GHTC global health technologies coalition

advancing innovation to save lives

GHTC Recommendations for Intergovernmental Negotiating Body Zero Draft

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.

GHTC welcomes the efforts by both the World Health Organization (WHO) and member states in recent months to arrive at the current draft of considerations for the intergovernmental negotiating body (INB) pandemic treaty, known as WHO CA+, which we believe is a strong starting point for negotiations. We appreciate the US government, particularly leadership from the Departments of Health & Human Services and State, for providing this consultative opportunity and highlight that our focus remains the innovation of and equitable access to health tools, thereby strengthening the world's capacities for preventing, preparing for, responding to, and recovering from pandemics.

Our comments build on previous comments GHTC made as part of the open consultations and public hearings, and in this submission, we seek to highlight issues within the zero draft for the US government that are either missing or could be further clarified or amended.

Recommendations for Objectives and Vision

1. **Addressing inequities in access to health tools should be a central objective.**

   There is currently no reference to ensuring equitable access to affordable health tools as part of the objective or vision. Addressing inequities in access to health tools should be a central objective of the WHO CA+. COVID-19 clearly showed that equitable access is the "unfinished business" of global health and is imperative to "save lives," as the WHO CA+ aim states. Suggested amendment: Article 3 objective(s) should be amended '[ADD Ensuring the discovery, development, availability, and timely and equitable access to affordable medical and other pandemic response products].'

Recommendations for Article 7: Access to technology: Promoting sustainable and equitably distributed production and transfer of technology and know-how

2. **Incentivize research for medical countermeasures (MCMs) for outbreaks in low- and middle-income countries (LMICs).**

   We note that this article does not cover incentivizing continuous research to develop MCMs for diseases that cause outbreaks primarily in lower- and middle-income countries but are not profitable for manufacturers to produce, such as those for cholera, Ebola/Marburg fever, and other neglected tropical diseases. Continuous research can accelerate the development of MCMs for novel pathogens, as was the case when research on an mRNA vaccine for HIV contributed to speeding up the development of the COVID-19 vaccine. A provision should be added for incentivizing such research.

3. **Ensure accountability of equity principles for MCMs.**

   Article 7 outlines important principles of an effective and equitable system for developing the research base needed to accelerate the production of pandemic countermeasures; however, the zero draft does not currently include provisions for accountability of these principles. GHTC would also appreciate more clarity on whether the newly proposed MCMs platform could eventually fit into this space.

Recommendations for Article 8: Regulatory strengthening

4. **Elevate the need for regional regulatory coordination and capacity.**

A stronger emphasis on building the capacity of regional regulatory bodies, like the newly formed African Medicines Agency, is important. Investing in the regulatory capacity, and not just harmonization, of these regional bodies, will help fill gaps for LMICs that are lacking national capacity.

5. **Highlight national and regional regulatory policies and protocols for health emergencies.**

Building on the language in sub-article 1 and 2, there is a need to include text that establishes national and regional 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.

Recommendations for Article 9: Increasing research and development capacities

6. **The title of Article 9 should be expanded.**

   In addition to strengthening capacity, there is a need to address the limitations and gaps in the way that research and development (R&D) is conducted and coordinated that have been exposed during COVID-19.

   To better reflect the need to focus on both aspects, and what is already included under Article 9 in the zero draft, the title of Article 9 should be amended to read: 'Increase [ADD and enhance/coordinate] research and development [ADD processes] and capacities.'

Recommendations for Article 9.10: Clinical research ecosystems

7. **Ensure measures to support regional clinical research ecosystems for preparedness and response by supporting new and existing clinical trial networks and infrastructure, especially those based in and led by LMICs.**

We support the reference to developing strong and resilient national, regional, and international clinical research ecosystems and would encourage the scope to include not only pandemic responses but also other existing health priorities to ensure sustainability. Just as the response to COVID-19 depended on years of investment in clinical trial networks for other health threats, moving forward, it will be important to establish clinical trial infrastructure and platforms that can be flexible, autonomous, and able to respond promptly and effectively to emerging outbreaks—and in non-pandemic times, be capable of supporting efforts to tackle ongoing health priorities, including malaria, tuberculosis, HIV, neglected tropical diseases, and the rising threat of antimicrobial resistance. Additionally, while efforts must be made to support existing infrastructure, it may be necessary to create new mechanisms.

Amend 9.10 (a) to read: Fostering and coordinating clinical research and clinical trials, including, as appropriate though [ADD new and] existing coordination mechanisms [ADD especially those based in and led by low- and middle-income countries].

8. **Ensure that measures to strengthen clinical research ecosystems include a broad diversity of populations (Article 9).**

   Support for inclusive clinical trials is needed to improve equity and understanding of health outcomes within specific populations. There should be an explicit reference to the inclusion of underserved populations in all their diversity, including children and people who are pregnant or of child-bearing age. Disaggregating clinical trial result data is another important aspect and should remain as Article 9 10 (d).

9. **Include measures to support regulatory authorities and ethics committees for clinical trial processes and oversight (Article 9).**

   Support for coordination and cooperation mechanisms for regulatory authorities and ethics committees is important to expedite and streamline clinical trial approval and review processes. Add a new point to 9. 10 [ADD (e) supporting the coordination and cooperation of regional and national regulatory authorities and ethics committee for clinical trial approval processes and oversight].

10. **Obligations for the transparent and rapid reporting of clinical research and trial results should be strengthened (Article 9).**

    Transparency and timely publication of clinical trial protocols and results is critical for the harmonization of protocols/comparisons and coordination of treatment guidelines. Transparency can be enhanced through requirements to include this information in publicly available registers, such as the International Clinical Trials Registry Platform, ClinicalTrials.gov, and the Pan African Clinical Trials Registry.