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A Potential 'Once-in-a-Lifetime' Treaty: The Pandemic Prevention, Preparedness and Response Accord Heats Up in Geneva

Key Points

- The anticipated zero draft of the WHO's Pandemic Prevention, Preparedness and Response Accord was released on February 1. This process will intertwine heavily with the renegotiations of the 2005 IHRs.
- Following procedural discussions, positioning and conceptual texts, this zero draft opens a path to a major multilateral negotiation, key friction points of that are shaping to be the concepts of equity and responsibility, the relationship between pathogen sharing and access to benefits, and the role of IP in times of crises.
- While the zero draft contains various, and often mutually exclusive, concepts, this is the basis of negotiations that start now with a view of finalizing an international instrument by May 2024—an ambitious timeline in the context of parallel multilateral negotiations and domestic political cycles in key players.
- These developments could have significant implications for a range of stakeholders involved in pandemic response, including medical product manufacturers. Such stakeholders should be closely watching for developments and opportunities to shape the policy and process given what is at stake for industry and public health.

Background: The Pandemic (Preparedness)

While the Biden-Harris administration recently issued a Statement of Administration Policy announcing its plans to let the COVID-19 public health emergency expire on May 11, 2023, the World Health Organization (WHO) recently affirmed COVID-19 as an ongoing Public Health Emergency of International Concern (PHEIC). Citing the ongoing outbreak in China, WHO officials remained concerned, but at the same time acknowledged a "transition point" of sorts, and indicated that an end to the PHEIC was likely later this year. These announcements come as delegations in Geneva and around the globe are gearing up for what are described by some as "once-in-a-lifetime" negotiations to prevent, be prepared for and respond to any future pandemic through the development of a "pandemic treaty," more formally known as the Pandemic Prevention, Preparedness and Response Accord.

Since its initial discovery in China in late 2019, SARS-CoV-2 has spread throughout the world causing significant short- and long-term impacts on both public health and

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the global economy. The pandemic has directly impacted health care delivery, a range of medical product development and supply chains around the world. In the midst of this complex dynamic, in March 2021, 25 heads of government and international organizations called for an international pandemic treaty. In December 2021, the World Health Assembly, WHO's highest governing body, launched negotiations toward an instrument to cover the whole cycle: prevention, preparedness, response and recovery of health systems. It sets an ambitious timeline: procedures and concepts by end of 2022, negotiations in 2023 and a draft agreement by May 2024.

The speed with which the global policy-making community launched into action on this effort is **unprecedented for this international forum**. Usually, multilateral treaty negotiations take years to launch and many more years to finalize. For example, the World Trade Organization's negotiations for the Trade Facilitation Agreement took eight years to launch (1996-2004) and another nine years to finalize in 2013. The World Intellectual Property Organization (WIPO) negotiations on genetic resources are only eyeing conclusion in 2024, 14 years since their launch.

Ready, Set, Go! The Zero Draft and Why it Matters

Now, in early 2023, the WHO is so far meeting the demands of this expedited timeline. The Intergovernmental Negotiating Body (INB), a body established and entrusted by the World Health Assembly to carry out these negotiations, met in December to set the stage and procedures. The INB Bureau, composed of two co-chairs and four vice-chairs, compiled concepts, positions and narratives and, on February 1, released these products in a zero draft worded as legal provisions. The INB meets for its fourth session (February 27-March 3) and its fifth session (April 3-6) to have a first reading of the zero draft, and to hold drafting group meetings on individual chapters. The INB Bureau may then prepare a first draft to be discussed at the INB's sixth session (June 12-16). These negotiations are set up as member-states-driven. While the INB meetings are webcast, only member states and recognized observers can actively participate. It is therefore of utmost importance for interested stakeholders to supply their views, evidence and proposals through those that have a formal say in the process.

The zero draft contains 38 articles in eight chapters. These span from definitions and scope to institutional arrangements. Within this spectrum, substantive provisions and concepts appear that will present challenges in the negotiations:

1. **Equity** is a unifying concept throughout the discussions. For some delegations, this means an obligation to provide everything (i.e., products and services to prevent, prepare for and respond to a pandemic) around the globe in an equitable fashion. Others understand the concept to mean an equity of opportunities with the responsibility for management placed on each state. This is going to be a difficult moment for the negotiations as a general sense of unfair behavior and unequal opportunities is held by many.
2. The concept of "common but differentiated **responsibility**" represents another dividing line. This was a concept first introduced in climate change talks. Many want to expand this principle to health. Others are against this expansion and prefer a shared responsibility paradigm.
3. **Intellectual property** (IP) is an area highlighted throughout the zero draft. While for some, IP seems to be the key piece of these negotiations, for others, IP and its

Trade-Related Aspects of Intellectual Property Rights (TRIPS), as well as transfer of technology and knowhow/knowledge, should be left to other forums. For example, one provision requires states to take appropriate measures to support time-bound IP waivers. Another provision obliges governments to use all TRIPS flexibilities. On the other hand, the text proposes provisions to recognize the importance of intellectual property for research and development of new medical products. Language addressing intellectual property as a barrier will be pushed by countries that succeeded only partially, so far, in their demands for a World Trade Organization (WTO) TRIPS waiver.

