CEPI

Written statement from the Coalition for Epidemic Preparedness Innovations (CEPI) on the proposal for negotiating text of the Pandemic Agreement (A/INB/7/3)

Strengthening global capacity to develop safe and effective vaccines within 100 days of recognition of a pandemic pathogen, together with enabling equitable access to vaccines and other biologic countermeasures, are critical for achieving our common objective to protect present and future generations from pandemics.

Based on CEPI's technical expertise and proven track record as a global leader and partner for research and development (R&D) and manufacturing for vaccines with epidemic and pandemic potential, we offer three suggestions as the INB considers the proposed negotiating text.

First, ensure R&D funding agreements include contractual obligations to enable equitable access.

- We welcome added emphasis on geographically diverse R&D capacities, sustained investment in R&D, and measures that support a rapid R&D response in line with the 100 Days Mission in Article 9.
- However, we urge the INB to consider reintroducing the provision to "establish conditions for publicly funded research and development" in Article 9, such as conditions for rapid data/sample sharing, tech transfers, volume allocations, pricing.
- Article 10 and 11 include provisions to encourage the recipients of public funding to enter into licensing and technology transfer agreements. To ensure that governments are able to enforce these requirements under appropriate conditions, such as pandemics, they must be transformed into obligations and commitments in R&D funding arrangements from the earliest stage.
- Those agreements could set minimum standards for the terms on which licensing and technology transfer must take place to ensure that they have the intended impact on access to the end product, such as royalties or other fees that may be charged to a licensee, expected territory for the license, or considerations beyond an initial technology transfer.

Second, support a global systemic approach that prioritises geographically distributed manufacturing and its long-term sustainability between pandemics to enable equitable access to medical countermeasures, if and when the need arises.

- We welcome Article 10 which aims to achieve more geographically and equitably distributed global production of pandemic-related products, including to support manufacturing facilities with a regional scope in developing countries.
- Article 10 is currently titled 'Sustainable Production', but licensing and technology transfer are more likely to support distributed manufacturing. "Sustainability" of manufacturers will depend on non-pandemic and pandemic product business models and national, regional, and international procurement decisions.
- The Parties should also acknowledge the costs associated with building successful distributed manufacturing partnerships. The developer's costs for performing technology transfer need to be included in the scope of the publicly funded project. Alternatively, the developer could be permitted to charge reasonable costs, potentially in the form of royalties or other technology transfer fees.

Third, support commitments to a multilateral system for access and benefits sharing for pathogens with pandemic potential (including biological samples and their genetic sequences) that will operate in a manner to **strengthen and expedite research and innovation at all times**, both during and between pandemics.

- The reason for the split between required obligations in Article 12.4(b)(ii) and those for consideration in Article 12.4(c) is not clear. Arguably, some of the additional options for consideration, such as a requirement to engage in technology transfer activities under appropriate conditions, could be more effective in supporting the objective of the Pandemic Agreement.

A key lesson from the pandemic is that equitable access needs to be considered at the earliest stage of research. **Without a clear commitment to ensuring the results of publicly-financed R&D are accessible to all, there is unlikely to be consistent equitable access to countermeasures in an end-to-end system.** While each Party should be permitted flexibility in negotiating detailed terms given the context of specific R&D agreements, equitable access conditions must be applied where R&D is supported by taxpayer funding.