that say we need to have it inside the agreement. We have [financial mechanisms] outside, but the problem is that we need something which is governed within the system and not by third parties or ... those that are providing financing via a non-transparent way."*

*(Global South negotiator, interviewed 4 July 2023)*

---

Another negotiator referred more explicitly to the World Bank's Pandemic Fund and its role in financing preparedness and prevention capacities – and more specifically expressed concerns regarding the permanence of the Pandemic Fund and whether its investments were comprehensively linked to all core competencies listed under the IHR:

---

*"The African group has put forward a proposal for a new financial mechanism, but other Member States have indicated that we already have the Pandemic Fund and therefore you don't really need another financial mechanism. My concerns about the Pandemic Fund are essentially that I don't know whether it's a permanent fund or whether it will only be in existence for a few years. Will they [the World Bank] have to come back in the future to make a decision on whether the fund should be continued? Secondly, I also wanted to know what the limitations of the Pandemic Fund are in financing IHR core capacities. There are 13 core capacities under the IHR and in what ways is financing directed towards all these other areas? Will they be funded in the future?"*

---

<sup>192</sup> Byanyima W, Lauterbach K, Kavanagh MM. Community pandemic response: the importance of action led by communities and the public sector. *Lancet*. 2023 Jan 28;401(10373):253-255. doi: 10.1016/S0140-6736(22)02575-2. Epub 2022 Dec 14. PMID: 36528036; PMCID: PMC9750179.

<sup>193</sup> Ibid

<sup>194</sup> Open Consulting, 'External Evaluation of the Access To COVID-19 Tools Accelerator (ACT-A)' (10 October 2022), p. 10 <[https://www.who.int/publications/m/item/external-evaluation-of-the-access-to-covid-19-tools-accelerator-\(act-a\)](https://www.who.int/publications/m/item/external-evaluation-of-the-access-to-covid-19-tools-accelerator-(act-a))> accessed 19 July 2023

<sup>195</sup> Ibid, p. 11

<sup>196</sup> WHO, for the G20 Joint Finance – Health Task Force, 'Surge financing for the coordinated international response to a pandemic through multilateral implementing agencies: An overview of the scale & speed of requirements' (20 March 2023), p. 2

*(Global South negotiator, interviewed 9 May 2023)*

---

Hence clarifications will be needed from the World Bank on whether it sees the Pandemic Fund as the main fund for prevention and preparedness in the CA+, and from Member States and other stakeholders on whether this is a desirable objective.

Other questions centre around the appropriateness of a financial mechanism for the IHR. According to Professor Gian Luca Burci from the Graduate Institute, the IHR were not originally designed for financing; however, this could change. There are additional complications: Article 44A of the IHR converts WHO into a financial institution, a role that it may not be capable of performing on a large scale.<sup>197</sup> According to Dr Ebere Okereke, Chief Executive Officer of the Africa Public Health Foundation, the status of the IHR as a regulation should not preclude financial mechanisms or processes being included therein:

---

*“While the IHR is indeed a technical regulation, it does include a requirement for defining financial processes for building capacity for compliance. Its evaluation processes lead to development of National Action Plans for Health Security (NAPHS). While developing the NAPHS includes the requirement for costing, the approach to it has been very much one-way, i.e., countries identify what capacities they need to fill, they cost them, and expect voluntary contributions, donations, or other philanthropic interventions to fund them. What is required is a much more systematic and strategic component approach to financing the gaps in capacity for compliance with the IHR that builds on a combination of national financial positions, prioritising which capacities need to be a crucial to not just pandemic preparedness for the nation state, but also contribute to health system resilience. Ultimately, the financing mechanism should build upon multiple approaches to funding that include philanthropy but are not exclusively dependent on donors filling in the gap. The idea that the IHR should not contain a financial mechanism because it is legalistically inappropriate is bound to repeat in the same problems we saw during the COVID-19 pandemic – an under-financing of IHR competencies.”*

*(Dr Ebere Okereke, Chief Executive Officer, Africa Public Health Foundation)*

---

Dr Sultani Hadley Matendechero, the Vice Chair of the WHO Working Group on Amendments to the IHR 2005 (WGIHR) echoed these thoughts – and further stated that if there was no financial mechanism placed in the IHR, then Compliance and Accountability provisions (see Section [below](#)) would fail. In his own words:

---

*“If for example, we look at implementation and compliance, then we must have a clear financing framework within the amended IHR, which will enable Member States to comply and implement. We really have to be apprised of the fact that a lot of the countries in the Global South have weak and fragile economies and their priorities are significantly different from those of most states parties in the Global North. Their priorities mainly revolve around basic needs such as trying to ensure that the people have something to eat. Therefore, if we start talking about building core capacities and ensuring the relevant data and information is promptly provided towards prevention of; preparedness for; response to; and recovery from pandemics, we must also talk about providing a very clear global mechanism through which these fragile economies will be funded to meet their obligations with regards to putting those core capacities in place. You cannot have compliance without a clear and predictable financing mechanism which is accountable to all Member States. It's not possible.”*

