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WHAT'S NEW IN THE DRAFT PANDEMIC AGREEMENT?

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EXECUTIVE SUMMARY

The COVID-19 pandemic served as a stark reminder of how disruptive and far-reaching pandemics can be, shaking the foundations of societies and economies worldwide. By their very nature, pandemics transcend borders, requiring a coordinated global response.

In recognition of this, World Health Organization (WHO) Member States are engaged in negotiations to establish new international rules to enhance Pandemic Prevention, Preparedness, and Response (PPPR). This ambitious effort, initiated over three years ago and set for conclusion in May 2025, is proving to be a complex undertaking. For these rules to be effective, they must navigate a vast policy and normative landscape, overlapping with existing international and national frameworks while ensuring coherence, complementarity, and synergy.

This paper provides a preliminary analysis of the draft Pandemic Agreement (PA), as reflected in the 21 February 2025 draft, highlighting key aspects of the ambition of this emerging framework. The content of the current draft PA builds on the lessons learned from the COVID-19 pandemic by proposing a systemic approach to PPPR. It moves beyond the emergency focus of the International Health Regulations (IHR) (2005) as amended in 2014, 2022 and 2024, creating a broader set of rules that extend both "upstream" (prevention and preparedness) and "downstream" (response and recovery). By doing so, it seeks to complement and reinforce existing international legal instruments while filling regulatory gaps.

This analysis highlights a notable degree of innovation in addressing critical gaps exposed by the COVID-19 pandemic, compared to existing international law. For instance, Articles 6 and 7 of the draft PA on resilient health systems and the protection of the Health and Care Workforce (HCW), emphasize how the draft PA aims to introduce legally binding obligations that formalize and elevate the normative content of previously non-binding instruments, such as World Health Assembly (WHA) resolutions and WHO policy guidance. This shift from soft law to hard law underscores the willingness of negotiators to move toward ensuring stronger global commitments and accountability in pandemic preparedness.

In other instances, the draft PA also seeks to create binding rules in areas where previous attempts have failed. A notable example is Article 9 on Research and Development (R&D), where past efforts to establish enforceable global commitments did not succeed. The renewed attempt in the current negotiations underscores the enduring challenge of securing agreement on these sensitive issues, and the progress made in doing so.

Additionally, the draft text strives to achieve coherence with other areas of international law, including trade regulations and intellectual property rules. Ensuring alignment with existing global legal frameworks will be key to avoiding conflicts and facilitating effective implementation.

At the same time, the text reaffirms a commitment to respecting national sovereignty, and provides space for ensuring that new norms remain adaptable to diverse national contexts. Striking the right balance—between reinforcing global cooperation and preserving national autonomy—has been a constant tension in the negotiations and will likely be crucial in securing broad consensus among countries.

The challenge ahead is historical in scale. Negotiators must reconcile divergent interests, bridge regulatory gaps, and create a robust yet flexible legal instrument capable of standing the test of future pandemics. The success of this endeavor will not only strengthen the effectiveness of the next global response but will also shape the broader landscape of international health governance for years to come.

INTRODUCTION

The purpose of this policy brief is to help delegates negotiating the draft PA as well as other actors observing the negotiations to consider the draft agreement in its totality and within its broader normative context. In other words, an assessment of the draft text should go beyond the interpretation of individual articles taken in isolation and identify thematic clusters of articles that are supposed to be interdependent and mutually supportive. Moreover, the draft PA is not taking shape in a legal vacuum but, once adopted, it will be placed in a normative ecosystem populated by other international instruments, whether binding or not, starting with the IHR.

Negotiators are currently working to reach consensus on a limited number of issues and articles that logically absorb most of their attention. However, many other articles have been wholly or mostly agreed and appear in "green" in the version released by the Bureau of the Intergovernmental Negotiating Body (INB) on 21 February 2025 and used for the purpose of this policy brief. Even though these articles are not attracting much attention at this stage of the negotiations, they cover important issues for PPPR and often constitute a step forward with regard to the extant normative landscape. In order to give a balanced assessment of the draft PA and its innovations, therefore, this policy brief will focus on a selected range of articles wholly or mostly agreed against the background of the currently applicable international normative instruments. This analysis is of a preliminary nature and the list of international instruments is non-exhaustive and based on research conducted with limited resources. When reproducing text from the draft PA, the quotations will use the same colour as appear in the version of 21 February 2025 for the purpose of factual accuracy.

