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Written Comment Re: Stakeholder Listening Session 2 for the IHR

Thank you for the opportunity to provide stakeholder feedback on the proposed amendments to the International Health Regulations (2005).

Public Citizen is a nonprofit consumer advocacy organization with more than 500,000 members and supporters. Public Citizen's Access to Medicines Program works with partners across the United States and around the world to make medicines available for all through tools in policy and law.

General Comments

We appreciate the United States' leadership in supporting negotiations of amendments to the International Health Regulations (2005) (IHR).

We are encouraged by many of the proposed IHR amendments that offer mechanisms for a more equitable global response to public health emergencies. In particular, amendments to Articles 3, 6, 13, and 44, and Annex 1 provide the opportunity to prioritize equity within the IHR by facilitating equitable access to medical countermeasures and increasing the capacity of developing countries to respond to public health emergencies. As the negotiations of the Working Group on Amendments to the International Health Regulations (2005) continue, we ask that the United States government considers the opportunities to make practical progress towards a more equitable global health architecture.

We welcome the United States' continued leadership on ensuring synergy and coherence between the WGIHR and the Intergovernmental Negotiating Body (INB) to draft and negotiate a WHO Pandemic Accord. The IHR and the proposed Pandemic Accord are both important instruments for global pandemic prevention, preparedness, and response (PPPR), and we strongly support the ongoing coordination between the two processes to ensure that a comprehensive framework for PPPR is created.

We would like to emphasize the importance of stakeholder engagement and transparency throughout the process to amend the IHR (2005). We appreciate the opportunity HHS has given to stakeholders to provide input into the United States' engagement with the process. But we encourage the U.S. to take a stronger role in ensuring that the WGIHR engages with non-state actors and civil society for technical expertise during the negotiations. Transparency of the negotiation process is key to meaningful and informed engagement.

Below, we provide article-by-article comments and recommendations in response to the proposed amendments to the International Health Regulations (2005) submitted by Member States.

Article 3: Principles

The principles outlined within Article 3 of the IHR will guide the implementation of the Regulations. During the COVID-19 emergency, high-income countries and pharmaceutical companies disproportionately controlled the manufacturing and supply of medical tools, leaving low- and middle-income countries with large gaps in access and causing unnecessary strain on health systems. An adequate global response to a future health emergency must consider the respective capacities of developed and developing countries to respond to health risks, and the different roles and responsibilities of countries within a Public Health Emergency of International Concern (PHEIC).

A recognition within the Regulations of the development divide between developed and developing countries would improve the ability of States Parties to meet their IHR obligations.[1] Thus, the IHR should include the concept of Common But Differentiate Responsibilities and Respective Capacities (CBDR-RC) within the guiding principles of the Regulations. To that end, we encourage the United States government to support the proposals of Malaysia, India, and Bangladesh to include equity, solidarity, and CBDR-RC as principles under Article 3 of the IHR.

Article 6: Notification

In potential health emergencies, it is critical that genetic sequence data is accessed in a timely manner to facilitate the rapid scale-up of medical countermeasures. However, the interests of justice and partnership recommend that a plan to share benefits accompany transfers of genetic sequence data. It would be regrettable if the IHR contributed, in effect, to a regime of surveillance of southern nations without shared benefits with the countries

[1] *See* Third World Network, *WHO: Text negotiations on equity proposals for International Health Regulations to start in April 2023*, available at https://www.twn.my/title2/biotk/2023/btk230302.htm

reporting genetic sequence and other pathogen data. This necessary complementarity of health and justice is among the lessons of the COVID emergency.

We urge the United States to support the development of a multilateral access and benefit sharing mechanism that facilitates concrete benefit sharing obligations and reflects the importance both of sharing pathogen information and guaranteeing benefits derived from such access. We note with interest Knowledge Ecology International's proposal on the open-source dividend as one model for benefit sharing.[2]

Article 13: Public Health Response

Article 13 outlines the requirements of States Parties to maintain core capacities to respond to public health risks and emergencies. The International Health Regulations (2005) have concrete legal obligations on preparedness, surveillance, detection, and notification. But there have been no concrete legal obligations on a coordinated public health response, particularly on ensuring equitable access to health products.