---

<sup>197</sup> Interview with Professor Gian Luca Burci, Adjunct Professor of International Law at the Graduate Institute of International and Development Studies (via Zoom, 17 July 2023)

*(Dr Sultani Hadley Matendecheo, Deputy Director General for Health, Ministry of Health Kenya, and Vice Chair of the WHO Working Group on Amendments to the International Health Regulations 2005 (WGIHR), interviewed 29 August 2023)*

---

One proposal that has been mooted is the expansion of the WHO Contingency Fund for Emergencies (CFE) to allow direct financing of national responses.<sup>198</sup> In 2022, the CFE disbursed US\$88 million for 35 emergencies in 40 countries and territories,<sup>199</sup> in line with its original mandate of supporting WHO-led deployments and response. Furthermore, a WHO/G20 document states that the fastest mechanism for deploying funds for COVID-19 response was the CFE, followed by the UN Central Emergency Response Fund (CERF), with the Global Fund and other agencies, and the World Bank's Global COVID-19 Multiphase Programmatic Approach (MPA),<sup>200</sup> coming in later with their own funds. This illustrates some capacity for funding of pandemic response. However, based on interviews, the CFE is unlikely to expand significantly without a mandate from Member States. On this point, one interviewee stated that, while the CFE could be marginally expanded to serve pandemic response, what was more critical was a pandemic financing coordinating body to consolidate and synergize across all sources of financing.

The Pandemic Fund is hosted by the World Bank, an external entity that is not Party to the CA+ and IHR. The fact that only five out of 55 African Union Member States<sup>201</sup> received Pandemic Fund disbursements in the first round of financing has raised questions about the ability of the Fund to effectively support development IHR core capacities. A separate financing mechanism for all elements of pandemic prevention, preparedness and response, with a 'fair share' model based on regular annual contributions from countries, could help to address negotiator concerns around the Pandemic Fund as the sole source of prevention and preparedness funding. One negotiator stated, however, that increasing assessed contributions would not work well for LMICs, as they were already struggling to pay current assessed contributions to WHO, and argued that other stakeholders that benefit from pandemic prevention should contribute financially:

---

*"We already agreed to the increase in assessed contributions at WHA76 [76th World Health Assembly]. Some developing countries are already struggling to keep up with their contributions to the WHO. The sources of financing for PPPR therefore have to come from somewhere else. Contributions from manufacturers of pandemic-related products and linking with the PABS system is a good idea. Additionally, the fund could receive funding from voluntary contributions from those who benefit from pandemic prevention. Sports bodies such as FIFA, NBA, and World Athletics must contribute to the WHO fund for PPPR."*

*(Global South negotiator, via Whatsapp, 7 August 2023)*

---

One negotiator stated their country did not support the option of the Pandemic Fund financing preparedness and prevention in the CA+ and rejected the notion that WHO could not operate as a fund for disbursement of funds for response as well as preparedness and prevention. This negotiator stated their experience with Gavi and actors external to WHO in COVAX was central to their position:

---

*"They [WHO] have been collecting assessed contributions from us. So, when people say you cannot have a fund that sits under WHO because it's beyond their competency, I totally disagree. They've been collecting contributions and they've also disbursed them to their regions, to whoever needs it. (The financial mechanism) shouldn't sit outside WHO; they should be the main player here. People keeping saying that we have the Pandemic Fund but that sits with the World*

---

<sup>198</sup> WHO, '10 proposals to build a safer world together: Strengthening the Global Architecture for Health Emergency Preparedness, Response and Resilience' (June 2022) < <https://cdn.who.int/media/docs/default-source/emergency-preparedness/whoheprjune30draftforconsult.pdf?sfvrsn=e6117d2c4&download=true> > accessed 19 July 2023

<sup>199</sup> WHO 'Contingency Fund for Emergencies: 2022 annual report - Enabling quick action to save lives' (15 June 2023) <<https://www.who.int/publications/i/item/WHO-WHE-EXR-2023.2>> accessed 19 July 2023

<sup>200</sup> WHO, for the G20 Joint Finance – Health Task Force, 'Surge financing for the coordinated international response to a pandemic through multilateral implementing agencies: An overview of the scale & speed of requirements' (20 March 2023), p. 8-9

<sup>201</sup> Africa CDC, 'The Africa Centres for Disease Control and Prevention (Africa CDC) Statement on the Allocation of Funding in the First Call for Proposals by the Pandemic Fund' (27 July 2023) <<https://africacdc.org/news-item/the-africa-centres-for-disease-control-and-prevention-africa-cdc-statement-on-the-allocation-of-funding-in-the-first-call-for-proposals-by-the-pandemic-fund/>> accessed 7 August 2023

*Bank. It has different set of rules and different conditions. And when they sit in a meeting, WHO is just one of their Board Members. We want WHO to play the main role. The best way is to have a financial mechanism that sits in WHO. We had experience with COVAX where even though WHO is one of the partners, it was the Gavi officers that we were dealing with and WHO was missing. We put in money for vaccines to supply 10% of our population, but we didn't get it all. We only got a few percent. And when COVAX wanted to close our account, we wondered where WHO was when we needed their advice. They were the missing player."*

*(Global South negotiator, interviewed 31 July 2023)*

---

While the World Bank is a different entity from Gavi, countries seem to have developed a distrust of agencies without representative country oversight. As a result, they perceive WHO to be a more appropriate location for a financial mechanism for pandemics.