The structure of this policy brief is the following: **Part 1** will compare and contrast the draft PA with the amended IHR to better understand the motives behind launching the negotiations of a new international agreement and how the two instruments are interlinked. **Part 2** provides a summary of the whole text of the draft PA grouping together articles dealing with interlinked topics in order to highlight the internal consistency of the various parts of the text. **Part 3**, as noted above, focuses on a number of wholly or mostly agreed articles, summarizes their content and shows how they innovate and factually represent progress when compared to existing international normative instruments. Finally, a conclusion follows.

PART 1 - BEYOND THE IHR: HOW THE PANDEMIC AGREEMENT INTENDS TO ADVANCE GLOBAL PPPR

The IHR are the legacy of a long historical lineage of international instruments to prevent and control the international spread of diseases. Their scope is relatively narrow because they focus on preparedness, early detection and containment and are triggered by "events," i.e. a manifestation of disease or an occurrence that creates a potential for disease. Even though the popular image of the IHR is about responding to emergencies, they include many routine measures to detect diseases at the border. They are considered a technical instrument and surveillance, alert and guidance functions are largely delegated to the WHO Secretariat. The 2024 amendments have responded to previous criticism inter alia by injecting equity into the principles and the operation of the IHR and giving States Parties more oversight over implementation.

The proposal for a PA came as a reaction to the reported limits and weaknesses of the IHR as well as their perception as a technical instrument with limited political leverage. It was felt by many Member States that a treaty would secure more government-wide political and financial commitment than a regulation. It was also felt by many Member States that an agreement under Article 19 of the WHO Constitution, requiring an affirmative consent to be bound through ratification, would be preferable to the opt-out mechanism of regulations as foreseen in Article 21 of the WHO Constitution.

The content of the current draft PA builds on the lessons learnt from the COVID-19 pandemic by proposing a systemic approach to PPPR and moving beyond the perceived emergency focus of the IHR. It goes more "upstream" and "downstream" than the IHR, i.e. with regard to prevention on the one hand, and to benefit sharing and technology transfer on the other hand. It aims at reducing the risk of a pandemic both through measures triggered by a pandemic or a high risk thereof as well as through more systemic measures to be implemented at all times to bolster prevention and preparedness and ensure equitable access to health products and resources as well as aim at broader public health objectives such as strengthening resilient health systems and achieving Universal Health Coverage (UHC).

The draft PA in a way is a mirror image of the IHR: it has a very broad scope but targets a very narrow factual situation, i.e. a pandemic which will hopefully remain a rare event in global health. The two instruments, as things stand at the current stage of negotiations, are largely complementary. An analysis of their interactions is provided in the Governing Pandemics Snapshot published in January 2025 and available on the web site of the Governing Pandemic Initiative.[1] In particular, a number of measures in the draft PA are triggered by the declaration of a public health emergency of international concern (PHEIC) or a pandemic emergency by the WHO Director-General under the IHR.

PART 2 - SUMMARY OF DRAFT PANDEMIC AGREEMENT: MAIN CONTENT AND INTERLINKAGES

Treaty negotiations must often focus on specifics – an article, a sentence, a single word. After over three years of intense negotiations, as the finish line approaches, it is not always easy to consider the totality of what has been negotiated and achieved, especially for those who have been closest to the process. Here we offer a high-level summary of the main substantive topics addressed by the draft PA, as reflected in the draft of 21 February 2025. We also highlight linkages among articles, since the provisions of a treaty cannot be read in isolation but have to be interpreted in light of the overall text, including the preamble and any annexes. While it is understandable that attention focuses on the issues where consensus has not yet been forged, it is also important to recognize the breadth, depth and novelty of what has been agreed.

After laying out the context, definitions, objectives, overarching principles and approaches (Preamble and Chapter I), the draft PA addresses five main thematic areas (Chapters II and III):

A. PREVENTING PANDEMICS (ARTICLES 4 AND 5)

These articles are still largely under negotiation. The current text lays out obligations on Parties to reduce the likelihood of pandemics by mitigating the risks that outbreaks emerge in the first place – whether in humans, animals, the environment, or the intersection among them – and that once they do, they are detected quickly through surveillance. The obligations go further upstream than the IHR in seeking to reduce the risk of outbreaks occurring in humans in the first place. It is recognized that obligations on a Party to implement such preventive measures will be "*in accordance with its national and/or domestic laws and subject to the availability of resources*," reflecting flexibility, and underscoring the importance of effective governance arrangements to enable the Conference of the Parties (COP) to discuss whether an appropriate balance is being struck between national sovereignty and effective implementation (Chapter III). In addition, international cooperation in the form of "*technical assistance, capacity building, technology transfer and financing*" may be needed to implement these articles fully, highlighting the connection to international support (Articles 19 and 20).

