GHTC global health technologies coalition

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Global Health Technologies Coalition Recommendations for US Department of Health and Human Services on the Implications of Access and Benefit Sharing (ABS) Commitments/Regimes and Other Proposed Commitments Being Considered Under a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response

The Global Health Technologies Coalition (GHTC) is a coalition of more than 45 nonprofit organizations, academic institutions, and aligned businesses advancing policies to accelerate the creation of new drugs, vaccines, diagnostics, and other tools that bring healthy lives within reach for all people.

We appreciate the US government, via the Departments of Health and Human Services and State, for providing this consultative opportunity to comment on the ongoing Intergovernmental Negotiating Body (INB) process, the Access and Benefit Sharing (ABS) commitments/regimes, and other research and development (R&D) provisions being considered.

Many provisions in the draft agreement are positive, recognizing and affirming key points related to human rights and inclusive provisions that prioritize vulnerable and marginalized populations. The draft recognizes vaccine inequity as a vital concern and affirms key principles of equity and non-discrimination and the need to ensure adequate support for both health workers and the World Health Organization (WHO).

However, we believe there are several areas in which the text could be strengthened, particularly when it comes to language around gender equity, a stronger focus of dual-use research and harmonizing pandemic preparedness investments with ongoing efforts to fight malaria, tuberculosis (TB), HIV/AIDS, neglected tropical diseases, and antimicrobial resistance (AMR). There are also ways the draft could be improved to include provisions that address the regulatory ecosystem and the distinct role of WHO.

Please find our recommendations below.

General Comments

- **Elevate gender equity more broadly throughout the text.**
  The agreement must meaningfully prioritize gender equity. The draft text promotes gender inclusion in areas such as workforce and clinical trials, but it misses other strategic opportunities to advance gender responsive policy essential to equitable pandemic prevention, preparedness and response (PPR). The draft should include specific language affirming the parties' commitments to collect, report, and analyze data disaggregated by gender, ethnicity, race, and age, and uphold social protections and the full spectrum of essential health services for all during health emergencies.

- **Broaden to all stages of R&D.**
  The text focuses very heavily on later stages of R&D rather than all stages needed for preparation and response. Despite member state proposals to widen the focus to include early-

stage collaboration, there are no provisions relating to early-stage R&D activities, including discovery research, where investments and collaboration are needed. Specific provisions should be added to Article 9 (Research and Development).

Article 9: Research and Development

- **Leveraging investments for PPR for health systems strengthening.**
  While the agreement includes language that highlights the interconnectedness of health system strengthening and PPR, it lacks provisions that underscore the need to focus on sustainability and "dual-use" R&D capacity and infrastructure that can be leveraged for both pandemic response and longstanding challenges. Article 9 (Research and Development) should therefore add language that explicitly highlights that building clinical trial and laboratory capacity and networks to address ongoing epidemics like HIV/AIDS, TB, malaria, and polio; re-occurring outbreaks of Ebola, Marburg, and cholera; and AMR contributes to both pandemic preparedness and overall health system strengthening.

- **Greater coordination between regulatory authorities and ethics committees for clinical trials.**
  The role of regulatory authorities extends beyond regulatory approvals for market-ready health tools. Conduct of clinical trials requires approvals from regulatory authorities and ethics committees as well. Regulatory authorities and ethics committees, working in a coordinated way to grant approvals, especially during a public health emergency, will speed up the conduct of clinical trials. Article 9 should add a provision under its clinical trials section that promotes greater coordination between ethics committees and regulators. We urge the United States to push for new language encouraging and incentivizing joint reviews of regulatory dossiers, which will maximize opportunities for cooperation between countries and can help optimize review timelines by allowing regulatory authorities to share data, validate findings, and streamline communications with the applicant, thereby expediting market access to the health tools developed.

- **The role of WHO.**
  The pandemic agreement should ensure that WHO is sufficiently empowered to play a strong normative role in helping define a priority research agenda and in coordinating research, building on the R&D Blueprint, to speed innovation and avoid unnecessary duplication and fragmentation of data.

Article 10: Sustainable Production

- **Going beyond rapid manufacturing scale-up.**
  Pandemic prevention and response is too often marked by cycles of panic and neglect. While Article 10 (Sustainable Production) outlines provisions that seek to strengthen manufacturing capacity, as well as more diverse and regionally distributed production capabilities to respond during an emergency, the draft currently does not cover incentivizing continuous research to develop vaccines, diagnostics, therapeutics, and other health technologies for epidemic-prone diseases that disproportionately impact low- and middle-income countries. A greater focus needs to be placed at looking beyond just rapid scale-up of production capacity during an emergency, to instead supporting sustained research into disease threats during "times of peace". Continuous research can yield discoveries that accelerate the development of medical

countermeasures for novel pathogens, as was the case when prior research on an mRNA vaccine for HIV contributed to speeding up the development of mRNA COVID-19 vaccines. A provision should be added for supporting such research.

- **Incentivize expanded registration of pandemic tools to accelerate equitable access.**
  To ensure timely global access to health tools developed, manufacturers must seek regulatory approvals or authorizations beyond high-income countries, particularly in developing countries where transmission is high and clinical trials have been conducted, to ensure fair and equitable access to the fruits of research. Therefore, Article 10 (Sustainable Production) should include new text that calls on countries to provide incentives for manufacturers to facilitate this, with a view to achieving a more equitable geographical distribution of the global production of pandemic-related products.

Article 11: Transfer of technology and know-how
Article 12: Access and benefit sharing

- **Equitable access to medical countermeasures.**
  The agreement must maintain language on global public health and equitable access at the center of policies, processes, and investments. This means ensuring low- and middle-income countries can create, manufacture, and buy countermeasures when needed and have the resources to respond quickly. Commitments to equitable access in Articles 11, 12, and 13 must be enshrined through robust language on distributed manufacturing capacity, technology transfer, and access and benefit sharing.

- **Regulatory policy that enables innovation and access.**
  The framework should include provisions strengthening the capacity of regional regulatory bodies, like the newly formed African Medicines Agency. Investing in bolstering the regulatory capacity of these regional bodies, and not just promoting harmonization, will help fill gaps for countries with lower regulatory maturity levels. Text should be included that standardizes policies or protocols for the regulation of products during health emergencies. Currently, the draft only highlights general regulatory harmonization and focuses on licensing of pandemic products, without taking into account broader elements of the regulatory ecosystem.