NUS CENTER FOR INTERNATIONAL LAW
GLOBAL HEALTH LAW NOTES

REVIEW OF AND COMMENTS REGARDING THE NEGOTIATING TEXT OF THE WHO PANDEMIC AGREEMENT ISSUED ON 16 OCTOBER 2023

Dr. Ayelet Berman & Kriti Sharma

23 October 2023

CIL
CENTRE FOR INTERNATIONAL LAW
National University of Singapore

Review of and Comments regarding the Negotiating Text of the WHO Pandemic Agreement Issued on 16 October 2023

Ayelet Berman and Kriti Sharma

23 October 2023

1. Introduction

On 16 October 2023, the World Health Organization (WHO) International Negotiating Body (INB) presented to WHO member states the most recent "Negotiating Text of the WHO Pandemic Agreement". Unlike the previous zero draft, which had multiple possibilities for each provision, this is a negotiating draft that consolidates the various options into one agreed-upon provision per topic. Furthermore, unlike earlier drafts, this draft overall uses clear and explicit obligatory language, with most (though not all) provisions beginning with "The Parties shall..."

The WHO pandemic agreement has a broad scope. It is made up of 36 Articles, 17 of which (Articles 4-20) contain state obligations on a variety of themes. The agreement aims to fill the various gaps that have been identified following the Covid-19 pandemic. First, it aims to **close national gaps in public health capacities**. Second, it aims to **improve research and development, manufacturing, and access to pandemic-related products** in developing countries. Third, recognizing that the IHR had not been implemented although being legally binding, the agreement **includes provisions focusing on implementation support and collaboration or solidarity.**

Several provisions are likely to be particularly difficult to reach agreement on due to their political and economic sensitivity, prompting concerns from the pharmaceutical sector (and the high-income countries where they are housed). Notably, to expedite vaccine access during a pandemic, the current draft includes a provision in which states agree to waive IP rights during a pandemic and to waive royalty payments. It also includes provisions requiring price transparency and establishing an access and benefit sharing (ABS) system.

The agreement is ambitious, and developing countries will have to invest a significant amount of money, time, and human resources to meet their responsibilities and establish or develop new capacities in a wide range of areas such as laboratory capacities, genomics, health workers and national laws and regulations. As a result, implementation support is critical. The agreement anticipates this through the establishment of financial, institutional, technical, and other implementation support mechanisms, though the details are left to be decided after the adoption of this agreement. This emphasis on implementation assistance is critical if the pandemic agreement is to effect genuine change in global pandemic preparedness and response. Most countries will be driven to improve their public health systems and production capacities but will have difficulty doing so without external support. Regardless, implementation will take years in countries that had little pandemic preparedness capacities prior to the pandemic.

This note provides an overview of the main provisions aimed at developing or strengthening national public health capacity (Section 2), provisions aimed at developing R&D and production capacity, as well as access to pandemic-related goods in developing countries (Section 3). Section 4 identifies some of the political hot topics. Following that, it lays out the

main monitoring and implementation mechanisms (Section 5), as well as those intended at supporting developing countries with implementation (Section 6). Section 7 concludes.

2. Strengthening National Public Health Capacities

As stated, a key component of the agreement is the development of national public health capacities. This table summarizes some of the most important provisions in this regard. For the full text of the detailed provisions please see the text.