B. SOCIETAL AND HEALTH SYSTEM CAPACITIES (ARTICLES 6, 7, 17, 18)

These articles are nearly uniformly green, and lay out obligations on Parties to "*develop, strengthen and maintain a resilient health system*" capable of providing healthcare services and public health functions during and between pandemics, and ensuring the appropriate HCW to do so (see further discussion of Articles 6, 7 and 17 below). Some of the key provisions in Article 4 on prevention (i.e. on routine immunization, infection prevention and control, and lab safety) rely on day-to-day functioning health systems. Parties also commit to strengthen their societal capacities to address pandemics by adopting inclusively-developed whole-of-government, whole-of-society plans, and increasing population literacy and trust through community-engagement and risk communication.

No other treaty binds countries to such specific or deep obligations on societal or health system capacities to address pandemics. Repeated throughout is language that gives Parties flexibility,

such as "*taking into account its national circumstances*" and "*as appropriate,*" underscoring the importance of effective governance arrangements (Chapter III). Implementing these obligations will also require domestic and in some cases international financing, and hence should be read alongside Articles 19 and 20 on international support.

C. PANDEMIC-RELATED HEALTH PRODUCTS (ARTICLES 9-14)

Convergence has largely been achieved on most of these articles, with the exception of Articles 11 on technology transfer and 12 on a Pathogen Access and Benefit-Sharing (PABS) system. They establish an interconnected set of obligations on Parties with the aim to improve equity in access to pandemic-related health products. Obligations span from R&D to manufacturing of products, from regulatory review to stockpiling. The provisions are both nationally-oriented (i.e. commitments to invest in R&D domestically or develop regulatory capacities), and internationally-oriented (i.e. licensing publicly-owned technologies and refraining from stockpiling more than a country needs). A connecting thread throughout is transparency, including Parties' commitments to transparency of R&D priorities, clinical trial protocols, research results, licensing agreements, supply chains, and relevant terms of procurement contracts. Another area of emphasis is consideration for access to health products in fragile or humanitarian settings.

The specificity of norms on what countries commit to do and/or should do with respect to pandemic-related products, and the depth of international cooperation they establish, are unprecedented in international treaty law (see, for example, further discussion of Articles 9 and 13 below). That said, throughout these articles, there is frequent appearance of language such as "*promote*", "*encourage*", "*within means and resources at their disposal*", and "*in accordance with national and/or domestic law and policy,*" underscoring (as elsewhere) a fair amount of flexibility for implementation and the importance of effective governance arrangements for follow-up and accountability.

Article 12 is still under negotiation, but if agreed close to its current form it would eventually establish a PABS system, with additional details to be negotiated subsequently in an Annex. This Article connects and mutually reinforces two major parts of the draft PA: a functioning PABS system could enhance international surveillance (Articles 4 and 5 on prevention and surveillance) while facilitating product development and access (Articles 9-14 on products). Under such a system, Parties would commit to provide access to "*PABS Materials and Sequence Information*" in accordance with data safety, biosafety and biosecurity standards, in a manner that would provide legal certainty to participating actors, and facilitate research and innovation. On an equal footing, Parties would commit to benefit-sharing during pandemic emergencies, with different benefits potentially during PHEICs and to prevent outbreaks from progressing into emergencies. Such benefits are envisioned to include monetary and non-monetary benefits, including a percentage of real-time manufacturing of products to be supplied to WHO for allocation to countries in need.

Implementing these obligations will require domestic and international resources, both financial and technological, such that Articles 19 and 20 on international support and financing are highly relevant here, as is Article 11 on technology transfer. The PABS system may generate its own financing through sources such as annual fees or royalties, but this issue remains to be agreed in future negotiations of the Annex.

D. INTERNATIONAL SUPPORT (ARTICLES 19 AND 20)

These articles are almost entirely green, and obligate Parties to cooperate to strengthen capacities for implementation, especially in developing countries. Domains of cooperation may include technology transfer, sharing of legal and scientific expertise, capacity-strengthening and financing. Parties commit to "*maintain or increase domestic funding*" for PPPR, "*work to mobilize*" additional international financing and establish a Coordinating Financial Mechanism that is to provide strategic information, analysis and support to Parties in securing financing. A core purpose of the Mechanism is coherence and increased transparency in a fragmented and opaque financing landscape; it is envisioned that a single Mechanism would address financing issues related to both IHR and PA obligations. As flagged above, financing and other forms of international support are critical to all three substantive thematic areas – prevention, societal and health systems capacities and pandemic-related health products.

