

Input from Global Health Council on the Working draft, presented on the basis of progress achieved, for the consideration of the Intergovernmental Negotiating Body at its second meeting (A/INB/2/3)

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Thank you for the opportunity to provide input on the Working draft, presented on the basis of progress achieved, for the consideration of the Intergovernmental Negotiating Body at its second meeting.

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 meaningfully engage a broad spectrum of stakeholders to ensure a successful outcome.

With input from a range of our diverse membership, please find below our recommendations for the substantive elements that should be included and prioritized in any new international pandemic prevention, preparedness, and response instrument:

1. Integrated: Create a more cohesive global health architecture by avoiding duplication with new and existing frameworks and mechanisms, such as the International Health Regulations, the newly established Financial Intermediary Fund at the World Bank, and other international organizations working on pandemic prevention, preparedness, and response. This could include creating a multidisciplinary and multisectoral platform of public health emergency operations centers, well integrated with existing global and national efforts, at the global, regional and national levels.

2. Equity: Ensure equity in prevention and responses to future health emergencies, including preventing pathogen spillover, the development of and access to lifesaving medical countermeasures, expanding national, sub-regional, and regional manufacturing capacity, supporting technology and knowledge transfer, ensuring capacity in the essential public health functions and immunization campaign planning and execution at ministries of health and national public health institutes, and maintaining access to quality, safe, and sustainable essential health services.

3. Governance and Accountability: Ensure collective, accountable leadership, prioritizing representation and engagement with non-State actors, civil society organizations, and historically marginalized and underrepresented communities from low- and middle-income countries.

4. Financing: Sustainably finance pandemic prevention and preparedness by providing equitable access to emergency financial mechanisms, as well as through the establishment of a dedicated fund, which links accountability mechanisms to progress indicators. Enhanced collaboration between the health, veterinary, environmental, and finance sectors is also needed to both achieve universal health coverage and support pandemic prevention, preparedness, and response.

Section-by-Section Feedback: General Comments and Suggested Line Edits

Preamble

- In the preamble, we recommend adding this clause between items 21 and 22:
 - **“Understanding that the pathogens that cause most emerging infectious diseases originate in animals, often wildlife, and then spill over into humans;”**

Vision

- No specific comments or feedback on this section.

Part 1: Introduction

- Article 1: Definitions and use of terms
 - “One Health” and “pandemic prevention” are important terms that should be maintained in this section of the final agreement. We also recommend adding the terms “primary pandemic prevention,” “secondary pandemic prevention,” and “spillover” to this section.
 - Proposed definitions for these terms are as follows:
 - One Health: One Health is an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. *(Note: This definition of One Health was developed by the One Health High-Level Expert Panel)*
 - Pandemic prevention: Pandemic prevention refers to the complete set of actions to prevent a pandemic from occurring and can be divided into primary and secondary pandemic prevention.
 - Primary pandemic prevention: Primary pandemic prevention refers to actions to prevent an outbreak of a pathogen in humans that has the potential to cause an epidemic or pandemic. This can be achieved particularly by reducing the risk of spillover.
 - Secondary pandemic prevention: Secondary pandemic prevention refers to actions that aim to curb human-to-human spread of a pathogen that has caused an outbreak so that neither an epidemic nor a pandemic occurs.
 - Spillover: Spillover is the movement of pathogens from non-human animals to humans.
- Article 2: Relationship with international agreements and instruments
 - No specific recommendations on this article.

Part 2: Objective(s), principles and scope

- Article 3: Objective(s)
 - Suggested line edit:
 - “(1) to continually and substantially increase and sustain the capacity to ~~prevent pandemics from occurring~~ **for primary and secondary prevention of pandemics**”
- Article 4: Principles
 - Suggested line edit:
 - “(4) Equity – A fair, equitable, effective and timely ~~approach response~~ to pandemics **prevention, preparedness, and response** requires **actions to prevent pathogen spillover**, ensuring fair access to well-functioning public health systems and immunization programs and affordable

pandemic response products, among and within countries, including between groups of people, irrespective of their social or economic status.”

