Global Health Council
The Collective Voice of the Global Health Community

Input from Global Health Council on the *Zero draft of the WHO CA+ for the consideration of the Intergovernmental Negotiating Body at its fourth meeting (A/INB/4/3)*

Submitted: February 24, 2023

Introduction

Thank you for the opportunity to provide input on the *Zero draft of the WHO CA+ for the consideration of the Intergovernmental Negotiating Body at its fourth meeting (A/INB/4/3)*.

Global Health Council is a coalition of more than 100 member organizations devoted to advancing global health priorities and improving health and well-being worldwide.

Global Health Council strongly supports ongoing pandemic instrument negotiations and their efforts to build a more comprehensive global health architecture that is better prepared to prevent, prepare for, and respond to emerging health threats. These negotiations must be inclusive, transparent, and efficient, and must continue to meaningfully engage a broad spectrum of stakeholders to ensure a successful outcome, including non-State actors (NSAs) in official relations with WHO as well as members of broader civil society.

With input from a range of our diverse members, please find included in this document our article-by-article comments for a new, international pandemic prevention, preparedness, and response instrument.

- **Summary of main comments**
  - More focus and emphasis on One Health, especially spillover prevention and workforce development;
  - More attention on investment in LMIC R&D capacity, including scientific workforce developing expertise to run clinical trials and see manufacturing to completion for better MCM access;
  - More focus on public health protections and prevention and how to build those systems, especially strengthening WASH capacities; and
  - Lacks accountability mechanisms and agreed-upon enforcement processes, how evaluation frameworks will be integrated/connected with existing ones, and how new ones will be developed.
- **Concerns over NSA and other stakeholder engagement**
  - At the INB briefing for relevant stakeholders on February 15, GHC learned the disturbing news that opportunities for NSAs and other stakeholders will be minimal going forward in the INB process. From our understanding of what was announced at the briefing, this closing of the meetings will happen much earlier than we previously understood. It will be regrettable if the Bureau views the public hearings and engagement so far as sufficient input from NSAs and civil society, especially since we were given no time to prepare for the meeting and no warning that the briefing on February 15 may be our last opportunity to provide verbal input. It is essential these negotiations remain open to input from NSAs and civil society to promote support and understanding of the accord. We

therefore urge the Bureau to clearly communicate how and when NSAs and civil society may provide input amid the ongoing negotiations and how the Bureau plans to communicate updates to the public.

- **Overarching Comments**
    - We welcome the inclusion of biosecurity in the zero draft of the Accord and appreciate Member States' interest in highlighting the importance of strong security systems as part of global agreements to prevent, detect, and respond to the next pandemic. However, we are concerned that current approaches to biosecurity as presently defined are insufficient to adequately prepare Member States and other entities for future pandemic threats. We encourage Member States to take a more expansive approach to biosecurity, addressing all measures needed to protect infectious agents and toxins from loss, theft, or misuse and the containment principles, technologies, and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release. This goes beyond laboratory settings – where biosecurity is currently addressed in the Accord – and should be incorporated into all developmental actions taken by Member States as they build the necessary systems to prevent, detect, and respond to infectious disease threats.
    - We have concerns that the duties imposed on parties have little apparent mechanism to monitor or enforce those duties. While we recognize that acquiring agreement to a set of mechanisms that might enforce freely accepted obligations may be hard to obtain, a lack of means to know or ensure that parties are fulfilling their obligations will create unfulfilled expectations as well as shift the burden of harms to countries least able to provide for their own safety and security.
    - The zero draft currently still largely places emphasis on downstream response measures such as manufacturing and registration. While these are critical elements to a country's global health security, they are not sufficient to ensure the end-to-end approach – from early-stage discovery research to clinical development to access and delivery of health tools post-registration - that is needed.
    - We note the current lack of security sector engagement throughout the current version of the Accord. Ensuring security and defense cooperation during pandemics and related events is critical to an effective response; a point that is underscored by how many countries relied on defense sector services to respond to COVID-19. We encourage Member States to take a critical eye to all provisions of the Accord and look for ways to constructively engage the security sector, particularly under Article 16.
    - Overall, there is still not enough of a focus on prevention and we are concerned that the removal of references to strengthening public health functions and building local capacity to deliver core public health competencies, including infection prevention and control measures, weakens the document.