E. GOVERNANCE AND THE ROLE OF WHO (CHAPTER III, ARTICLES 21-37)

These articles are largely green, with the exception of Articles 30 and 31 on Annexes and Protocols. They establish the governance arrangements for the PA, including a COP, voting rights, reporting obligations, settlement of disputes, reservations and amendments, annexes and protocols, and arrangements for entry into force and withdrawal. As flagged above, effective governance is critical for meaningful implementation in all three substantive thematic areas, since many commitments are subject to caveats (i.e. "*within means and resources at their disposal*," "*taking into account its national circumstances*," "*in accordance with national and/or domestic law and policy*," "*as appropriate*") or exhortatory rather than obligatory (i.e. "*encourage*," "*promote*," "*work to*"). Establishing what is "*appropriate,*" for example, will certainly be discussed by the COP and other governance arrangements. How monitoring and accountability will function has been left to a "mechanism" that the COP is to establish at its second meeting; the draft PA specifies that the mechanism is to "*facilitate and strengthen effective implementation*" and is to be "*transparent, cooperative, non-adversarial, non-punitive and cognizant of respective national circumstances*."

Article 24 establishes the WHO Secretariat as the Secretariat of the PA. The role of WHO is also specified in various articles throughout the draft PA, for example, as a provider of support to Parties including reviewing national policies; offering training programs; developing norms, frameworks and recommendations; coordinating technology transfer; operating the PABS system; convening the Global Supply Chain and Logistics (GSCL) Network; and coordinating with other international relevant organizations and bodies. While the envisioned role of WHO is varied and extensive, a key distinction between the PA and IHR is that the PA entails far more extensive obligations on states (Parties) as also discussed above in Part 1.

PART 3 - WHAT IS NEW?: A PRELIMINARY ANALYSIS OF SELECTED PROVISIONS WITH "GREEN TEXT"

In this section we analyze in greater detail selected articles for which consensus has been wholly or mostly reached (as reflected in nearly all green text), focusing on what would be new with respect to existing international law and other non-binding normative instruments.

ARTICLE 6 - PREPAREDNESS, READINESS AND HEALTH SYSTEM RESILIENCE

WHAT DOES THE ARTICLE PROVIDE?

Article 6 of the draft PA outlines commitments for parties to build resilient health systems, with a strong focus on primary health care and equity, to achieve UHC.

Particularly, Parties will commit "*to take appropriate measures to develop or strengthen, sustain and monitor health system functions and infrastructure for*:" a) "*equitable access to scalable clinical care and quality routine essential health care services*" while maintaining public health functions during pandemics, including mental health and psychological support; b) "*transparent and cost effective procurement practice and supply chain management of pandemic-related health products;*" c) "*laboratory and diagnostic capacities through the application of relevant standards and protocols, including for laboratory biological risk management;*" d) "*promoting the use of social and behavioural sciences, risk communication and community engagement*;" and e) plan for "*post-pandemic health system recovery.*"

Additionally, Parties, in collaboration with WHO, will be required to enhance national health data systems using international standards for better public health response. To strengthen accountability, Parties will be required to monitor and to regularly evaluate their pandemic preparedness, identifying gaps and seeking WHO support if necessary.

WHAT IS NEW?

Article 6 establishes a binding obligation upon Parties to develop, or strengthen, resilient health systems, explicitly linking pandemic preparedness to the realization of UHC. By emphasizing primary health care, it suggests that preparedness is not just about emergency responses but also about the systematic and continuous enhancement of health infrastructure, to ensure its operational functionality during public health emergencies, including pandemics.

Article 6 endorses the principle of equity in healthcare access, and focuses explicitly on persons in vulnerable situations, addressing disparities in pandemic response, which were starkly evident during the COVID-19 crisis. If adopted, this provision would formalize and elevate the normative content of prior non-binding instruments, such as resolutions of WHO governing bodies,[2] by introducing legally enforceable commitments. It would also build upon and expand the obligations included in the IHR, which focus primarily on the development and strengthening of national core capacities on outbreak detection, containment, and response.

For State Parties that are also parties to international human rights treaties such as, for example, the International covenant on economic and social and cultural rights (ICESCR), this provision echoes key obligations concerning the "right to health", including on healthcare systems. For instance, the Committee on Economic, Social and Cultural Rights' General Comment 14[3] – which constitutes an authoritative, albeit non-binding interpretation of the normative content of the right to health, affirms that core obligations arising from the right to health include ensuring the right of access to health facilities, goods, and services on a non-discriminatory basis; assuring medical services and medical attention in the event of sickness; taking measures to prevent, treat, and control epidemic and endemic diseases; and providing education, access to information concerning health and appropriate training for health personnel.