Some global health law scholars have suggested that the financing mechanism could resemble the [International Financing Facility for Immunization \(IFFIm\)](#), a mechanism based on social impact bonds on capital markets with legally binding commitments of sovereign donors.<sup>202</sup> These scholars also state that the CA+ should establish a standing committee on sustainable financing composed of experts in economics, financial services, donor and investor relations, and capital markets, as well as representatives of ministries of finance.<sup>203</sup> However, this would remove financing from the purview of the WHO, which some countries are reluctant to agree to. By contrast, other countries would prefer that WHO remain removed from any financial administration during pandemics.

Professor Gian Luca Burci also argued that a paradigm shift in pandemic financing, characterized by a redevelopment of the model of financing away from the Global North to Global South donor model, was long overdue. According to Professor Larry Gostin, professor of global health law at O'Neill Institute, 'a robust financing framework would allocate countries' responsibilities to provide a fair share of needed resources.'<sup>204</sup>

In addition, due to concerns about fragmentation, he suggested that it was not necessary for each instrument to have a financial mechanism.<sup>205</sup> Conversations with negotiators conducted for this report indicate that countries are inclined towards one financial mechanism or body that would fund prevention, preparedness *and* response:

---

*"We want a new financial mechanism that is overarching and not only covers emergencies, but also IHR core capacities and other CA+ capabilities when decided."*

*(Global South negotiator, via Whatsapp 11 July 2023)*

---

Negotiators were less certain on what should trigger the financing mechanism for response – whether this is the intermediate trigger contained in Article 12(New 6) of the IHR amendments or the PHEIC declaration. As discussed in the [Declarations section](#), negotiators continue to consider and study which declaration would be optimal for triggering a financial mechanism. Some countries view the PHEIC declaration as too late to trigger financing, and suggest that this should occur with an intermediate health alert. Others believe that a more flexible approach is necessary, as not all outbreaks of pathogens of pandemic potential will progress to a PHEIC or a pandemic, and a financial trigger at an intermediate level would be premature. Further studies and scenario-building will need to take place to determine the optimal approach.

Positions on Article 19(6) on debt swaps for pandemic preparedness and response were less clear. Given that 44% of least-developed countries (LDCs) and other low-income developing countries were at high risk of external debt distress

---

<sup>202</sup> Lawrence A Gostin and others, 'Advancing Equity In The Pandemic Treaty' Health Affairs (9 May 2023) <<https://www.healthaffairs.org/content/forefront/advancing-equity-pandemic-treaty>> accessed 18 May 2023

<sup>203</sup> Ibid

<sup>204</sup> Gostin LO. A New Architecture for Global Health Emergency Preparedness and Response—The Imperative of Equity. *JAMA Health Forum.* 2022;3(6):e222197. doi:10.1001/jamahealthforum.2022.2197

<sup>205</sup> Interview with Professor Gian Luca Burci, Adjunct Professor of International Law at the Graduate Institute of International and Development Studies (via Zoom, 17 July 2023)

or were already in debt distress prior to the outbreak of the pandemic,<sup>206</sup> it is possible to understand why this provision is of particular importance to LDCs. From a legal standpoint, Option 19.A, which states that the Parties shall establish debt swap programmes, may need to be redrafted as it presently creates obligations for agencies and multilateral development banks that are not Parties to the CA+. According to one legal expert, this could be redrafted to, for example, “Parties are encouraged to explore debt swap arrangements with appropriate organizations...” Alternatively, more specificity could be included to ensure that the provision only applies to bilateral debt.

However, according to one negotiator who was supportive of debt swaps, a wide range of tools are necessary for pandemic prevention, preparedness and response:

---

*“The Global Fund has a Debt2Health programme. Germany has in the past forgiven its debt to Indonesia for TB investments. We need a wide range of tools for PPR financing, [including] encouraging parties to the CA+ to enter into these [debt swap] agreements. Debt to health swaps is only one option [for PPPR financing].”*

*(Global South negotiator, via Whatsapp, 7 August 2023)*

---

From an ideological and practical standpoint, another negotiator spoke to the concern of how and who would quantify the value of debt swaps and pandemic-related investments. Another negotiator stated that they had yet to formulate a position due to not having engaged their ministry of finance on the issue.

**Summation.** Two separate financing mechanisms established by the IHR and CA+ may fragment pandemic financing further. While some consider multiple sources of financing as necessary, and even a function of political realism (that diverse pots of funding will continue to exist because of the different priorities of donors), others express concern that existing funds such as the Pandemic Fund are already vastly oversubscribed and that it would be difficult to raise additional funding for a separate mechanism.

Negotiators argue that increased transparency, accountability and Member State influence are needed on financing of pandemic response, with the ACT-Accelerator model cited as insufficiently transparent and inclusive to suit equitable pandemic financing. Arguments were made that pandemic-related funding should come from a multitude of sources, not just countries.

