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Building Capacities for Equitable Access and Strengthening Accountability

IHR 2005 Amendments: Setting the Legal Framework for Equity

Von Nithin Ramakrishnan

After negotiations spanning over 2 years, International Health Regulations (IHR) 2005 was amended by consensus during the 77th Session of World Health Assembly (WHA77) in the first week of June 2024 (WHO, 2024). The amendments set out the legal framework for delivery of equity in health emergency preparedness and response.

77th World Health Assembly June 1st 2024. Photo: Pan American Health Organisation/flickr.com; CC BY-NC-ND 4.0 Deed

The IHR 2005 are the regulations adopted under the Article 21 of the Constitution of WHO and contain legal obligations of the States Parties and mandates of WHO for addressing public health emergencies of international concern (PHEIC). One of the drawbacks of the IHR adopted in 2005 was the lack of explicit legal provisions requiring WHO and States Parties to ensure equitable access to health products to prevent disease outbreaks from becoming public health emergencies of international concern (PHEIC).

The amendments adopted by WHA77 address this gap. Around 24 Articles out of 66 Articles, and 6 Annexes out of 9 Annexes were amended substantively and 2 new Articles were added. Amendments in Articles 1, 3, 13, 15-18, 44, and Annex 1 and the two new Articles, 44 bis and 54 bis, help in particular addressing the gaps relating to equitable access to health products.

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This addition in IHR principles is further augmented by several other amendments that can operationally deliver equity in health emergency preparedness and response, provided the amended regulations get implemented in their true spirit. These amendments are:

- obligations of States Parties and WHO to facilitate equitable access to health products and technologies including through building national core capacities and scaling up or diversifying manufacturing of the health products (Article 13 and Annex 1);
- to support and assist each other in building or strengthening core capacities and implementing regulations (Article 44);
- to enable access to financial resources for addressing needs and priorities of developing countries (Article 44 and 44 bis); and
- the establishment of the States Parties Committee for Implementation of IHR 2005 to look after the implementation particularly through international collaboration and assistance (Article 54 bis).

Article 1 is amended to include a definition for "relevant health products" which among others include medicines, vaccines, diagnostics, vector control products, as well as health technologies required for responding to PHEIC, including pandemic emergencies.

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What really changed in IHR 2005 about access to health products?

As mentioned above, the IHR 2005 places significant emphasis on developing and enhancing specific public health core capacities identified in Annex 1. States Parties are required not only to regularly maintain these capacities but also to assist each other in their establishment and upkeep. The IHR mandates states to conduct surveillance and report public health events that could potentially become international concerns to the WHO and then forge an internationally coordinated response to such events, especially when the situation is considered as PHEIC by the WHO. The recent amendments have integrated legal provisions into all these mandates and processes to ensure equitable access to health products.

The amendments to Annex 1 identify capacities for "access to health services and health products needed for the response" as core capacities including at the sub-national levels. The States Parties are obliged to develop such capacities ranging from local production and

distribution capacities to procurement, stockpiling, deployment and surge capabilities. They should support each other, particularly assist developing countries in maintaining these capacities. The WHO and the Coordinating Financial Mechanism, established under Article 44 bis, are also mandated to provide assistance to developing countries in this regard.

The newly incorporated paragraph 8 of Article 13 mandates WHO to facilitate, and work to remove barriers to, timely and equitable access by States Parties to relevant health products and technologies, during a PHEIC or the newly incorporated category of "pandemic emergency". Paragraph 2.d. of Article 44 also reiterates to provide assistance to States Parties upon request in this regard.

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For the above purposes, WHO Director-General (DG) is further mandated the following tasks under Article 13, paragraph 8:

- periodically review and update, assessments of the public health needs, as well as of the availability and accessibility including affordability of relevant health products, and consider them while issuing recommendations under various provisions of IHR;
- make use of or coordinate with mechanisms or networks that facilitate timely and equitable access to relevant health products, including establishing such mechanisms if needed;
- support States Parties, upon their request, in scaling up and geographically diversifying the production of relevant health products through WHO coordinated Mechanisms and Networks;
- share product dossiers with regulatory agencies for the purpose of regulatory evaluation and authorization with consent of the manufacturer;

- promote research and development, local production and facilitate other measures relevant for the full implementation of this provision.

Some commentators express worries about these amendments whether they indicate transitioning of WHO into a supply agency (Clark and Sirleaf 2024). They question whether WHO is best suited for this role.