Article 4 Pandemic Prevention and Public Health Surveillance	The purpose of this provision is to strengthen public health surveillance and pandemic prevention capacities. Parties undertake to develop their National Prevention and Surveillance Plans and align them, inter alia, with International Health Regulations. This includes improving key capacities in pathogen risk-assessment, sanitation and infection control measures, managing healthcare waste, preventing zoonotic spill-over, enhancing lab safety and biosecurity, and addressing antimicrobial resistance through a One Health approach.
Article 5 One Health	The purpose of this provision is to implement a One Health approach in all jurisdictions. The Parties commit to promote collaboration and cooperation at the interface of the human, animals and environmental systems. They commit to implement science-based actions, and whole of government and whole of society approaches to control zoonotic outbreaks and promote One Health training and education. They commit towards developing international rules on preventing zoonoses.
Article 6 Preparedness, readiness and resilience	The Parties commit to strengthening national health systems, founded on principles of equity, resilience and universal health coverage. States commit to adopting and reinforcing policies (including in line with the International Health Regulations) for public health functions, including but not limited to continued provision of health services during a pandemic, collaborative surveillance and timely outbreak notification, building digital and data-sciences capacity, and developing rehabilitation and post-pandemic recovery systems. They agree to conduct surveillance and share emerging pathogens with pandemic potential according to the proposed WHO Pathogen Access and Benefit Sharing (WHO-PABS) mechanism in Article 12.
Article 7 Health and care workforce	The parties undertake to build and sustain a skilled, trained, competent and committed health workforce that is integral to providing health services and performing public health functions during a pandemic. To this end, Parties commit to workforce empowerment such as strengthening education and training, address inequalities and security concerns within the healthcare workforce, investing in developing a multidisciplinary global public health

	emergency workforce, and building a network of training institutions to bolster capacity-building and skill development at subnational, national and regional levels.
Article 14 Regulatory Strengthening	The purpose of this provision is to strengthen /put in place national and regional regulations and laws, as well as strengthening regulatory authorities. The aim is to expedite approvals of pandemic-related products.
Article 15 Compensation and Liability Management	Parties commit to develop national strategies for managing risks and liability regarding new vaccines.

3. Developing and Strengthening R&D, Manufacture and Access to Pandemic-related Goods in Developing countries

During the Covid-19 pandemic, it became obvious that there is a significant disparity in access to pandemic-related products between high-income and low-income countries. As a result, one of the key conclusions has been that developing countries must strengthen research and development (R&D) and manufacturing capacities, as well as boost access to essential supplies. The agreement establishes obligations with the intention of achieving these aims, some of which is accomplished by state commitments to encourage non-governmental groups (pharmaceutical developers, manufacturers in industrialized countries) to collaborate. Below are summaries of some of the main provisions. For the detailed provisions, please see the text.

Article 9 Research and Development	The purpose of this provision is to advance R&D in developing countries, and the parties commit to cooperate to this end. They commit to promote R&D cooperation and access to research through open science approaches for rapid sharing of information and results. This includes sustained investment in R&D, technology co-creation and joint ventures that engage participation of scientists from developing countries and knowledge translation. Parties commit to cultivate research capabilities by increasing clinical trial capacities and strengthening international cooperation on clinical trials. States commit to publishing the terms of government funded R&D agreements, including regarding pricing, licensing and terms for affordable, equitable and timely access to said products.
Article 10 Sustainable Production	This purpose of this provision is to decrease disparity in global production and access to pandemic-related products between developed and developing countries. States commit to identifying and maintaining national and regional production facilities and entering contracts with manufacturers during a pandemic if domestic capacity to supply pandemic related products is deficient. States are also obligated to encourage publicly funded manufacturers of pandemic related products to waive royalties in granting licenses to other manufacturers, promote voluntary licensing and transfer of technology and know-how.

Article 11 Transfer of Technology and Know-How	The purpose of this provision is to promote the transfer of technology and know-how of pandemic related products to manufacturers in developing countries. The parties undertake to incentivize manufacturers to transfer technology and know-how through technology transfer hubs, provide voluntary licenses and use TRIPs flexibilities and more.
Article 13 Global Supply Chain and Logistics	Parties establish the WHO Global Supply Chain and Logistics Network (WHO SCL Network) whose purpose is to ensure supply of pandemic products to developing countries. The network prioritizes needs of developing countries and its functions include assessing demand and mapping suppliers for raw materials for sustainable production of pandemic related products, and estimating cost of stockpiling pandemic related products.