As in other provisions of the draft PA, caveats such as "*within the means and resources at its disposal*" or "*as appropriate*" and "*in accordance with national or domestic law, subject to availability of resources*" are common. While these clauses allow for flexibility in the implementation, they also risk diluting the impact of the norm.

ARTICLE 7 - HEALTH AND CARE WORKFORCE

WHAT DOES THE ARTICLE PROVIDE?

Article 7.1 establishes legally binding provisions on Parties, in line with national circumstances, "*to develop, strengthen, protect, safeguard, retain and invest in a multi-disciplinary, skilled, adequate, trained, domestic health and care workforce*" to ensure healthcare systems globally are sufficiently equipped to respond to pandemic emergencies whilst maintaining essential health services – closely linked to Article 6 on health system resilience and its goal of achieving UHC. The article also mandates decent working conditions, prioritizing the "*safety, mental health, and well-being*" of the HCW.

The COVID-19 pandemic illustrated inadequate working conditions and revealed stark gaps for the protection of the mental[4] and physical health of the HCW.[5] These working conditions lacked the safeguards needed to protect the HCW which led to a mass exodus of health care workers, leaving health systems even more understaffed and underprepared compared to pre-COVID-19 times.[6,7] Article 7 addresses this global issue by setting legally binding obligations on its Parties to strengthen health systems and protect the HCW.

Furthermore, paragraph 5 of the article expands protections beyond the HCW, with protection and safeguards extended to other health and care occupations, including those that provide a role in the delivery of the essential public health functions.[8]

WHAT IS NEW?

Article 7 complements non-binding guidance and documents[9] by reflecting their core principles into the draft PA, thus establishing new international legally binding obligations on Parties and requiring them to take concrete measures to build and protect their HCW.

The article title and paragraph 7.1 reaffirm the increasing shift by governments worldwide towards assuming stewardship over the HCW, aligning WHO's normative position with the International Standard Industrial Classification of All Economic Activities (ISIC) Rev 4 developed by the United Nations Statistics Division (UNSD),[10] and the International Standard Classification of Occupations (ISCO) maintained by the International Labour Organization (ILO).[11] Both are publicly available, international frameworks adopted and used by governments to define,

categorize and compare economic and occupational statistics, including for the HCW, allowing for comparability of data and the development of robust national statistical systems.

Paragraph 2(b) of Article 7 is of particular importance as it reinforces the principles established in the 1979 Convention on the Elimination Of All Forms Of Discrimination Against Women (CEDAW). It obliges Parties "*to take appropriate measures to ensure decent work [...] by [...] eliminating all forms of inequalities and discrimination and other disparities, such as unequal remuneration and barriers faced by women.*" The explicit mention of 'women' is especially significant given 67% of the global HCW are women,[12] who are disproportionately affected by unequal pay[13] and the mental health effects of working during health emergencies.[5]

Article 7.4 explicitly references the WHO Global Code of Practice on the International Recruitment of Health Personnel (WHO Code[14]), and other international voluntary codes. The direct reference to the Code in the draft PA demonstrates support for it, reinforcing its norms and encouraging adherence to it.

Resolution WHA74.14: *Protecting, safeguarding and investing in the health and care workforce*[15] requested the WHO Director General to develop, in consultation with Member States, the Global Health and Care Workers Compact: Technical Guidance Compilation (WHO Compact[16]) which was adopted in resolution WHA75.17[17] in 2022. This non-binding technical guidance provides WHO Member States with a comprehensive review of relevant international legislation and recommendations on the safeguarding of rights and ensuring decent working conditions for the HCW. The WHO Compact provides WHO Member States with updated technical guidance to implement, monitor and enforce relevant available laws and regulations that protect the HCW.

A 2024 study analysing laws and policies in 182 countries found that only 62% of countries are somewhat aligned with international standards for HCW protection and rights.[18] Moreover, almost every country studied requires further work to align with the WHO compact. This highlights the progress of Article 7 in trying to ensure adequate legal safeguards for the HCW.

ARTICLE 9 - RESEARCH AND DEVELOPMENT

WHAT DOES THE ARTICLE PROVIDE?

Articles 9.1 and 9.2 establish commitments seeking to strengthen R&D for Pandemic Preparedness and Response and to "*build, strengthen and sustain geographically diverse capacities and institutions for research and development, particularly in developing countries*."