- **Preamble and Vision: The world together equitably**
    - This section should recognize the increasing frequency of outbreaks of zoonotic origin and that the prevention of pandemics is significantly less costly than responding to pandemics once they have emerged.
    - Prior to the stated vision, it should be recognized that pandemics can originate from natural sources or because of accidents or deliberate events and prevention, detection, and response systems should be designed accordingly to account for these different sources of origin. Clearly noting that pandemics come from a variety of sources is necessary to ensure proper scope of later articles.

Article-by-Article Comments

Chapter I. Introduction

Article 1. Definitions and use of terms

- This article should include the definition of One Health developed by the One Health High Level Expert Panel and the definition of prevention used by the World Bank-hosted Pandemic Fund. It should also include a definition of spillover.
- We propose including the definition of UHC: Universal health coverage means that all people have access, without discrimination, to nationally determined sets of the needed promotive, preventive, curative, rehabilitative and palliative essential health services, and essential, safe, affordable, effective and quality medicines and vaccines, while ensuring that the use of these services does not expose the users to financial hardship, with a special emphasis on the poor, vulnerable, and marginalized segments of the population. (Reference from: UHC Political Declaration 2019, para. 8). Universal health coverage, based on primary health care, plays a critical role in pandemic prevention and response by ensuring all people have access to essential services.

Article 2. Relationship with other international agreements and instruments

- There is no specific reference to how the Accord links to and coordinates with other United Nations entities that seek to address these sorts of issues under Article 2, such as the Biological and Toxins Weapons Convention (BWC). We strongly recommend that Member States revisit these principles and find ways to effectively coordinate in times of emergency, including across the United Nations system.

Chapter II. Objective, guiding principles and scope

Article 4. Guiding principles and rights

- The principle on equity should acknowledge the role of addressing the drivers of spillover events in order to achieve global health equity. Focusing only on containing outbreaks accepts the deaths of vulnerable populations who live in emerging infectious disease hotspots. On the other hand, spillover prevention protects everyone equally. This section should also acknowledge the role of the Quadripartite, as their participation is critical to achieve the instrument's objectives. It must be formalized, alongside the central role of the WHO.
- It is critical that Member States find ways to address, investigate, and attribute the source of an infection in a transparent and non-political manner. Despite underscoring the need for "Transparency" in the guiding principles under Article 4, the Accord does very little to create sustainable and effective mechanisms to address these problems. Moreover, the draft treaty does little to suggest how parties will or might adjudicate among these principles in cases or situations where two or more principles are in conflict.

Chapter III. Achieving equity in, for and through pandemic prevention, preparedness, response and recovery of health systems

Chapter three outlines procedures and mechanisms that will encourage the dissemination of new and developing technologies throughout the world. While we support increased technical capabilities and the right of countries to pursue development, we strongly encourage Member States to build in provisions that address the importance of pairing these developments with

requirements for robust safety and security systems that mitigate potentially catastrophic risks from accidental and/or deliberate pathogen release. Added biosecurity provisions will only make the Accord stronger and the world safer.

Article 7. Access to technology: promoting sustainable and equitably distributed production and transfer of technology and know-how

- The article is strong but does not cover incentivizing continuous research to develop medical countermeasures for diseases that cause outbreaks primarily in the Global South but are not profitable for manufacturers to produce, such as those for cholera, Ebola/Marburg fever, and other neglected tropical diseases. Not only could such a disease evolve into a pandemic-causing form, continuous research can also accelerate the development of medical countermeasures for novel pathogens, such as in the case of research on an mRNA vaccine for HIV contributed to the speed at which the COVID-19 vaccine was developed. A provision should be added for incentivizing such research.
- It is critical to recognize the strengthening not only of national but also regional health systems.

Article 8. Regulatory strengthening

- Stronger emphasis on building the capacity of regional regulatory bodies like the newly formed African Medicines Agency is important. Investing in the capacity (vs. just harmonization) of these regional bodies will help fill gaps for low- and middle-income countries that are lacking national capacity.
- It is critical to recognize the dual-use nature of pandemic-related research and/or technology enabling such research. While conducting research and sharing information publicly involving emerging biotechnologies - such as AI-synthetic biology interface - and pathogens of pandemic potential, appropriate barriers must be in place to avoid misuse.
- There is a need to include text that establishes national and regional policies or protocols for the regulation of products during a health emergency. 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.