Access to affordable health products is a key and requisite component to the global public health response during a PHEIC. Several amendment proposals for Article 13 aim to strengthen the ability of developing countries to achieve the core capacities required in the Regulations, including through provisions that would facilitate access to health products and technologies. The Regulations should include strong commitments for States Parties to support a WHO-led public health emergency response and the WHO to in turn provide assistance to a State Party in response to public health risks. Obligations for technology transfer and sharing health product supply must be included in these commitments in order to ensure equitable access to countermeasures.

Bangladesh and the Member States of the WHO Africa Region have both made proposals for a new Article 13A that would enable equitable access to health products, technologies, and know-how during a public health emergency. The mechanisms developed during the COVID-19 pandemic to facilitate access to medical countermeasures for LMICs fell short of achieving equitable global access. The addition of an Article 13A to the International Health Regulations (2005) would help ensure that LMICs have access to the tools needed to mitigate and end public health emergencies.

We would welcome the United States' support of the principles in the proposals for a new Article 13A, creating concrete obligations for equitable access to health products.

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[2] Knowledge Ecology International, *The open source dividend as a model for incentives to share biological resources, inventions, data, and other inputs,* available at https://www.keionline.org/wp-content/uploads/Open-Source-Dividend-INB-24June2022.pdf

New Article 13A: WHO Led International Public Health Response

Bangladesh proposes to create additional obligations for the WHO and States Parties in a new Article 13A. This proposal aims to address the availability, affordability, and supply of health products, and the access to technology and know-how during health emergencies. We note with interest the provision to require the WHO to assess the availability and affordability of the health products for public health emergencies, and the proposal for a database "containing the details of the ingredients, components, design, know-how, manufacturing process or any other information required to facilitate manufacturing." These obligations could help the WHO and States Parties identify key drivers of inequitable access to pandemic health products and facilitate rapid scale-up of production of those products during a PHEIC.

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

The Article 13A proposal from the Member States of the WHO Africa Region also addresses the sharing of knowledge and technology to facilitate equitable access to health products during PHEICs. We note with interest the proposal's reference to measures that would increase local production of required health products during a public health emergency. The concentrated pharmaceutical manufacturing power in the high-income countries during the COVID-19 pandemic left low- and middle-income countries vulnerable to supply shortages of life-saving health products. Practical mechanisms to facilitate increased local production of health products will enhance the capacity of developing countries to effectively address public health emergencies and outbreaks without relying on donations.

New Article 44A

The COVID-19 pandemic made it clear that global pandemic prevention, preparedness, and response is not adequately financed. Many components of the Regulations are important but will not be effective if there is not sustainable and equitable financing. The proposal from the Member States of the WHO Africa Region for a new Article 44A within the IHR aims to close the financing gap that has hindered the implementation of the Regulations. In response to the proposed Article, the Review Committee regarding amendments to the International Health Regulations (2005) highlighted the role of the Pandemic Fund in PPPR. We are concerned that the Pandemic Fund is an inadequate tool to ensure equitable financing for the IHR due to the limited role of developing countries and the WHO in the management of the fund. Sustainable and equitable financing should be prioritized to assist in the implementation of the Regulations.

Annex 1

The capacity of States Parties to respond to COVID-19 was inadequate to avoid unnecessary loss of life and economic damage. The challenges during the COVID-19 pandemic illuminated the need for developed and developing countries alike to better prepare for public health risks. The core capacities currently included in Annex 1 of the Regulations are limited to requirements for surveillance and response. It is important that the core capacities are amended to reflect the lessons that have been learned during the COVID-19 pandemic. We encourage the U.S. government to consider the proposals from the Member States of the WHO Africa Region, Bangladesh, and India to expand the public health response capacities and to include health system capacities in Annex 1.

We appreciate the opportunity to comment. Thank you.