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ABSTRACT

The amendments to the International Health Regulations (2005) (IHR) agreed upon in May 2024 are important for strengthening global health emergency preparedness and response. The negotiations resulted in the IHR amendment now recognizing the importance of equity, including equitable access to health products, enhancing IHR core capacities, and mobilizing financing. The amendments note the role of the World Health Organization (WHO) in facilitating timely access to necessary health products by removing barriers and supporting local production and distribution. However, the WHO authority to effectively act in those areas is limited. The IHR as amended will establish a Coordinating Financial Mechanism to provide predictable and sustainable financing for its implementation, particularly in developing countries.

Despite some advancements, the amendments fall short of imposing concrete obligations on developed countries to facilitate timely access to health products and financial support and transfer of technology to developing countries. Overall, the amended IHR represent a significant step toward a more equitable global health framework, setting a precedent for future international health instruments, including the proposed pandemic treaty.

Las enmiendas al Reglamento Sanitario Internacional (2005) (RSI) acordadas en mayo de 2024 son importantes para reforzar la preparación y respuesta a las emergencias sanitarias mundiales. Como resultado de las negociaciones, la enmienda al RSI reconoce ahora la importancia de la equidad, incluido el acceso equitativo a los productos sanitarios, la mejora de las capacidades básicas del RSI y la movilización de la financiación. Las enmiendas señalan el papel de la Organización Mundial de la Salud (OMS) a la hora de facilitar el acceso oportuno a los productos sanitarios necesarios mediante la eliminación de barreras y el apoyo a la producción y distribución locales. Sin embargo, la autoridad de la OMS para actuar eficazmente en esos ámbitos es limitada. El RSI enmendado establecerá un Mecanismo Financiero de Coordinación para proporcionar una financiación previsible y sostenible para su aplicación, especialmente en los países en desarrollo.

A pesar de algunos avances, las enmiendas se quedan cortas a la hora de imponer obligaciones concretas a los países desarrollados para facilitar el acceso oportuno a los productos sanitarios y el apoyo financiero y la transferencia de tecnología a los países en desarrollo. En general, el RSI enmendado representa un paso significativo hacia un marco sanitario mundial más equitativo, sentando un precedente para futuros instrumentos sanitarios internacionales, incluido el tratado propuesto sobre pandemias.

Les amendements au Règlement sanitaire international (2005) (RSI) adoptés en mai 2024 sont importants pour renforcer la préparation et la riposte aux urgences sanitaires dans le monde. Les négociations ont abouti à l'amendement du RSI reconnaissant désormais l'importance de l'équité, y compris l'accès équitable aux produits de santé, le renforcement des capacités de base du RSI et la mobilisation des financements. Les amendements soulignent le rôle de l'Organisation mondiale de la santé (OMS) dans la facilitation de l'accès rapide aux produits de santé nécessaires en supprimant les obstacles et en soutenant la production et la distribution locales. Toutefois, l'autorité de l'OMS pour agir efficacement dans ces domaines est limitée. Le RSI, tel qu'il a été modifié, établira un mécanisme financier de coordination afin de fournir un financement prévisible et durable pour sa mise en œuvre, en particulier dans les pays en développement.

Malgré certaines avancées, les amendements ne parviennent pas à imposer aux pays développés des obligations concrètes visant à faciliter l'accès ponctuel aux produits de santé, le soutien financier et le transfert de technologies vers les pays en développement. Dans l'ensemble, le RSI modifié représente une étape importante vers un cadre de santé mondial plus équitable, créant un précédent pour les futurs instruments de santé internationaux, y compris le projet de traité sur les pandémies.

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I. INTRODUCTION

The 2024 World Health Assembly (hereinafter "the Health Assembly") of the World Health Organization (WHO) adopted a number of important amendments to the International Health Regulations (2005) (IHR) – an international legal instrument adopted under article 21 of the WHO Constitution. The IHR is currently the principal normative tool of the WHO to respond to international health emergencies.

The IHR precedes the establishment of the WHO in 1948. International treaties relating to specific diseases, known as the "International Sanitary Conventions" in the nineteenth century, were later adopted by the WHO as International Sanitary Regulations (ISR) under article 21 of the WHO Constitution. The ISR were revised and approved as the IHR in 1969. The nineteenth century origin of the IHR in the sanitary conventions has significantly shaped the basic approach followed in the IHR towards international health emergencies. The sanitary conventions were focused on safeguarding the mercantile powers from pandemic threats originating in the colonies and other impoverished countries through quarantine standards and other border health protocols. Notably, two normative principles of the sanitary conventions are also fundamental principles of the IHR – that every government must notify other governments on disease outbreaks within their borders, and that there should be an international clearing-house mechanism for notification and exchange of information on epidemics.[1]