4. Contentious Topics: IP, Pricing and Access and Benefit Sharing

While the provisions listed above will necessitate significant investments, there are certain provisions that are particularly contentious, owing to their political economy nature, as they would essentially require pharmaceutical companies to forego some of their revenues in the interest of equitable access to life-saving medicines/vaccines during pandemics. Provisions requiring states to waive IP during pandemics and to waive royalty payments, or provisions requiring pharmaceutical companies to publish the pricing terms of their agreements are contentious as they conflict with profit-driven interests of the pharmaceutical industry. Likewise, the ABS mechanism is going to be contentious as it underscores the long-standing issue of pharma companies accessing pathogens from developing countries, to develop vaccines/medical countermeasures and in exchange, share stipulated benefits arising from their development.

This will be highly contested by the industry and by the high-income countries representing their interests, and it remains to be seen whether these provisions will be retained, or perhaps watered down. Indeed, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has already criticized the negotiating text saying it would have "a chilling effect on the innovation pipeline for medical countermeasures".

The table highlights three problem areas.

Article 11 on Transfer of Technology and Know-How	Parties commit during pandemics to agree on time bound waivers of intellectual property rights, and to encourage patent holders to waive royalties' payments, and to require those that receive public financing to waive royalty payments (Article 11(3)).
Pricing Transparency	Parties must publish the terms of government-funded R&D agreements for pandemic-related products, including the pricing of end-products (Article 9(4)).
Article 12 Access and Benefit-Sharing	States establish the multilateral WHO Pathogen Access and Benefit Sharing System (WHO PABS System) to govern sharing of WHO PABS Materials (defined as pathogens with pandemic potential and their genetic sequences). The purpose of the WHO PABS System is to create a multilateral system

	enabling rapid sharing of PABS Material in exchange for the receipt of benefits arising from the use of such materials, such as access to medicines developed from these materials. The PABS System is expected to be operational by May 31, 2025. The PABS System shall be complementary to the PIP Framework and consistent with the Nagoya Protocol (NP), recognized as a specialized international ABS instrument within Article 4(4) of the NP.

5. Monitoring and Implementation Mechanisms

One of the major gaps identified after the Covid-19 pandemic was that states had not carried out their commitments under the IHR, despite its legally-binding nature. As a result, the pandemic agreement gives more attention to monitoring mechanisms and implementation support, and the table below highlights the main ones identified in the current draft. There is some potential overlap, and many mechanisms are not detailed/operationalized. Further fine-tuning is, thus, to be expected.

Be that as it may, it is crucial to point out that the current draft only includes soft, or “carrot" mechanisms (in the form of reviews, self-reporting, institutional monitoring), and there are no legal "sticks" or sanctions for noncompliance (as is found in other international instruments). The main consequence for noncompliance would appear to be of a reputational nature, or it may raise concerns about the lack of reciprocity among states. States appear to have little appetite for inclusion of stricter sanctioning mechanisms (such as a complaints mechanism or independent inspections). That said, it remains to be seen how certain mechanisms, such as the Global Peer Review Mechanism, will be operationalized.

The table summarizes the main monitoring and implementation mechanisms identified.

Article 8 Preparedness Monitoring and Functional Reviews	**5-year self-assessment** (Article 8(1)): Each party shall assess no less than every five years and with WHO Secretariat support its functioning, readiness and gaps.
	Monitoring and Evaluation System (Article 8(3)): The parties commit to developing a pandemic prevention, preparedness and response monitoring and evaluation tool.
	Global Peer Review Mechanism (Article 8(4)) The parties undertake to establish by December 31, 2026 a Global Peer Review Mechanism to assess capacities, gaps and levels of readiness. It will support learning, best practices, actions and accountability at the national, regional and global levels to strengthen national preparedness and capacities.
Article 21: Conference of the Parties (COP)	COP is comprised by delegates representing the parties of the agreement and has a key role in overseeing and orchestrating the implementation of the accord (Article 21). It oversees and manages the funding mechanism (Article 20(2)(d)) and facilitates the mobilization of the financial resources necessary for implementation support (Article 21(7)(c) (see below). It may take decisions necessary for effective implementation (e.g., adopt amendments, annexes

	and protocols to the accord) (Article 21(7)), including considering the annual implementation reports submitted by the parties (Article 23), request cooperation of other regional and international organizations, NGOS and others in strengthening implementation and more. It will review every three years the implementation of the accord (Article 23(9)).
Article 23: Periodic Reporting by States	Each party is required to submit periodic reports to the Conference of the Parties on implementation. The reports will include information on legislative, executive and administrative measures, good practices or other measures taken to implement the accord, information on difficulties encountered in implementation, and information on support received.
Article 24 A WHO Pandemic Agreement Secretariat	This WHO Pandemic Agreement Secretariat will provide administrative support to the COP for supporting the implementation of the agreement. It is also tasked with providing support to developing countries in implementing the agreement.