- Article 5: Scope
 - We applaud the inclusion of 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. The INB could consider language to the effect of “All Parties are accountable and must comply with international treaties and conventions such as the Geneva Convention and Biological Weapons Convention to assist in the rapid discernment of the origins of novel pathogens.”
 - We recommend that the text also include the importance of capacity building, particularly to develop surveillance systems that are able to determine baseline transmission in addition to the ability to detect an outbreak.

Part 3: General Obligations

- We recommend further emphasis on the following:
 - Additional language specificity in language throughout the document to include better definition of terminology and roles and responsibilities (e.g., must define language beyond just “experts” where feasible)
 - (1) Importance of disease detection and surveillance.
 - (3, 10, 11) Funding and sustainment of national budget lines within planning processes. Additional specificity is needed, particularly on seeking new funding sources and funding availability
 - (3) Recognizing the importance of meeting international standards and agreements, such as the International Health Regulations (2005), to provide further clarity on importance and draw upon existing legal frameworks.

Part 4: Specific provisions/areas/elements/obligations

1. Achieving equity
 - It is critical to recognize the importance of additionality and financial assistance within this goal. For example, in addition to MCMs, PPE, etc, the document should recognize broader streams of need.
 - Suggested line edit:
 - “(e) measures to ensure equitable and affordable access to quality, safe and effective pandemic response products, **including technology transfer and support for local manufacture of publicly financed health technologies for vaccines, assays and therapeutics**, as well as products drawn from strategic stockpiles, and their equitable distribution;”
 - We recommend adding this clause:
 - **“(g) measures to reduce the risk of spillover of pathogens”**
2. Fair, equitable and timely access and benefit sharing
 - No specific recommendations on this element
3. Strengthening and sustaining health systems’ resilience and capacities
 - The INB should take due care to emphasize the kind of surveillance data that is requested as well as prominently safeguard the privacy of personal health information, genetic information, and other sorts of personality identifiable

information that might be collected. Recommend including a separate point on protecting the integrity of information/data so that it can reliably be used to guide informed action—and to ensure that all research participants benefit from the products of research.

- It is critical that the INB considers the full spectrum of biological threats. Zoonoses and spillover events are important, but understanding and including broader possibilities is also needed. For example, including additional outbreak modalities to ensure accidents and deliberate use are considered ‘in-scope’ and that countries are held accountable for preparing against these types of events.
 - The INB should consider point-of-care rapid diagnostics in addition to laboratory capacities when considering measures to strengthen public health laboratory and diagnostic capacities and networks.
 - The INB must be sure to include data standardization and reporting within this section.
 - It is necessary to recognize that there are ways to enhance disease pathogenicity without “genetically” modifying anything. Language should be kept broad enough to recognize this fact and perhaps “modification” is sufficient and more encompassing.
4. Local production and transfer of technology and know-how
- The generation of pandemic response products cannot only be done during response times. Manufacturing and stockpiling must continue throughout peacetime as well, and it is essential to support and strengthen local production of medical countermeasures to ensure that every country has access to the tools they need. There should be added attention to the need for “quality” within production to ensure that substandard products or medication are not generated.
5. Governance and coordination, collaboration, and cooperation
- The INB should recognize the importance and benefit of external assessments in addition to self-assessment. This should include intergovernmental tools, such as the Joint External Evaluation (JEE) and coordination of JEE implementation through the Global Health Security Agenda action packages and task forces, but include civil society actors as well (i.e., the Global Health Security Index) so that fully independent data can be utilized as part of decision making.
6. Health workforce
- It is critical to include laboratory technicians and operators within existing language and scope. This is particularly important as the current text specifies that the document seeks “to ensure laboratory capacity for conducting genomic sequencing through sustainable funding support...” if “genomic sequencing” is to be included, there should be mention of other critical responsibilities of laboratory technicians.
 - Ongoing training of clinical researchers is also essential to ensuring there is sufficient local and regional workforce to conduct late-stage research and clinical trials to support development of medical countermeasures.
 - This element also fails to mention diagnostic testing, which should be included given its importance during COVID-19.
 - Suggested line edit:
 - “(a) measures to **scale-up and** strengthen pre-, in- and post-service training **and retention** of adequate numbers of health workers, at the

national and local levels, equipped with public health competences and to ensure laboratory capacity for conducting genomic sequencing through sustainable funding support, deployment and retention for a **resilient health workforce resilience that can large enough and skilled enough to meet national health goals while also being sufficient to be mobilized for *emergency* pandemic response;**