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These worries are unfounded, as the amendments are not reducing WHO into a supply agency. In fact, they reinforce constitutional functions of WHO in directing and coordinating international health work. Several coordinated mechanisms and networks such as i-MCM-Net, Health Technology Access Pool, and the International Coordinating Group (ICG) on Vaccine Provision are already existing with WHO. The amendments place these mechanisms within a legal framework enhancing their accountability and delivery. They empower Member States to demand predictable and timely services from such mechanisms. For example, they can demand the Local Production and Assistance Unit of WHO to develop resources or processes for sharing knowledge, or skills including through development of technical specifications of relevant health products or for removing barriers in technology transfer process for local manufacturing. Consequently, these amendments reduce the ad hoc, or charitable nature of WHO's emergency assistance operations.

Article 13 also mandates States Parties to support WHO-coordinated response activities, including the implementation of WHO mandates. They must engage with stakeholders within their jurisdictions to ensure equitable access to relevant health products. This could include incentivizing or mandating stakeholders to collaborate with WHO-coordinated networks or mechanisms, and implementing recommendations from the DG. States are further obligated to disclose the terms of their research and development agreements that facilitate equitable access to relevant health products, promoting transparency in these engagements.

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Implementation Challenges and Need for Continued Engagement

Several commentators have highlighted implementation as a critical challenge of IHR 2005, both before (Aavitsland et al., 2021) and after amendments (Habibi, 2024; Fiddler, 2024; Searchinger, 2024). The co-chairs of the Working Group on Amendments to IHR 2005 (WGIHR) have acknowledged the absence of compliance measures within the mandate of the newly established Implementation Committee (Bloomfield & Assiri, 2024). Concerns about potential reservations by States Parties or opting out of amendments are also prevalent (Patnaik, 2024a; Clark and Sirleaf, 2024).

Another critique is that the amendments are not subjecting States Parties to concrete obligations but "*to weak, loophole-laden, and process-oriented duties on health-product access, such as undertaking to collaborate with and assist other parties and support the WHO's activities, subject to applicable law and available resources*" (Fiddler, 2024).

Despite the challenges mentioned above, the amendments offer a crucial merit: they lay down the legal framework for the delivery of equity and infuse accountability in the WHO's work relating to health emergencies, including through the coordinated mechanisms and networks. It provides a platform for examining the implementation barriers within these mechanisms or other structural barriers in enabling equitable access and devising effective solutions.

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Article 44, as amended, specifies that the DG shall report all its work on expanding access to and funding for relevant products to the health assembly (CRS, 2024). States Parties will also report the outcomes to health assembly. The Implementation Committee is also specifically tasked to facilitate the effective implementation of these Regulations, in particular of Article 44 and 44 bis. A subcommittee is also established to provide technical advice.

The terms of reference, conduct of business and modalities of the above committees and the coordinating financial mechanism are yet to be developed, with this process slated for adoption such modalities at the first meeting of the Implementation Committee. The WHA Resolution 77.17 which adopted the amendments requires commencement of the work towards the first meeting of the committee by the DG.

Civil society organizations can and should play a pivotal role in this work as well as in the future operations of these bodies to ensure that these committees and the financial mechanism operate inclusively, transparently, and accountably.

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Towards "IHR Plus Equity" in the Pandemic Instrument

The WHA77, while adopting amendments to IHR 2005, also extended the mandate of the Intergovernmental Negotiating Body (INB) negotiating for the development and adoption of a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response. Some commentators have noted a significant overlap (Michaud et al., 2024) between IHR 2005 and the proposed pandemic instrument. WGIHR Co-chair also enunciates amendments to IHR 2005 clearly applies to pandemic prevention, preparedness and response (Patnaik 2024b).

Regardless, the amendments to IHR 2005 incorporated a new alert of "pandemic emergency" to trigger more effective international collaboration in response to PHEICs that are at risk of becoming, or have become, a pandemic (Article 12). It is evident from the definition of pandemic emergency (Article 1) that the alert represents a higher level of alarm (WHO, 2024) and requires enhanced coordinated international action. Therefore, the new pandemic instrument should definitely reflect a higher standard of equity and solidarity.

The INB is mandated to take into account discussions and outcomes from the WGIHR, the successor of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR) (WHA Decision SSA2(5)). All these means the INB Negotiations should look into where the current negotiating text stands in comparison with the equity already guaranteed under IHR 2005. The INB should work towards enhanced equity provisions that should detail the actions States Parties and WHO must undertake or refrain from in pandemic prevention, preparedness and response.

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