6. Supporting Implementation by Developing Countries

States will most likely take years to implement these obligations. Existing systems, infrastructures, laboratories, strategies, regulations, and policies will need to be updated, altered, or expanded, and new fields will need to be developed. The disparities will be greatest in developing countries. This gap in developing countries capacity is acknowledged throughout the agreement.

The agreement makes no mention of a deadline for implementation. Furthermore, the agreement recognizes capability constraints in developing countries throughout the agreement. Some obligations begin by requiring the party to perform their obligations "in line with its respective capacities" or "in accordance with its capabilities" (for example, Articles 4(4),7(1),17(5)).

Furthermore, the agreement emphasizes the need that parties give technical and financial implementation support to developing countries. Many provisions include a sub-provision that states that “the parties shall cooperate…to provide financial, technical and technological support, assistance, capacity-strengthening and cooperation, in particular with respect to developing countries…” (for example, Articles 6(3) and 7(2)). It also states that “the parties should give particular consideration to the specific needs and special circumstances of developing country Parties for financial and technical assistance to support the implementation of this agreement.” (Article 19(3)).

How should such implementation support be provided? The note identifies the main implementation support methods envisioned in the agreement: Financial, institutional, and technological assistance, as well as partnerships and international bodies, are among them. The details of these mechanisms are, however, not fleshed out yet.

The table summarizes the main provisions containing implementation support to developing countries.

Article 20 Financing Mechanisms	The Conference of the Parties will establish a "sustainable funding mechanism" by 31 December 2026, which will include a capacity development fund and an endowment. The funding mechanisms' purpose is to provide resources to assist developing countries (Article 20). Further funding shall be sought by other regional and international organizations and financial and development institutions (Article 20(3)).
Article 23 Support by COP	Developing countries in need of support in carrying out their periodic reporting duties can receive support from the COP (Article 23(3)).
Article 24 Support by the WHO Pandemic Agreement Secretariat	The Secretariat provides implementation support to developing countries and economies in transition (Article 24(2)(c)) .
Article 19(1) and Article 16(2)(e) Cooperation between Parties or through International Bodies	Parties undertake to assist developing countries through multilateral and bilateral partnerships to develop and support capacity, including with respect to the transfer of technical, scientific, legal expertise and technology.
Article 19(4) Partnerships	Article 19(4) determines that "The Parties, where a Party lacks the necessary capacity to implement specific provisions of this Agreement, work together to identify the most relevant partners that can support the development of such capacities…"
Article 14(1) Technical Assistance	The agreement mentions in diverse provisions that the parties will receive "technical assistance". For example, Article 14(1).

7. Conclusion

The WHO Pandemic Agreement is ambitious in its scope. It seeks to close the many gaps in public health systems and in developing countries, identified during and after the Covid-19 pandemic. The current draft also includes some provisions on IP and ABS that are contentious and it remains to be seen what the final agreement will look like.

Implementing the agreement will be challenging, and the draft appears to recognize this by setting out a host of monitoring and implementation mechanisms. Most are of a soft nature, providing support or at most requiring peer review which can give rise to reputational concerns. The details of most mechanisms are also not fleshed out yet. Legal sanctions are not included, at least in this draft. However, it appears that most member states do not have an appetite for accepting stringent accountability mechanisms that provide legal oversight or inspection powers to a third party.

The draft also recognizes the needs of developing countries and envisions financial, institutional and technical implementation support. This approach is excellent as it is hard to see how the agreement will be able to make any effective change in global preparedness and response without massive support to developing countries in building and enhancing national and regional public health capacities. That said, it remains to be seen what the final agreement will include, and how effectively such support will be operationalized.