7. One Health

- We recommend recognizing or noting the critical impacts of deforestation and/or climate change.
- Suggested line edit:
 - “(b) measures to strengthen multisectoral, coordinated, integrated One Health surveillance systems to ~~minimize spill-over events and mutations and~~ **rapidly detect outbreaks and** prevent ~~small-scale outbreaks~~ **them** from becoming a pandemic;”
- We recommend adding this clause:
 - **“(h) measures to reduce the risk of spillover of pathogens”**

8. Governance, whole-of-government and other multisectoral actions at national level

- The INB must clearly recognize the importance of including long-term, sustainable multi-year financing as part of governance activities.

9. Governance, community engagement and whole-of-society actions at national and subnational levels

- No specific recommendations on this element

10. Global supply chain and logistics network

- Within part (e), the language "avoid the imposition of unnecessary disturbances to international travel and trade, as well as discriminatory travel and trade restrictions" should also be used in 5 (e) Part IV to ensure document cohesion.
- The INB should consider inclusion of the establishment and implementation of regular assessments of current stockpiles at national, regional, and international levels.

11. Research and development

- Research and development must be a central pillar of the framework. This includes strengthening norms and standards that support access and benefit sharing of data related to emerging pathogens, supporting mechanisms that strengthen local manufacturing and regulatory authority capacities to accelerate the process of licensing and approving pandemic response products for emergency use in a timely manner, and facilitating research coordination that spurs innovation and the development of medical countermeasures that are accessible to all who need them, particularly in low and middle-income countries

12. Preparedness monitoring, simulation exercises and peer review

- We recommend updating the title of this section as follows: “12. **Prevention and preparedness monitoring, simulation exercises and peer review**”
- Rather than reinvent tools and processes, the INB must incorporate existing capabilities, such as the JEE, eSPAR, and PVS. There should be language noting their importance and recommending their regular usage and update.

- We recommend changing the language of “peer review” to “external assessment.” Peer review is too restrictive and doesn’t immediately imply regional, international, or CSO-led assessments. Instead the world should leverage existing measures of global and national indicators and work to help inform the evolution of new measures to be included. This has the added benefit of better including civil society and private sector entities in these efforts.

13. Pandemic and public health literacy

- No specific recommendations on this element

14. Financing

- Once again, we recommend that the INB explicitly state that multi-year financing be included. Ideally, this should be done on 3-5 year planning cycles.
 - Suggested line edit:
 - “(b) measures to ensure sustainable and predictable financing of global systems and tools, and global public goods, through existing or new mechanisms, **such as the PPR FIF, hosted by the World Bank**, in order to guarantee equitable access to emergency financial mechanisms and to facilitate rapid and effective mobilization of adequate financial resources to affected countries, based on public health need;”

Part 5: Institutional Arrangements

1. Governance mechanism for this WHO CAII

- Governance mechanisms must be developed and described in coordination with the broader global system. For example, how are these efforts coordinated with the new PPR FIF and separate from and/or integrated with other multilateral funding mechanisms and implementers?
 - Suggested line edit:
 - “The WHO CAII shall include a governance mechanism to support its operation and implementation. Depending on the provision of the WHO Constitution under which the instrument is adopted, this governance mechanism could be established as a Conference of the Parties or a Member State mechanism. It would be expected that the governance mechanism would be based in WHO, ~~and~~ supported by the WHO Secretariat, **and include a formal system for civil society to regularly contribute to policy making**. The functions of the governance mechanism could include, without limitation:”

2. Oversight mechanisms for this WHO CAII

- No specific recommendations on this section

3. Assessment and review

- No specific recommendations on this section

4. Financial mechanisms and resources

- No specific recommendations on this section

Part 6: Final Provisions

- No specific recommendations on this part