Article 9. Increasing research and development capacities

- As the countries build up their capacities and share knowledge, they must agree upon the oversight framework and broad definitions of biosafety and biosecurity. Moreover, the parties must be agile, resilient, and adaptive to fast-paced scientific innovations and be proactive in securing this powerful knowledge from accidental or deliberate misuse. The “free dissemination of knowledge” must be done in a way that avoids information hazards to ensure that it is not exploited by bad actors for nefarious purposes.
- Article 9 should include a reference to measures to support the coordination and cooperation of regional and national regulatory authorities and ethics committees for clinical trial approval processes and oversight. There is also a need to ensure that clinical trials include diverse populations in order to improve equity and understanding of health outcomes between populations. The participation of individuals from lower-and middle income countries, pregnant people, and other communities often excluded from clinical trials research should be strengthened.

Chapter IV. Strengthening and sustaining capacities for pandemic prevention, preparedness, response and recovery of health systems

Article 11. Strengthening and sustaining preparedness and health systems’ resilience

- Article 11's focus on strengthening and sustaining preparedness and health system resilience is welcome and a commendable part of the Accord. However, we must stress the need to add additional language addressing the need to build robust biosecurity systems as part of efforts to build and reinforce the public health system under item 4.
- When referencing Health Systems Strengthening, governments are often speaking on the assumption that countries have WASH. We should note that WASH is not only a social determinant but also a tool for primary prevention and containment.
- We need to ensure we are integrating the concept of primary health care (particularly in Articles 4 and 11) when referring to strengthening/building resilient health systems…add language like "strengthening health systems requires a focus on primary health care and community level interventions."

Article 12. Strengthening and sustaining a skilled and competent health and care workforce

- This section is solely focused on the public health workforce. It should also commit Parties to invest in establishing, sustaining, coordinating, and mobilizing an available, skilled, and trained One Health workforce, which includes the animal health workforce. Furthermore, the workforce should include a focus on the scientific and research workforce needed to advance clinical research, as well as the need for a trained regulatory and manufacturing workforce for end-to-end development and regulatory approval of safe and effective medical countermeasures.
- Summary of recommended additions: The Parties shall develop and implement comprehensive strategies for all health workers, including community health workers, to ensure: 1) Protection of the workforce from infection, including high-quality and properly fitting personal protective equipment, 2) priority access to medical and non-medical countermeasures, including vaccines and access to safe water, sanitation and hygiene 3) freedom from violence and intimidation in the course of carrying out pandemic prevention, response, and recovery, 4) effective workforce planning capacity to make possible effective and efficient deployment of health workers during pandemics, as well as communication systems that permit rapid and efficient communication with all health workers, and 5) support for intersectoral approaches to addressing labor market failures that that result in misalignment between pre-service education and employment.

Article 13. Preparedness monitoring, simulation exercises and universal peer review

- The monitoring proposed here is limited to monitoring of preparedness capacity; these provisions may already be covered by the Universal Health and Preparedness Review (currently under pilot) and Joint External Evaluations (JEEs) (which are under widespread use). We recommend building on existing tools available through the IHR Monitoring and Evaluation Framework.
- There are no provisions for monitoring new obligations agreed under the instrument; these should be added.
- Article 13 would benefit from leveraging existing assessment mechanisms, such as the Joint External Evaluation and the State Party Self-Assessment Annual Report mechanisms as well as existing external evaluations that provide more regular, independent, and comprehensive evaluation of countries' capacities. It will be important to reduce duplication by acknowledging the potential resource constraints of leveraging existing and new WHO tools in addition to WHO staff time. The outcome of these reviews should highlight a country's commitment to multi-year pandemic preparedness financing that is transparent to international partners and other countries. For all the recommended exercises, after action reviews, assessments, and monitoring systems, it

is paramount that this data be made publicly available to ensure commitment towards a global preparedness and response infrastructure.