These commitments include promoting sustained investment and support for research institutions and networks; scientific research programmes, projects and partnerships; research collaboration; sharing of information; capacity-building programmes, projects and partnerships. Additionally, it calls for sustained support for all phases of R&D, for accelerating innovative R&D, and for the participation of relevant stakeholders.

Article 9 also sets out obligations aimed at addressing equity in R&D for Pandemic Preparedness and Response, including promoting "*the sharing of pandemic-related vaccines, therapeutics and diagnostics for use as comparator products in the conduct of clinical trials*" (access to comparator products) in Article 9.3(ii) and "*access to safe and effective products that result from these trials for such trial populations and for populations at risk in their communities*" (post-clinical trial access) in Article 9.3(iii).

Article 9.5 requires Parties to "*develop and implement national and/or regional policies [...] regarding the inclusion of provisions in publicly funded R&D grants, contracts, and other similar*

funding arrangements, [...] for the development of pandemic-related health products, that promote timely and equitable access to such products, [...] during public health emergencies of international concern including pandemic emergencies."

WHAT IS NEW?

The global health community has repeatedly advocated for an international agreement on R&D in the past. Most notably, in 2005, a letter signed by 162 experts asked the WHO to evaluate a new treaty framework for medical research and development.[19] In 2008, the WHA adopted Resolution WHA61.21[20] establishing an Expert Working Group (EWG) to "examine current financing and coordination of research and development." The result of their work was presented to the WHO Executive Board in 2009.[21]

In 2010, the WHA adopted Resolution WHA63.28,[22] which established the WHO's Consultative Expert Working Group on Research and Development (CEWG). In 2012, the CEWG recommended, unsuccessfully, to negotiate a "binding agreement based on Article 19 of the WHO constitution" aimed at "providing effective financing and coordination mechanisms to promote R&D."[23]

Several proposals from these earlier efforts are now incorporated in Article 9, including obligations aimed at promoting investment in the discovery and development of pandemic-related health products, as well as fostering cooperation, collaboration and information sharing.

Additionally, Article 9 would complement and strengthen national and regional legislation, as well as non-legally binding instruments such as, for instance, the May 2022 WHA Resolution on Strengthening Clinical Trials (WHA75.8),[24] which contains no elements on post-trial access to health products or access to comparator products. It would also complement the World Medical Association (WMA) Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Participants,[25] which only contains a paragraph on "post-trial provisions", and the Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Health-related Research Involving Humans,[26] which includes a guide on benefit sharing, referring to the information and knowledge resulting from the trials.

Article 9 would be the first clause of an international, legally binding instrument to include a provision on post-clinical trial access to products, advancing equity for the trial populations and for populations at risk in their communities. It would also be the first time that a legally binding instrument would include a provision on access to comparator products (Described in a draft PA's footnote as: "*an investigational or marketed product (active control) or placebo (inactive control) used as a reference in a clinical trial*"), addressing a challenge that was experienced during COVID-19 and other emergencies where some originator companies have been unwilling to grant access to relevant health products for research purposes.

Additionally, Article 9 calls for the establishment of a concrete measure to promote equity in Pandemic Preparedness and Response. Paragraph 5 outlines, for the first time in a legally binding instrument, the requirement to develop and implement national and/or regional policies regarding the inclusion of access provisions in publicly funded R&D.

This provision suggests that Member States recognized it would be more effective for governments to leverage public funding to embed access conditions in the early stages of R&D rather than intervening later or in the midst of responding to a pandemic. In this early phase, governments are often the main and largest investor in R&D for pandemic-related health products.

Furthermore, the draft PA acknowledges the importance of using the leverage governments have in their funding to promote effective pandemic-related health products development and access, with a comprehensive end-to-end approach, through R&D agreements and procurement contracts. This is evident in the interlinkages between Articles 9, 11 and 13 on access conditions.

ARTICLE 10 - SUSTAINABLE AND GEOGRAPHICALLY DIVERSIFIED LOCAL PRODUCTION

WHAT DOES THE ARTICLE PROVIDE?

Article 10.1 commits Parties to taking measures to diversify manufacturing geographically and rapidly scale up production to improve access to pandemic-related health products.

Article 10.2 lists specific measures to be taken by Parties, which include supporting new and existing production facilities, particularly in developing countries, through skill development and capacity building, and facilitating their continuous and sustainable functioning through transparency of non-protected information across the value chain. Parties shall also encourage "*public and private sector investments, purchasing arrangements, and partnerships, including public-private partnerships*."