There is disagreement on WHO’s suitability to manage a financial mechanism. Some negotiators argue that the WHO was not designed to operate as a bank for country response, although this has been proposed in a WHO document through the proposed expansion of the CFE.

Finally, negotiators have yet to decide on what declaration should trigger the financing for response. Some countries believe that triggering on the declaration of a PHEIC would be too late to ensure a timely and effective response, so triggering by an intermediate health alert would be more appropriate. Others think that this earlier triggering would be premature, given uncertainties in how outbreaks evolve. Based on these issues, key questions to be considered include:

1. Do member states support an expansion of the WHO CFE to support country response? If not, which entity should host the financial mechanism? Should a separate entity be established to house a financing mechanism?
2. What governance of the financial mechanism is necessary to ensure transparency and accountability?
3. How would a financial mechanism within the IHR change how they are implemented?
4. How can countries ensure a proportionate amount of funding across different types of pandemic-related products?
5. How can debt swap arrangements be included in the Pandemic Accord when multilateral development banks (MDBs) are not Party to the agreement?
6. At what stage should financing for response be triggered?

---

<sup>206</sup> UNDP, ‘United Nations Statement to the Development Committee’ (17 April 2020) < <https://www.undp.org/speeches/united-nations-statement-development-committee> > accessed 7 August 2023

7. What happens to a financial mechanism if negotiations are concluded on the IHR amendments but not the CA+?

### *Compliance and Accountability*

**Introduction.** The global response to the COVID-19 pandemic saw gaps in accountability. An independent evaluation of the ACT-Accelerator, for example, concluded that there was insufficient accountability and transparency in COVID-19 financing,<sup>207</sup> and that allocation and distribution targets were defined without sufficient input from low- and middle-income countries. One consequence of this was that a 20% allocation target was set when high-income countries were aiming for higher coverage (>70%), which “undermined a fair vaccine allocation based on the WHO-led model”.<sup>208</sup>

Furthermore, the IHR were heavily criticized as inadequate to prevent pandemics. According to the [Review Committee on the Functioning of the IHR \(2005\) during the COVID-19 Response](#), many countries had only applied the IHR in part,

---

<sup>207</sup> Open Consulting, ‘External Evaluation of the Access To COVID-19 Tools Accelerator (ACT-A)’ (10 October 2022), p. 10

<[<https://www.who.int/publications/m/item/external-evaluation-of-the-access-to-covid-19-tools-accelerator-\(act-a\)>](https://www.who.int/publications/m/item/external-evaluation-of-the-access-to-covid-19-tools-accelerator-(act-a)) accessed 19 July 2023

<sup>208</sup> Ibid, p. 26



were not sufficiently aware of these regulations, or deliberately ignored them; it also suggested that WHO did not make full use of the powers given to it through the wording and spirit of the IHR.<sup>209</sup>

Given these findings, Member States are seeking more robust compliance, implementation and accountability mechanisms in both the IHR and CA+. Various options have been proposed, including the option of an “obligatory periodic reviews of national IHR capacities, including their functionality”,<sup>210</sup> and an independent assessment body ‘at arm’s length’ from Member States to assess country performance.<sup>211</sup>

### Relevant Provisions.

CA+ Pandemic Accord Article 8	Each Party, consistent with its national laws and context, shall undertake regular and systematic assessments, including multi-country or regional tabletop exercises no less than every five years.  No mechanism established. [Option 8.A]  Parties to establish a peer review mechanism to leverage the use of existing monitoring and evaluation tools to assess national, regional and global preparedness capacities and gaps [Option 8.B]  Parties to establish a universal health and preparedness review mechanism involving intergovernmental dialogue among Member States that aims to promote collective global action and accountability for preparedness. [Option 8.C]
CA+ Pandemic Accord Article 20(1)	Establishes a Conference of the Parties (COP) to be comprised of Member State Parties and with observers from UN agencies and representatives from other bodies, including non-governmental organisations.
CA+ Pandemic Accord Article 20(3)(c)	States that if Parties to the IHR determine that an IHR-specific Implementation and Compliance Mechanism should operate within the third main Committee of the WHA (similar to the CA+ COP), then further steps will be agreed to accommodate this.
CA+ Pandemic Accord Article 20(8)	The work of the COP to be carried out by four specific bodies and other bodies that the COP may establish: (a) Implementation and Compliance Committee (Article 22); (b) Panel of Experts to provide scientific advice (Article 23); (c) The Pandemic-Related Products Expert Committee (Article 24); and (d) Benefit-Sharing Expert Committee (Article 25)
CA+ Pandemic Accord Article 22	The Implementation and Compliance Committee is established as a subsidiary body of the COP, and will consist of independent experts elected by the COP. It will address matters of non-compliance and report periodically and make recommendations.
IHR Amendments Article 5(1)	Surveillance capacities shall be periodically reviewed through the Universal Health Periodic Review mechanism in replacement of the Joint External Evaluation, and such a review will identify resource constraints and other challenges in attaining these capacities.
IHR Amendments Article 53A	IHR States Parties to establish an Implementation Committee comprising States Parties meeting annually and playing the role of monitoring, advising on, and facilitating provision of technical assistance, logistical support, and mobilisation of technical resources