The IHR (1969) was revised in 2005 to expand its scope to cover the international spread of any disease, including health emergencies that do not relate to a particular disease.[2] The IHR lays down minimum core capacities that States parties must put in place to detect, assess, report and respond to potential public health emergencies of international concern (PHEIC). However, most developing countries have not been able to fully establish these core capacities due to domestic resource constraints, and very few developed countries have provided them technical cooperation or financial support to build core capacities, despite the requirement in the IHR to do so.[3] In addition, significant gaps in the IHR with regard to the powers of WHO to assist States parties and obtain information in the early stages of outbreaks, as well as deficiencies in the process, timing, criteria of making PHEIC declarations, transparency of decision-making, compliance of States parties to the temporary recommendations, and preparedness of national public health systems, were widely acknowledged in the aftermath of the COVID-19 pandemic.[4] The Review Committee on the Functioning of the IHR (2005) during the COVID-19 Response found that there was inadequate compliance with IHR obligations by States parties, inadequate application of early alert mechanisms and processes, and insufficient political will and financial resources, which contributed to COVID-19 becoming a protracted global health emergency.[5]

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[1] See N. Syam, *Leading and Coordinating Global Health: Strengthening the World Health Organization*, Research Paper 174 (South Centre, Geneva, 2023), available from https://www.southcentre.int/wp-content/uploads/2023/02/RP174_Leading-and-Coordinating-Global-Health-Strengthening-the-World-Health-Organization_EN.pdf.

[2] Ibid. The 2005 revisions were adopted 10 years after the 1995 World Health Assembly instructed the WHO secretariat to revise the IHR and create mechanisms to make States parties adhere to technical regulations.

[3] L. O. Gostin and R. Katz, "The International Health Regulations: The Governing Framework for Global Health Security", *The Milbank Quarterly*, vol. 94, no. 2 (2016), available from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4911720/.

[4] See A. Phelan and P. Pillai, "International Health Law in Perspective", Background paper 16, The Independent Panel for Pandemic Preparedness and Response, May 2021, available from https://theindependentpanel.org/wp-content/uploads/2021/05/Background-paper-16-International-treaties.pdf.

[5] P. Aavitsland, *et. al.,* "Functioning of the International Health Regulations during the COVID-19 pandemic", *The Lancet*, vol.398, 2021, pp.1283-7, available from https://www.thelancet.com/action/showPdf?pii=S0140-6736%2821%2901911-5.

In January 2022 the WHO Executive board by decision EB150(3) mandated the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies to allow discussions on strengthening the IHR, including through implementation, compliance and potential amendments, and urged member States to consider potential amendments to the IHR which should be limited in scope and address specific and clearly identified issues, challenges —including equity, technological or other developments— or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation and compliance of IHR.[6] The WHO Executive Board mandated the amendment of the IHR in response to the COVID-19 pandemic, aiming to strengthen international legal norms for pandemic preparedness and response, following a US proposal and consultations among Member States.[7] Decision WHA75(9) in May 2022 revised the mandate of the working group to rename it as the Working Group on Amendments to the International Health Regulations (2005) (WGIHR) to work exclusively on consideration of proposed targeted amendments to the IHR for consideration by WHA77.[8]

Pursuant to its mandate eight sessions of the WGIHR were held between November 2022 and May 2024 focusing on amendments to the IHR proposed by Member States.

The WGIHR engaged in text-based negotiations on about 300 proposals from both developed and developing countries. Proposals from developing countries emphasized creating legal obligations and mandates for States parties and the WHO to ensure equitable access to health products and technologies necessary for public health emergency preparedness and response for all populations.[9] A major concern for developing countries in view of the experience of the COVID-19 pandemic was that calls and pledges for solidarity and equity-based actions to enable such countries to respond to the pandemic promptly, effectively and on an equal footing with developed countries, were ignored in practice. This resulted in delayed and inadequate access to medical and health products such as diagnostics, vaccines and therapeutics, and the sharing of technologies (including know-how), and the components for scaling up local production and supply of such products in developing countries.[10] This happened even though health products such as vaccines and therapeutics were developed with unprecedented speed and pathogen sequences were rapidly shared by all countries to facilitate their rapid development.[11] On the other hand, for developed countries, the priorities in the IHR amendments were focused on strengthening obligations on compliance, accountability, access to information, and surveillance.[12]

The negotiations in the WGIHR took place in parallel with the negotiations on a WHO convention, agreement or other international instrument on pandemic prevention,

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[6] WHO, Decision EB150(3), 26 January 2022, available from https://apps.who.int/gb/ebwha/pdf_files/EB150/B150(3)-en.pdf.