Chapter V. Coordination, collaboration and cooperation for pandemic prevention, preparedness, response and health system recovery

Article 16. Whole-of-government and whole-of-society approaches at the national level

- The comprehensive national pandemic prevention, preparedness, response and recovery plans suggested in this section should include national One Health actions plans that address the drivers of spillover and antimicrobial resistance. The One Health approach is critical to prevent future pandemics, so it must be an integral part of these plans, not separate.
- When referring to social participation (particularly in principle 10 and article 16), we must explain what that means in practice. For example: “Meaningful engagement should include activities such as creating a national coordinating mechanism made up of representatives from multiple sectors including civil society and communities. These mechanisms are responsible for ensuring all stakeholders, including communities and civil society, can participate in relevant decision-making processes. These types of institutionalized mechanisms make participatory governance part of the modus operandi of the health system.”

Article 17. Strengthening pandemic and public health literacy

- We applaud the focus on strengthening pandemic and public health literacy, and propose the inclusion of frontline health workers as a key and trusted channel for outreach to vulnerable and under-served populations.

Article 18. One Health

- We welcome the focus of this section on spillover prevention. However, the list of the drivers of disease emergence at the human-animal-environment interface must be expanded. It includes, but is not limited to: land use change; the loss, fragmentation, and degradation of ecosystems; wildlife trade and markets; weak animal health systems and management; climate change; human-wildlife conflict; desertification; and antimicrobial resistance. The absence of any mention of animal health systems in this section is particularly concerning. Historical data shows that domesticated animals, including farmed species normally occurring in the wild, are often a reservoir for zoonotic pathogens with pandemic potential. Investments to strengthen animal health systems and management are critical to prevent future pandemics and they must be acknowledged in this section, especially given current concerns about avian influenza. We also recommend the creation of comprehensive One Health action plans which do not focus only on addressing antimicrobial resistance but also on addressing spillover.
- Strengthen water, sanitation and hygiene as a core component of the One Health approach to breaking disease transmission pathways at the human-animal-environment interface.

Chapter VI. Financing for pandemic prevention, preparedness, response and recovery of health systems

Article 19. Sustainable and predictable financing

- We commend Member States for their commitment to generating sustainable financing for efforts outlined in the Accord. In doing so, the world will be made safer from infectious disease threats, and countries will be empowered to fulfill their obligations under the IHR

and other frameworks. We welcome innovative mechanisms that catalyze new resources and connect to broader global financing architecture. These should welcome private sector and non-state actor engagement in clear, concrete, and meaningful ways.

Chapter VII. Institutional arrangements

Article 20. Governing Body for the WHO CA+

- GHC seeks clarification as to why the Conference of the Parties is set to meet only every three years instead of on an annual basis, following the lead of the UN Climate Change Conference of Parties.

Article 21. Consultative Body for the WHO CA+

- From the outset, the Consultative Body shall also include a specified number delegates from civil society, including a specified number of delegates from civil society organizations in low- and middle-income countries, rather than being admitted solely upon application.

Article 22. Oversight mechanisms for the WHO CA+

- This article proposes delaying an agreement on accountability mechanisms until the first meeting of the governing body, rather than in the treaty negotiations themselves. This means the treaty would enter into force without accountability mechanisms already in place. There is no mention of independent accountability mechanisms, including monitoring systems. It will be important to advocate for accountability mechanisms to be agreed upon from the start. This should include an independent monitoring committee to assess compliance with and reporting on the accord, which is empowered to escalate non-compliance to a high-level political body.
- The draft must articulate accountability and enforcement processes and outline how evaluation frameworks will be integrated into the Pandemic Accord. We applaud the inclusion of language focused on transparency and accountability within the framework. However, the scope should also include “compliance.” Not only does this put language and terminology in line with the International Health Regulations (2005), it emphasizes the importance of addressing these international concerns collectively. There should also be a more explicit callout for how compliance and adherence to the principles will be measured. There are a number of existing evaluation tools and metrics for pandemic preparedness, such as the Joint External Evaluations, and the text should outline how these assessments factor into reporting. In addition, given the insufficiency of existing evaluation frameworks in regard to primary health system capacity, there should be a provision requiring open and transparent health system data, and a requirement to collect essential data, that would facilitate civil society evaluation of health systems preparedness, including universal health coverage indicators. This section needs particular attention from designated experts.