<sup>209</sup> Preben Aavitsland, Ximena Aguilera, and others, ‘Functioning of the International Health Regulations during the COVID-19 pandemic’ (2021) *Lancet* 398(10308):1283-1287. doi: 10.1016/S0140-6736(21)01911-5

<sup>210</sup> Ibid

<sup>211</sup> Barbara Stocking, Lawrence Gostin, and others, ‘Independent Assessment & Governance Committees: Addressing Accountability and Governance in a Pandemic Accord’ Geneva Health Files (28 June 2023) < <https://genevahealthfiles.substack.com/p/independent-assessment-and-governance>> accessed 12 July 2023

on matters relating to IHR, including to assist States Parties in the development and maintenance of IHR core capacities.

IHR Amendments Article 54

States Parties and the Director-General shall report to the Health Assembly on the implementation of the IHR and (New 4) will maintain a webpage/dashboard on the details of the activities carried out.

IHR Amendments New Article 54 bis

States Parties to meet every two years in a dedicated segment on Implementation during the regular annual session of the Health Assembly. A Special Committee is established as an expert committee and shall assist the Health Assembly in discharging its functions in this Article.

IHR Amendments Chapter IV

The Compliance Committee shall submit an annual report to the Health Assembly describing the work of the Compliance Committee during the reporting period and concerns regarding non-compliance during the reporting period.

### Areas of Concern

1. Would separate compliance and implementation committees result in fragmentation and lost opportunities for synergies and collaboration?
2. Given that IHR implementation and compliance have been historically weak, can proposed improvements realistically be operationalized and ensure greater accountability than a Conference of Parties mechanism?
3. How can proposed compliance mechanisms increase accountability while simultaneously encouraging transparency and trust?
4. Is there sufficient clarity on how a peer review mechanism (and findings therefrom) in the CA+ would interact with the COP and the Implementation and Compliance Committee?

**Opportunities for Consensus.** Most multilateral regulatory instruments have some form of compliance mechanism and/or procedure to address non-compliance. Hence the questions around feasibility centre not on whether compliance mechanisms should be included, but on which specific mechanisms would be feasible in the context of the resourcing available, and whether proposed mechanisms can ensure increased accountability without being punitive. There is a perceived risk that peer mechanisms would be rooted in shaming of countries. There are also concerns relating to whether sufficient resources could be raised to support development of country IHR competencies, so operationalization would also depend on agreement on the financing mechanism.

Compliance mechanisms in international treaties often take time to mature and may evolve to reflect shifts in scientific consensus and deficiencies in initially decided compliance mechanisms. As such, a mechanism considered unpopular at time of ratification may be reconsidered at a future time depending on learnings and deficiencies in institutional design. Furthermore, compliance mechanisms should ensure that countries can be transparent about progress without fearing repercussions.

The exchange of reliable information is dependent upon both trust and transparency; however, no one existing treaty uses the same approach to encourage transparency and trust between parties.<sup>212</sup> Some treaties, such as the Paris Climate Agreement, use a combination of self-reporting, a global stocktake, and an Implementation and Compliance Committee that explicitly states that it is “expert-based and facilitative in nature and functions in a manner that is transparent, non-adversarial and non-punitive”.<sup>213</sup>

**Cross-References/Incompatibilities.** Article 22 CA+ proposes an Implementation and Compliance Committee as a subsidiary body of the COP, and the IHR amendments propose an Implementation Committee in Article 53A, self-

---

<sup>212</sup> Strobeyko, A., Morich, D., Burci, G. L., Moon, S. 'Synthesis: Implementation and Compliance Tools In International Law And Pandemic Rulemaking' in: Burci et al. 'Implementation and Compliance in International Law: Implications for Pandemic Rulemaking.' Global Health Centre Discussion Paper, Geneva Graduate Institute, 2023. Retrieved via: <https://repository.graduateinstitute.ch/record/301626>, p. 27

<sup>213</sup> Daniela Morich and Adam Strobeyko, 'Lessons from Multilateral Environmental Agreements: Mechanisms For Implementation, Compliance And Disputes Resolution' in Burci et al. 'Implementation and Compliance in International Law: Implications for Pandemic Rulemaking.' Global Health Centre Discussion Paper, Geneva Graduate Institute, 2023. Retrieved via: <https://repository.graduateinstitute.ch/record/301626>, p. 26

reporting to the Health Assembly, and maintenance of a WHO webpage or dashboard providing details of activities carried out, both in Article 54. While there are distinct areas of scope and implementation periods that would require separate Implementation Committees, there are overlapping provisions in both texts which would pragmatically necessitate either joint committees or joint sittings of both committees. One example relates to provisions on R&D capacity building, which are contained in both the CA+ and the proposed IHR amendments. However, such joint sittings would only be possible if the two instruments establish similar oversight bodies such as plenary bodies comprising all Parties.