[7] N. Syam, "Mainstreaming Equity in the International Health Regulations and Future WHO Legal Instruments on Pandemic Preparedness and Response", Policy Brief No.108, South Centre, Geneva, 25 March 2022, available from https://www.southcentre.int/policy-brief-108-25-march-2022/.

[8] WHO, Decision WHA75(9), 27 May 2022, available from https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75(9)-en.pdf.

[9] N. Ramakrishnan and K.M. Gopakumar, "WHO: IHR 2005 amendments adopted, includes equity-related provisions", TWN Info Service on Health Issues, 7 June 2024, available from https://twn.my/title2/health.info/2024/hi240601.htm.

[10] See, e.g., Correa, C. (2021). Expanding the production of COVID-19 vaccines to reach developing countries: Lift the barriers to fight the pandemic in the Global South. Policy Brief 92, South Centre, Geneva. Available from https://www.southcentre.int/wp-content/uploads/2021/04/PB-92.pdf.

[11] Syam, *supra* note 7.

[12] P. Patnaik, "Choice Facing Countries: Expand Scope or Preserve Core Functions? [Amendments to the International Health Regulations], *Geneva Health Files*, 17 February 2023, available from https://genevahealthfiles.substack.com/p/choice-facing-countries-expand-scope. See also Priti Patnaik and Nishant Sirohi, "Countries Split Between Retaining Existing Scope on Surveillance vs Widening Commitments on Equity in the Amendments to IHR", *Geneva Health Files*, 21 April 2023, available from https://genevahealthfiles.substack.com/p/exclusive-countries-split-between?utm_source=post-email-title&publication_id=79396&post_id=115805034&isFreemail=false&triedRedirect=true.

preparedness and response (hereinafter the "pandemic treaty") in the Intergovernmental Negotiating Body (INB) established by the Special Session of the World Health Assembly held in December 2021.[13] Given the overlapping nature of issues being addressed in the two negotiations, a coherent approach to ensure complementarity between the two instruments was critical. In this regard, the Bureau of the WGIHR and the INB held regular joint meetings, and in addition the member States of the WGIHR and INB also held a number of joint plenary sessions. In the first joint plenary session in July 2023, developing countries emphasized the need to incorporate equity in both the new pandemic treaty as well as in the amended IHR. In particular, developing countries strongly urged for the inclusion of provisions to facilitate equitable access to health products and technologies in both instruments.

Developing countries also stressed in this meeting that the IHR and the pandemic treaty should be approached as two instruments on an equal footing, which are interrelated and inseparable as they address two stages of the same issue.[14]

This has resulted in a number of equity-related provisions in the IHR text being transposed from the proposals in the pandemic treaty text. At the same time, some equity issues such as pathogen access and benefit-sharing and transfer of technology have not been addressed in the IHR text. This makes it critical to see how the continued negotiations[15] on such issues in the pandemic treaty text link to the IHR text and complement it.

In the following sections, this paper discusses the new amendments to the IHR, as adopted in May 2024. These amendments encompass significant changes aimed at strengthening global health emergency preparedness and response. The changes introduce new definitions for "National IHR Authority," "pandemic emergency," and "relevant health products"," enhancing clarity and operational roles. The amendments expand the IHR scope to emphasize disease preparedness and incorporate equity and solidarity as guiding principles. They mandate the creation of a National IHR Authority for better national coordination and establish a Coordinating Financial Mechanism to support core capacities, promoting equitable access to health resources. The Emergency Committee's advisory role is strengthened, and a States Parties Committee for IHR Implementation is set up to enhance cooperation and best practice sharing. However, the amendments fall short in imposing concrete obligations on developed countries to provide financial or technological support to developing countries, delegating these responsibilities to WHO instead. The effectiveness of these changes will largely depend on the support and cooperation from Member States.

[13] WHO document, SSA2(5), 1 December 2021, available from https://apps.who.int/gb/ebwha/pdf_files/WHASSA2/SSA2(5)-en.pdf.
[14] N. Ramakrishnan, "WHO: South calls for "equity across the board" in joint WGIHR/INB meeting", *TWN Info Service on Health Issues,* 14 August 2023, available from https://twn.my/title2/health.info/2023/hi230802.htm.
[15] The 2024 World Health Assembly decided extend the mandate of the INB and instructed the INB to submit its outcome to the Health Assembly in May 2025 or , if possible, in a special session of the Health Assembly in 2024. WHO document, A77/A/CONF./15, 1 June 2024, available from https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_ACONF15-en.pdf. https://globalhealth.us17.list-manage.com/track/click?u=4d339f44c001ce41a5109b477&id=a95e434ff5&e=268da452da

II. Definitions, Purpose and Scope, Principles and Responsible Authorities

II.1 Definitions

In the context of the recent amendments to the IHR, the inclusion of new definitions is crucial for enhancing the clarity and operational effectiveness of the regulations. The new definitions are intended to streamline coordination and response efforts, ensuring all parties have a clear understanding of their roles and responsibilities. This section outlines the specific definitions added to article 1, providing the foundational context for these amendments.