Linked to Articles 11 and 13, Article 10 urges Parties to "*support relevant WHO technology, skills and knowledge transfer and local production programmes*," facilitate procurement from regionally diverse facilities, and, during emergencies, scale up production by contracting manufacturers if existing capacity is insufficient.

Article 10.3 tasks WHO, upon request of the COP, with providing training, capacity-building, and production support to achieve geographically diversified manufacturing.

WHAT IS NEW?

Article 10 addresses these problems by seeking to establish the first legally binding global framework for sustainable and geographically distributed health product manufacturing, addressing current gaps and guiding state actions.

The COVID-19 pandemic exposed the risks of concentrated manufacturing in a few companies, primarily in high-income countries (HICs). Vaccines reached low- and middle-income countries (LMICs) only after HICs had secured more than enough doses for their own populations. While significant production took place in middle-income countries (MICs), global vaccine access remained limited, with governments prioritizing domestic vaccination efforts.[27] National authorities hold regulatory power over companies in their jurisdictions and are likely to prioritize the demands of their populations in times of crisis by means of export bans.

In the wake of the COVID-19 pandemic, the WHO has launched initiatives such as the mRNA Technology Transfer Hub in South Africa and the Global Training Hub for Biomanufacturing (GTH-B) in the Republic of Korea to address the need for access to relevant technology and a skilled workforce in LMICs. Additionally, collaborations such as the African Vaccine Manufacturing Accelerator (AVMA), bringing together the African Union (AU), Africa CDC, and Gavi, aim to strengthen regional health product manufacturing. The need to strengthen local manufacturing has been recognized in the implementation of the World Health Organization's Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property (GSPOA).[28] These developments have occurred in the absence of a global legal framework and could potentially be strengthened and expanded if Parties implement new rules. The COP of the PA would also be able to request WHO to support geographically diverse manufacturing facilities.

It is also worth noting that while Article 10 employs binding legal language—evident in the repeated use of "shall" throughout the provision—it grants Parties discretion in its implementation. The use of caveats such as "*as appropriate*," or "*subject to national and/or domestic law*" may potentially limit its scope of application.

ARTICLE 13 - SUPPLY CHAIN AND LOGISTICS & 13*BIS* PROCUREMENT AND DISTRIBUTION

WHAT DOES THE ARTICLE PROVIDE?

Article 13 establishes a GSCL Network that aims at rationalizing and stabilizing the international supply chains of pandemic-related health products in order to promote "*equitable, timely, and affordable access*" to such products. The responsibility for developing, coordinating and convening the GSCL Network falls on WHO under the authority of the COP, but the functions of the GSCL Network will be discharged by the organizations best placed to perform them.

Article 13 is of a general nature. The COP shall define the structure, functions and modalities of the GCSL Network in order to fulfill the objectives and carry out the functions defined in the Article. Even though the detailed content of the GCSL Network remains to be fleshed out and not the whole text is in green, it is clear that the purpose of Article 13 is to stabilize and make more predictable the global supply chain on the specific range of products needed to respond to a pandemic emergency. That in turn may reduce the risk of disruptions to international trade in health products during PHEICs and pandemic emergencies such as those observed during the COVID-19 pandemic when a number of states refused or delayed exporting products such as ventilators, masks and personal protective equipment.

Also in response to the problems revealed by the COVID-19 pandemic, Article 13 bis requires Parties to ensure transparency in their purchase agreements with manufacturers of pandemic-related health products (paragraph 1), commit to promoting equitable access and to sharing health products with countries in need (paragraphs 2 and 3) as well as to avoid market disruptions through excessive stockpiling (paragraph 6).

WHAT IS NEW?

Reducing the risk of restrictions and disruptions to international trade during a pandemic through a broadly agreed market stabilization mechanism that clarifies available production and commits Parties to transparency and sharing may be seen as the contribution of Articles 13 and 13bis to moving beyond the current legal status quo.

From a legal point of view, international supply chains are based on a number of rules and instruments, i.e. 1) the general default rules on international trade contained in the World Trade Organization (WTO) agreements, in particular The General Agreement on Tariffs and Trade (GATT); 2) The growing number of free-trade agreements that take precedence on the WTO agreements among their parties; 3) special rules within the EU and possibly other economic integration organizations for trade among their members; 4) and most importantly the network of contractual arrangements among companies selling, transporting, insuring and purchasing goods.