## Analysis

In April 2023, IHR States Parties attended an informal briefing with experts and agencies to discuss various compliance and implementation mechanisms within and external to global health. For example, experts described the Montreal Protocol on Substances that Deplete the Ozone Layer, which requires annual mandatory reporting and includes a non-compliance procedure through which concerns about a country's non-compliance are "addressed in writing to the Secretariat", with a copy of the submission shared with the country concerned; subsequently, the submission, the reply by the country, and additional information are shared with the Implementation Committee.<sup>214</sup> Article 21 of the Framework Convention on Tobacco Control (FCTC) was also discussed. Each Party to the Convention submits periodic reports on FCTC implementation, with arrangements being made "to assist developing country Parties and Parties with economies in transition".<sup>215</sup> Crucially, Member States also considered what accountability measures should exist should a country not report an outbreak, as well as the type of leadership that was needed in responding to allegations of non-compliance.<sup>216</sup>

As mentioned in the Introduction, there has been criticism of how the IHR were implemented during the COVID-19 pandemic. In defence of the IHR mechanism, the Review Committee for the Functioning of the IHR (2005) during the COVID-19 Response stated that its provisions were "well considered, appropriate, and meaningful" but that "many countries had only applied the IHR in part, were not sufficiently aware of these regulations, or deliberately ignored them, and that WHO did not make full use of the powers given to it through the wording and spirit of the IHR".<sup>217</sup> This points to the need for a more robust monitoring and compliance mechanism. Other commentators note that, in order to have a stronger mechanism, additional financial and technical resources would be needed to enable countries to meet their IHR obligations.<sup>218</sup>

Most negotiators interviewed for this work stated either that they would prefer to discuss compliance when more contentious issues (such as PABS and IP) have been resolved, or that they had not yet formulated a position. However, of the three negotiators that discussed compliance, one argued that it was important to have a compliance mechanism that could "push member states to implement the obligations", with the second emphasizing that such a mechanism should not be punitive, and the third saying that they would not support a mechanism that 'shames' other countries:

---

*"We want something that can push Member States towards ensuring that they comply with the obligations. This body will see the extent to which Member States, including developed states, have implemented the obligations, whether it's on tech transfer, international cooperation, health systems or any other obligation that they might have in the Treaty or the IHR."*

*(Global South negotiator, interviewed 9 May 2023)*

*"On compliance, one principle that is important for us is that it's not punitive but rather is to help the countries fulfil their obligations. That's very important for us. For the IHR we had some mechanisms that made it possible, although not as effective as they should be. Whether it is self-evaluation, the idea of joint external evaluations... for us basically the principle that we don't like is very small groups discussing compliance. Some proposals at IHR talk about an implementation*

---

<sup>214</sup> The Montreal Protocol on Substances that Deplete the Ozone Layer, 'Non-Compliance Procedure' (1998) <<https://ozone.unep.org/node/2078>> accessed 28 July 2023

<sup>215</sup> Framework Convention on Tobacco Control, Article 21(3) <<https://fctc.who.int/who-fctc/overview>> accessed 28 July 2023

<sup>216</sup> WGIHR informal briefing session on other mechanisms related to compliance (13 April 2023)

<sup>217</sup> Preben Aavitsland, Ximena Aguilera, and others, 'Functioning of the International Health Regulations during the COVID-19 pandemic' (2021) *Lancet* 398(10308):1283-1287. doi: 10.1016/S0140-6736(21)01911-5

<sup>218</sup> [Katherine F. Ginsbach, John T. Monahan, Katie Gottschalk](#), Beyond COVID-19: Reimagining The Role Of International Health Regulations In The Global Health Law Landscape' *Health Affairs* (1 November 2021) <<https://www.healthaffairs.org/content/forefront/beyond-covid-19-reimagining-role-international-health-regulations-global-health-law>> accessed 28 July 2023

*committee which has a broader number of memberships. We think that model might be interesting, but we don't have a very strong position on it."*

*(Global South negotiator, interviewed 5 July 2023)*

---

In summary, while most negotiators have yet to develop hard decisions on compliance, the preference appears to be for a non-punitive approach, one that would provide accountability not just on capacities development in developing Member States but also for developed Member States on their obligations, and one that would support compliance and implementation. A further important requirement is for such a mechanism to encourage quick reporting of health emergencies by countries and to ensure that countries are not subject to unnecessary travel bans, as occurred during the COVID-19 pandemic.<sup>219</sup>

Strobeyko and colleagues emphasize the need for a non-punitive mechanism, particularly in an environment where states may not have resources to comply with agreed obligations.<sup>220</sup> In an extract from their report:

⋮ ⋮ ⋮

*"Capacity constraints can be addressed through non-punitive, supportive implementation arrangements, such as the provision of funding, technical support, or differential targets. The issue can also be addressed "upstream" through inclusion of capacity building provisions in the text of the pandemic instrument and amended IHR."*<sup>221</sup>

*– Strobeyko, Morich, Burci, and Moon, 'Synthesis: Implementation and Compliance Tools in International Law and Pandemic Rulemaking' (2023)*<sup>222</sup>

