

Global Health Council Input on Proposed Amendments to the International Health Regulations (2005) Under Consideration by the WGIHR

Submitted: March 31, 2023

<u>Introduction</u>

Thank you for the opportunity to provide input to the ongoing work of the Working Group on Amendments to the International Health Regulations (2005).

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 negotiations of the WGIHR as it continues to advance discussions of the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies, as it now focuses its work exclusively on consideration of proposed targeted amendments to the Regulations. These negotiations must be inclusive, transparent, and efficient, and must find ways to meaningfully engage a broad spectrum of stakeholders to ensure a successful outcome.

With input from a range of our diverse members, please find included in this document our article-by-article comments on the proposed amendments to the International Health Regulations (2005).

Overarching Comments

Overall, there is a lot of content on surveillance, technology transfer, and public health response after a PHEIC is declared, but very little on prevention/spillover and working through a One Health approach. We think that the current compiled list of proposed amendments falls short of its potential without addressing these more upstream efforts. Also, the proposed amendments still lack the "teeth" that the IHR 2005 are most often criticized for lacking. There is a significant amount of training and technical assistance called for in the collaboration sections, as well as assisting with supply of fit-for-purpose PPE and other material resources to countries in need, but it is unclear who will be held responsible for these actions.

Additional points for the US government to consider:

- More clarity is needed on what issues to tackle through IHR amendments vs those in the INB process. What is the interplay and interconnectedness between the mechanisms?
- GHC recommends that the US government focus on amendments that will have the most impact and are feasible to secure consensus, with special attention to the health workforce as included in the "health systems capacities" section of Annex 1.
- More clarification on the US proposal for a tiered alert system (indicators for national vs regional vs international issue of concern) would be useful to increase support for the update to the PHEIC framework.
- Given the agreed upon modalities for the work of the WGIHR, how can non-State actors and broader civil society best provide input and lend their expertise to the negotiations they proceed?



Article-by-Article Comments

Article 5: Surveillance

5.1: Will the UHPR mechanism be replacing the JEE process that countries have been doing through GHSA for years? We would concur with the Review Committee that it is premature to insert UHPR in lieu of JEE without fully understanding the extent of UHPR and its pilot phase results, acceptance by Member States, and how implementation (including tools) would occur.

WHO should also consider revisions or expansion of JEE to better reflect the range of health preparedness requirements, including the ability to develop and manufacture medical countermeasures, as well as regulatory indicators that assess the capacity of rapidly approving new health technologies.

New 5 on Developing Early Warning Criteria: Consider taking into account disaggregated data by key demographics, including gender, age, and others.

Article 6: Notification

New 6.3: Earlier statements in the article call for sharing genetic/genomic sequence data in a timely manner, but this new statement says "No sharing of genetic sequence data will be required"? And "shall only be considered after effective access and benefit sharing mechanism is agreed to by Member States and operational." Additional clarification is needed.

Article 13: Public Health Response

13.5: States parties shall provide diagnostics, PPE, therapeutics, vaccines to WHO to assist in response to PHEIC in another state jurisdiction. To what degree is this expected? Is this more of a guideline in principle?

We suggest adding another line calling for each State Party to put robust mechanisms in place to prevent and respond to cases of sexual exploitation, abuse, and harassment against women and girls during a PHEIC.

NEW Article 13A: WHO Led International Public Health Response

13A.2: When is this assessment occurring? Immediately following PHEIC? How will it work for a new pathogen or disease where diagnostics/therapeutics/vaccines may not exist?

13A.6: Database of ingredients of all materials involved in health products for PHEIC response – this seems very visionary and potentially unrealistic.

NEW Article 13A: Access to Health Products, Technology, and Know-How for Public Health Response

13A.3: We anticipate that this will receive a lot of pushback from PhRMA and other industry stakeholders, is there a plan for meeting this requirement?



Article 44: Collaboration and Assistance

We concur with the Review Committee that revisions and changes to this Article should be closely aligned with ongoing discussions and changes through the INB process to reduce duplication and ensure we build a coherent and effective global health security architecture.

44.1.c: Calls for a new international financial mechanism for providing financial assistance to developing countries to accomplish core capacities required under IHR. Is this mechanism different from the Pandemic Fund or other financial mechanisms? Who is required to fund? Who is leading this?

We concur with the Review Committee's assessment that a) it is unclear that WHO has the authority to do financing, and b) we must be cautious in creating duplicative structures given WHO's role in the Pandemic Fund. Recommend asking for added clarity from Member States who proposed these funding mechanisms and encourage coherent and effective systems building connected to ongoing efforts under the INB.

ANNEX 1:

Core capacity requirements – these are a great list of goals in capacity building, but at the moment quite unrealistic for many countries (i.e., "state of the art facilities," ensure technologies and access to health care products, collaborative surveillance efforts to quickly identify spillover, laboratory networks with genomic sequencing capability, etc.)

New 7. Health System Capacities

(iv) Health information systems: We suggest including

(iv) Health information systems: We suggest including a line about disaggregating data by gender, age, and balance to this bullet.

ANNEX 10:

It sppears that this is the only place where obligations are mentioned. Is this the only method of calling for accountability? Last iterations of IHR were criticized for not having any "teeth." Are these obligations the extent to which WHO can hold Member States accountable?