Spark Street Advisors
Data Driven Strategies

# Draft Pandemic Agreement - Questions for Negotiators
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This document outlines some governance and accountability-related issues to be resolved in the upcoming negotiations of the Pandemic Agreement. While we do not comment on every article, we note for most, where commitments exist, the language could be strengthened.

## What's good to see in the document:

- Recognizes as a principle of Common but Differentiated Responsibilities
- Puts in place the Conference of the Parties (COP) and allows them to consider information from non-state actors in reviewing implementation
- Recognizes the centrality of primary health care to preparedness, resilience, and recovery
- Includes strong links to the International Health Regulations (IHR)
- Allows for regional economic blocs (e.g., African Union, European Union) to join as a Party subjecting their members to obligations (and they can't double vote)
- Includes provisions on including access conditionalities in publicly funded research and development (R&D) agreements

## What's puzzling?

**"According to national legislation"**
Reference "national laws," "national capacities," and "national circumstances" appear multiple times throughout the text (14, 5, and 7 times, respectively). There is little consistency in how this terminology is used.

- Is there an expectation that national legislation would be amended to align with the treaty or that if existing national legislation is not aligned, the Party would not need to comply with a specific provision? Would these caveats exempt Parties from implementing commitments in the Accord to all equally, in accordance with human rights standards?

## What's not clear:

**Article 1. Use of terms**
The definition of pandemic has been removed from the list of definitions.

- When would certain actions related to Member States' response be required to kick in (e.g., only after a declaration of a Public Health Emergency of International Concern)?

**Article 5. One Health Approach to Pandemic Preparedness and Response (PPR)**
Much of the language in the March draft has been changed to “promote” vs. “implement” (e.g., “promote a One Health approach").

- What does “promote” mean from a technical point of view? How is that quantified or measured?

**Article 8. Preparedness Monitoring and Functional Reviews**
There is a reference to an “inclusive, transparent, effective and efficient monitoring and evaluation system,” and a five-year preparedness review focused on functioning, readiness, and gaps. These would be conducted by Member States with technical support from the WHO according to tools and guidelines to be developed by the WHO.

- What exactly would be included? Who would participate (e.g., also non-state actors)? How would the information provided by Member States be verified?

**Article 9. Research and Development**
This article commits countries to promote a series of actions (equitable access to research knowledge, capacity building, etc.) and to develop national policies including provisions that promote timely and equitable global access during PHEICs and pandemics for government-funded R&D. The scope is also expanded from previous versions (e.g., R&D value chain vs. only focusing on clinical trials). While the intent is good, the commitment is weak (e.g., to “promote”)

- What is the definition of “promote”? How would countries be held accountable for even these illustrative activities listed?
- Conditionalities on public R&D funding of “pandemic-related products” should promote “timely and equitable global access… during public health emergencies.” Given the provisions would need to be actioned before the declaration of the emergency, how does anyone know in advance what products would be in scope? And if the provisions trigger only “during” a pandemic, how does that promote preparedness?

**Article 10. Sustainable and geographically diversified production**
The language is similar to previous versions and is overall quite positive. As with the previous draft, the focus is primarily on manufacturing, with tech transfer addressed in Article 11.

- How will countries be held accountable for this commitment? How can actions be tracked with no monitoring system included in the agreement?

**Article 11. Transfer of Technology and Know-how**
The language in this article is soft and hedging, using words like “promoting” and “incentivising" with no actual commitment (e.g., manufacturers are “encouraged” to forgo or charge “reasonable royalties” for the use of technology and know-how; “consider supporting” time-bound waivers of intellectual property rights, etc.)

- How would compliance with this provision be assessed (e.g., how to measure “promote” or “consider”)? What are “reasonable” royalties? What about “trade secrets” - are they also included?
- Time-bound waivers only kick in “during pandemics.” What does that mean in practice for R&D and keeping manufacturing “warm” as part of preparedness? What is the trigger for the waiver?
- Why would manufacturers, who are not parties to the agreement, agree to the provisions if they are not a conditionality of public funding? (see Article 9)

**Article 12. Access and Benefit Sharing**

As with article 10, this language is quite similar to the previous draft (released ahead of INB8). We outline some governance-related issues below.

***Access to products***. The document states that manufacturers who created countermeasures using the Pathogen Access and Benefit-Sharing (PABS) system must contribute 10% free of charge and 10% at non-profit prices in “real time.” Each Party is also asked to set aside a portion of its total procurement of pandemic products.

- As the majority of the world’s population lives in low- and middle-income countries, how will 20% of available supply address the issue of equitable access? How will it be apportioned?
- Does the total 20% apportionment apply for the duration of the health emergency, or as a one-time contribution (i.e., if supply increases over time, as more countermeasures are produced to meet demand, will this apply as a percent of each point of distribution)?
- How much product will Parties themselves set aside?
- How would the system be paid for? If manufacturing contributions do not cover the full amount required, where would funding come from?
- If a manufacturer, not part of PABS, has pathogen material of pandemic potential, what is the incentive for it to participate?

***Nagoya Protocol*.** The Agreement specifies that the PABS system should be consistent with the Nagoya Protocol. Not all countries have signed the Nagoya Protocol. Among them, the United States, where some major manufacturers of pandemic products are located.

- While the section later states that Parties who are not party to the convention shall take measures to ensure alignment with the objectives of the convention. How will this be enforced or monitored?

**Article 21. Conference of the Parties**

The COP is established to promote the effective implementation of the agreement and would conduct reviews every 3 years. There is also a provision for considering information from non-state actors. There is a provision for the COP to establish subsidiary bodies although any references to specific committees including on Compliance have been removed and there is no reference to independent monitoring (e.g., the word “independence” is only used in the context of humanitarian organizations.

- What would be the frequency of COP meetings? What would the review include (e.g., global state of the world or monitoring of Parties' compliance)?
- Would information from non-state actors (e.g., shadow reporting) be collected systematically or ad hoc?

**Article 23. Reports to the Conference of the Parties**

States are obliged to submit periodic reports to the COP through the Secretariat. Specifying the governing body as a COP rather than a committee of the World Health Assembly (WHA) is a sign of political elevation. However, there is a lack of clarity on the timing of meetings, reporting, and how information from non-state actors would be systematically included in reports. Also, there is no specific consideration of any type of monitoring mechanism and there is a "carve out" that reporting and information exchange are "subject to national laws regarding confidentiality and privacy."

- What would be the frequency, content, or format of reporting?
- How would information from non-state actors be considered?
- How will Party compliance be monitored?
- What if critical information for PPR is considered confidential or private?

## For further reading on specifics, check out these resources:

PABS; Article 19 vs 21; Independent monitoring; Compliance.