There have been several proposals by experts. Professor Larry Gostin and colleagues propose that there should be three compliance mechanisms: the COP under the CA+, with a major role for civil society (Committee 1); a Compliance and Complementarity Committee that would comprise all Member States of WHO and other relevant stakeholders to ensure complementarity between the CA+ and the revised IHR (Committee 2); and an Independent Assessment Body that would operate at arm's length to assess country performance, but would be overseen by Committee 1 (COP) on matters related to CA+ and Committee 2 on matters relating to IHR.<sup>223</sup> Others note that agencies such as the International Atomic Energy Agency are empowered to conduct on-site verification visits. While not presently included in the CA+ and IHR texts, this type of approach could be an option for monitoring development of health emergency-related competencies.<sup>224</sup>

Other experts have discussed a peer-review mechanism similar to the Universal Periodic Review (UPR)<sup>225</sup> for human rights as proposed in Article 8, which could offer a possible model for a "common compliance mechanism for both instruments".<sup>226</sup> Professor Gian Luca Burci noted that the CA+ should be an improved version of the UPR involving stakeholder and expert review in addition to Member State review.<sup>227</sup> However, some have suggested that the UPR model has led to 'interstate shaming' and is an "inherently political exercise that operates through strategic

---

<sup>219</sup> Jenny Lei Ravelo, 'Pandemic negotiations eye incentives instead of sanctions' Devex (9 May 2023) <<https://www.devex.com/news/pandemic-negotiations-eye-incentives-instead-of-sanctions-105488>> accessed 28 July 2023

<sup>220</sup> Strobeyko, A., Morich, D., Burci, G. L., Moon, S. 'Synthesis: Implementation and Compliance Tools In International Law And Pandemic Rulemaking' in: Burci et al. 'Implementation and Compliance in International Law: Implications for Pandemic Rulemaking.' Global Health Centre Discussion Paper, Geneva Graduate Institute, 2023. Retrieved via: <https://repository.graduateinstitute.ch/record/301626>,

<sup>221</sup> Ibid, p. 26

<sup>222</sup> Ibid

<sup>223</sup> Barbara Stocking, Lawrence Gostin, and others, 'Independent Assessment & Governance Committees: Addressing Accountability and Governance in a Pandemic Accord' Geneva Health Files (28 June 2023) < <https://genevahealthfiles.substack.com/p/independent-assessment-and-governance>> accessed 12 July 2023

<sup>224</sup> Christos Zois and Fuad Zarbiyev, 'Unpacking Compliance with International Law' in Burci et al. 'Implementation and Compliance in International Law: Implications for Pandemic Rulemaking.' Global Health Centre Discussion Paper, Geneva Graduate Institute, 2023. Retrieved via: <https://repository.graduateinstitute.ch/record/301626>, p. 9

<sup>225</sup> Universal Periodic Review < <https://www.ohchr.org/en/hr-bodies/upr/upr-main#:~:text=The%20UPR%20is%20a%20State.fulfil%20their%20human%20rights%20obligations>> accessed 28 July 2023

<sup>226</sup> Gian Luca Burci and others, 'Implementation and Compliance In International Law: Implications For Pandemic Rulemaking' (upcoming 2023) p. 17

<sup>227</sup> Interview with Professor Gian Luca Burci, Adjunct Professor of International Law at the Graduate Institute of International and Development Studies (via Zoom, 17 July 2023)

relationships”,<sup>228</sup> enabling states that have more allies than others to avoid scrutiny. One negotiator stated that they would not be supporting the UPR model:

---

*“(Compliance) shouldn’t occur via shaming [other countries]. We don’t like this UPR idea. There’s a great interest on the part of some Member States on this. At this stage, we don’t think it will be beneficial to have UPR [as a compliance model]. We’re flexible but think that it would be a major exercise to even have in future because some countries would want us to focus more on preparedness while we might be focusing more on response in case of a PHEIC. We think it’s too early to put it in the Pandemic Accord, because it’s not been accepted by all of us. No one has agreed to it.”*

*(Global South negotiator, interviewed 31 January 2023)*

---

This illustrates that there may be a concern that the UPR model is too punitive for the purposes of pandemic competencies, although it is unclear how widely accepted this notion is.

Finally, the instruments propose multiple different compliance/implementation/monitoring mechanisms, including Compliance Committees, the COP, and peer-review mechanisms. Further detail will be needed on both the added value and complementarity of these various mechanisms.

### **Summation.**

Discussions around compliance mechanisms are very preliminary. While only three Member States commented on compliance mechanisms for this report, these were consistent with publicly available analysis and media reporting on compliance – that compliance mechanisms should not be punitive and should work to support implementation by all Member States.

Some questions for consideration include:

1. Would a peer-review mechanism be too punitive? Would it be necessary to ensure fulfilment of obligations? Would it be more effective than self-reporting?
2. What role is there for onsite visits? Are they an adequate replacement for peer-review mechanisms?
3. Can sufficient financial resources be raised for the effective operation of the IHR Implementation and Compliance Committees?
4. What additional value would a peer mechanism akin to the UPR provide to the proposed Implementation and Compliance Committee or to self-reporting mechanisms?
5. Would a joint compliance mechanism or a Complementarity Committee be needed?