4. Rapid, efficient and adequate **pathogen sharing** is considered a key part of these negotiations by many delegations and experts. To this end, the text proposes setting up an effectuating mechanism—the WHO Pathogen Access and Benefit-Sharing (PBAS). The draft provides contours for how the PBAS should work, including a principle that pathogen sharing should occur in a matter of hours from discovery, but leaves states to work on the specifics after the conclusion of this treaty.
5. **Access** to pandemic-related products is placed as a condition by many in exchange for agreement to pathogen sharing. The text proposes provisions to oblige **sharing of pandemic-related products**. For example, the text as it stands would oblige 20 percent of the total production to be donated and sold at cost to a WHO mechanism that will distribute the products among developing countries. It also commits countries to facilitate shipments. Although access is also an important condition for many countries, it has been a sore spot during this pandemic, caused by, among other things, hoarding of vaccines. Quickly set up mechanisms, such as COVAX, also suffered from inadequate supplies at first, and inadequate demand thereafter.
6. **Transparency**, including with regard to private sector manufactures that receive public funding, also holds special significance in the zero draft. For example, the proposed text obliges governments and encourages manufacturers to disclose prices and contractual terms of public procurement of pandemic products.

Potential opportunities arise with addressing gaps in regulatory approvals and processes, or early warning and early response mechanisms, based on early and reliable pathogen sharing. The proposed provisions also hint at strengthening the fight against substandard and falsified products, as well as hint at countering trade restrictions. To have any teeth, all these provisions would need serious strengthening.

What Happens Now?

Delegations have named their chief negotiators. Ambassador Pamela K. Hamamoto, the chief U.S. negotiator named last October by Secretary Blinken and Secretary Becerra, has publicly spoken to all aspects and concepts of the zero draft. In short, the U.S. wants an instrument agreed to by consensus, focused on equity, that sticks to the WHO mandate, and that is interlinked with the renegotiation of the International Health Regulations (IHR) of 2005.

Notably, the IHR provide an overarching legal framework of legally binding universal rights and obligations. The U.S. and other countries pushed for an update to the IHR in early 2022 to enable quicker and more effective reaction to health events of international concern. What was to be an update is now turning into a full renegotiation. A number of countries submitted proposals and proposed amendments

to the IHR. These aim at, to name just a few examples, the following: creating automatic triggers for a declared health emergency of international concern; making WHO a central coordinating entity with rights; and binding member states to change their IP laws to provide for exceptions and limitations on health products. These negotiations are being carried out by the Working Group on Amendments to the IHR (WGIHR), composed of member states, and advised by the Review Committee, composed of experts. The latter submitted its report in early February. The IHR negotiations will run in parallel and will mutually impact the overall process and result of the Accord.

The zero draft has significant room for editing by member states. The approach by delegations and subsequent agreement and ratification will depend heavily on the domestic politics of multiple key players as well as other processes running in Geneva and culminating in early 2024, such as the U.S. 2024 elections, a presently divided U.S. Congress, complaints of diminishing sovereignty, U.S.-China relations, China's approach to these negotiations, Indian and South African general elections in first half of 2024, and the WTO's 13th Ministerial Conference scheduled for February 2024. These complexities form the backdrop for these negotiations and will color everything that happens in the coming months.

The legal nature of this instrument is yet to be decided (hence the cryptic "CA+"). Nonetheless, many will push for a legally binding treaty. This would mean that signatory countries would be required to reflect the final provisions in their national laws and regulations. Furthermore, the WHO would play a key role on coordinating, distributing and advising on regulation, especially in developing countries. As such, the WHO's recommendations or pre-qualifications would be even stronger guideline for many countries around the globe in pandemic and intra-pandemic times. Once in force, the impact on existing and potential innovators and manufacturers of pandemic-related products, such as vaccines, diagnostics, therapeutics, personal protective equipment (PPE), medical devices, etc., will be significant throughout the product cycle. For such stakeholders, it is important to inform the process, so that the final result is realistic, effective and compatible with business models.

Navigating this maze with so many important, strongly held and competing interests will not be easy. The finish line is set for a little over a year from now and the negotiations have started. Those that have an interest in the final result are already involved or must do so very soon.

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