International trade law, using the GATT agreement as providing a quasi-universal default benchmark, introduces a number of carve-outs and exceptions to the principles of free and competitive trade that states can use when introducing restrictive measures, especially at times of crisis. Some of them are temporary but others, in particular Article XX (b) and XXI, can lead to the introduction of permanent restrictions.[29]

The GATT provisions referenced in endnote [29] show that WTO members enjoy broad discretion in restricting international trade at times of need or crisis, in ways that may be particularly disruptive during a pandemic. The WTO system of dispute settlement – currently hobbled by the paralysis of the Appellate Body – functions too slowly to enforce limits on export restrictions introduced during emergencies.

This conclusion is strengthened by Article 13bis paragraph 4 that reads as follows: "*The Parties recognize the importance of ensuring that emergency trade measures designed to respond to a pandemic emergency are targeted, proportionate, transparent and temporary, and do not create unnecessary barriers to trade or unnecessary disruptions in supply chains*."

Articles 13 and 13bis complement and mirror the amendments to Article 13 of the IHR adopted by the WHA in 2024. These new provisions task WHO with facilitating equitable access by States Parties to health products, including through assessing needs and the availability, accessibility and affordability of such products and through the use of WHO-coordinated mechanisms such as arguably the GSCL Network. Articles 13 and 13bis in turn place most obligations on the Parties to the PA.

Moreover, Articles 13 and 13bis build on the lessons learnt from the establishment during the COVID-19 pandemic of the Access to COVID-19 Tools Accelerator (ACT-A) - including COVAX as its vaccine pillar - as an emergency multi-stakeholder initiative to rationalize and centralize procurement and equitable access to diagnostics, therapeutics and vaccines.

While those platforms were able to supply "2 billion vaccine doses to countries in need and secured substantial volumes of diagnostics, oxygen, and therapeutics by the end of 2023,"[30] they also revealed substantial limits and were criticized for not being sufficiently inclusive and transparent. The articles under consideration aim at moving beyond those emergency initiatives through the establishment of a permanent mechanism operating under the oversight and responsibility of the Parties, WHO and the COP.

ARTICLE 17 - WHOLE-OF-GOVERNMENT AND WHOLE-OF-SOCIETY APPROACHES

WHAT DOES THE ARTICLE PROVIDE?

Article 17 encourages Parties to "*apply a whole-of-government and whole-of-society approach at national level*" to "*empower and enable community ownership*" for readiness and resilience. Parties are urged to "*establish or strengthen a national multi sectoral coordination mechanism*" for pandemic prevention, preparedness and response and to promote the engagement and participation of Indigenous People, communities, and relevant stakeholders.

Article 17.3(b) also requests Parties to "*take appropriate measures to mitigate the socioeconomic impacts of pandemics*." Each Party is also called to develop a comprehensive and transparent plan(s) covering pre-, post-, and inter-pandemic periods, fostering collaboration with relevant stakeholders and promoting and facilitating education and community engagement initiatives on pandemic and public health emergencies.

WHAT IS NEW?

Article 17 introduces the Whole-of-Government and Whole-of-Society Approach with the aim to expand the focus beyond health systems to include broader social, economic, and governance structures in PPPR. This approach reinforces and addresses some of the key deficiencies identified during the COVID-19 crisis including the lack of capacity or governance mechanism

for pandemic preparedness; the integration of social and economic factors into health resilience; and improving participation of Indigenous Peoples, communities, and relevant stakeholders to strengthen trust and compliance.

The necessity of this approach has been legally recognized in the past. The requirement for National Focal Points (NFPs) under Article 4 of the IHR (2005) was an early effort to facilitate government coordination during health emergencies. However, it lacked the broader governance mechanisms now introduced with the establishment of the National IHR Authority in the IHR amendments adopted in June 2024 but not yet in force. The National IHR Authority will now be responsible for coordinating national IHR implementation, reinforcing the need for a "whole-of-government" approach to health emergency response.

Additionally, other non-legally binding instruments[31] have also underscored the importance of this principle. Outside the field of global health, international treaties have acknowledged the need for cross-governmental collaboration to achieve policy goals. For example, the Paris Agreement emphasizes the importance of engagement from all levels of government and various actors to address climate change.[32]

CONCLUSIONS

The content of the current draft PA builds on the lessons learned from the COVID-19 pandemic by proposing a systemic approach to PPPR. By doing so, it seeks to complement and reinforce existing international legal instruments while filling regulatory gaps. It also builds on the lessons of initiatives taken during the acute phases of the COVID-19 pandemic and introduces standing institutions and mechanisms aimed at fulfilling the same functions but this time based on a broad intergovernmental consensus and with guarantees of transparency and accountability.

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