## **Conclusion**

Negotiations on both the IHR and CA+ are complex and interlinked. At time of writing, divergence in opinion is most stark on PABS, One Health, R&D and IP, although many areas continue to require elucidation, including Financing and Supply & Logistics. Some countries have yet to formulate positions on financing (particularly on debt swaps) and on compliance.

As in most negotiations, concessions are required to move beyond deadlock, and there are several approaches negotiators use to achieve this, including modifying power asymmetries through ideation,<sup>229</sup> noting that countries are bound by stakeholders’ demands at the national level,<sup>230</sup> asserting Member States’ structural power (security,

---

<sup>228</sup> Terman, R., Voeten, E. The relational politics of shame: Evidence from the universal periodic review. *Rev Int Organ* **13**, 1–23 (2018). <https://doi.org/10.1007/s11558-016-9264-x>

<sup>229</sup> For example, in security negotiations between a government and rebel groups, while a government may have economic might and international legitimacy, ‘the rebels’ intense commitment to their cause as the single defining mission of their existence creates an obvious challenge to the others’ straightforward application of its power... and can create a destabilising effect’,<sup>229</sup> and this situation can ‘modify’ an asymmetrical relationship. Harris P and B Reilly (eds), *Democracy and Deep-Rooted Conflict: Options for Negotiators* (International IDEA 1998) 76

<sup>230</sup> Robert D Putnam, ‘Diplomacy and Domestic Politics: The Logic of Two-Level Games’ (1988) 42(3) *International Organization* 427–460, 436



production, finance, knowledge, and values of a particular set of actors),<sup>231</sup> or, if deadlock cannot be overcome, to express reservations at the time of agreeing to or acceding to a treaty.<sup>232</sup>

Moving to consensus will require discussion of key considerations, including:

1. **Declarations.** What will each declaration trigger? How can the timing of declarations ensure that responses are timely, appropriate and effective?
2. **CBDR.** Can equivalence be drawn between increased contribution to greenhouse gas emissions and increased contribution to pandemic tools scarcity? To what degree can equivalencies be drawn between industrialization and practices of industrialized countries, and pandemic inequities? To what extent has CBDR in treaties been effective at mobilizing action? To what extent have other principles, such as equity and respect for human rights, been able to mobilize action in other treaties? What practically does CBDR mean financially for countries? Can countries fulfil One Health obligations without inclusion of the CBDR principle? Would inclusion of CBDR risk undermining compliance and accountability mechanisms?
3. **R&D.** When should countries attach conditionalities – within R&D funding contracts or within procurement contracts? Can manufacturers be compelled to share pricing information?
4. **One Health.** Has One Health as an approach been adequately discussed and endorsed by Member States? Would Member States consider transition periods for implementation? Could Member States use treaty reservations to move beyond deadlock? What funding mechanisms would exist to support One Health implementation? Can One Health obligations be adhered to without CBDR? What appetite is there for separate negotiations on One Health?
5. **Supply Chain & Logistics.** Would new mechanisms create an ‘ACT-Accelerator 2.0’, without addressing oversight, governance and operational shortcomings of the ACT-Accelerator model? How can countries be equitably represented in decision-making of an allocation/supply mechanism? How should Article 13 be linked to production, and what concrete production-related obligations can be established for Member States with manufacturing capacity?
6. **Co-Development of Technology Transfer and Know-How.** Would opposition to time-bound IP waivers result in (a) poor regional manufacturing capabilities in the next pandemic and/or (b) deadlocked negotiations on the CA+?
7. **PABS.** Can a pandemic PABS mechanism be modelled on the influenza PIP framework, using the IPSN? Can manufacturers be compelled to transfer technology instead of providing donations? Would manufacturers be subject to extensive compliance burdens? Would transactional models create barriers to rapid sharing of samples and sequence data, slowing intervention development?
8. **Financing Mechanism.** Would a financial mechanism be best placed within the IHR to have widest possible application? Will countries agree to expanding assessed contributions for pandemic prevention, preparedness and response? Is WHO equipped to operate with additional banking and financing functions? Is the Pandemic Fund a permanent entity and could allocation be subject to CA+ or IHR oversight?
5. **Compliance & Accountability.** What are the pros and cons of a peer-review mechanism? Would onsite visits be an adequate replacement for peer-review mechanisms? How can compliance mechanisms across instruments be coordinated?

---

<sup>231</sup> Christopher May, ‘Strange Fruit: Susan Strange’s Theory of Structural Power in the International Political Economy’ (1996) 10(2) *Global Society* 167-189, 174; Susan Strange, ‘The Persistent Myth of Lost Hegemony’ (1987) 41(4) *International Organization* 551-574, 553

<sup>232</sup> United Nations, ‘Guide to Practice on Reservations to Treaties’ (2011), Article 1.1.1

<[https://legal.un.org/ilc/texts/instruments/english/draft\\_articles/1\\_8\\_2011.pdf](https://legal.un.org/ilc/texts/instruments/english/draft_articles/1_8_2011.pdf)> accessed 7 August 2023