Three new definitions have been incorporated in article 1 of the IHR. These are definitions of "National IHR Authority", a "pandemic emergency", and "relevant health products".

A "National IHR Authority" is defined as the entity designated or established by the State party at the national level to coordinate the implementation of the IHR within its jurisdiction. Thus, the amended IHR will have two authorities at the national level – a national IHR authority as designated by a State party to coordinate IHR implementation nationally, and a national IHR focal point designated by a State party to be accessible at all times for communications with WHO IHR contact points.

A "pandemic emergency" is defined as:

a public health emergency of international concern that is caused by a communicable disease and:

(i) has, or is at high risk of having, widespread geographical spread to and within multiple States; and
(ii) is exceeding, or is at high risk of exceeding, the capacity of health systems to respond in those States; and
(iii) is causing, or is at high risk of causing, substantial social and /or economic disruption, including disruption to international traffic and trade; and
(iv) requires rapid, equitable and enhanced coordinated action, with whole-of-government and whole-of-society approaches.[16]

However, critics point out that this definition merely formalizes what the WHO Director-General (DG) was empowered under IHR (2005) to do —declare a PHEIC on disease events that were or could become a pandemic— and does not substantially alter the IHR provisions and processes, enhance the DG's authority, or create specific obligations relating to pandemics.[17] This is because the discussion was, first, how to refer to a situation of "pandemic" in the pandemic treaty in a way that was aligned with the IHR. It was agreed that the IHR should specify that a "pandemic emergency" is a type of PHEIC in order to include the same language in the pandemic treaty. Second, there were some parties that wanted an intermediary level of alert to trigger action by the WHO DG prior to a PHEIC, but there was finally no agreement on that.

[16] WHO document A/77/9, Annex 1.
[17] David P. Fidler, "The Amendments to the International Health Regulations Are Not a Breakthrough", *ThinkGlobalHealth*, 7 June 2024, available from https://genevahealthfiles.substack.com/p/exclusive-countries-split-between?utm_source=post-email-title&publication_id=79396&post_id=115805034&isFreemail=false&triedRedirect=true.

A new definition of “relevant health products” clarifies that all health products needed to respond to a PHEIC, including a pandemic emergency, will be considered to be relevant health products under the IHR. The definition is non-exhaustive and includes within its scope not only finished health products but also any health technology needed to respond to PHEICs and pandemics.

II.2 Purpose and Scope

The purpose and scope of the IHR as stated in article 2 has been expanded to include preparedness for the international spread of diseases. Inclusion of preparedness within the scope of IHR is important because it transforms the scope of the IHR from an instrument that is shaped by health security concerns of protection and response against international spread of diseases, to an instrument that is based on a public health approach focused as well on preparedness for PHEICs and pandemics. This broadened scope of the IHR is further elaborated through specific obligations in subsequent provisions on expanding IHR core capacities beyond surveillance capacities to include access to health services and health products.[18] These amendments are particularly crucial for developing countries. This expansion of IHR core capacity requirements seeks to ensure that these countries can not only detect and report public health emergencies but also respond effectively by having the necessary medical resources and services in place. By improving access to health services and products, these amendments aim to address the significant disparities in health infrastructure and resource availability, thereby enhancing equity and preparedness globally.

II.3 Principles

Article 3.1 of the amended IHR has included equity and solidarity as principles for the implementation of the IHR. This is a first for a normative instrument on global health to refer to equity and solidarity as principles. In this sense, the IHR sets an important precedent for any future instrument on global health, such as a pandemic treaty. In particular, as an interpretative tool, the explicit reference to equity means that every provision of the IHR must be interpreted in the light of this principle.

II.4 Responsible Authorities

The IHR (2005) required States parties to establish or designate a National IHR Focal Point. The scope of the IHR in this regard has been expanded to require States parties to designate or establish a National IHR Authority[19] to coordinate the implementation of the Regulations in their territories.[20] While States parties have the obligation to establish two responsible authorities, they have discretion in the setting up of these authorities. The powers of these authorities may be vested in the same agency if a State party so desires. States parties are also required to share the contact details of their national authorities with the WHO for sharing with States parties.

While the new requirement for States parties to designate an additional national authority is reflective of existing concerns about IHR implementation, the mere designation of an additional national authority may have limited significance. This is because, as pointed out by Fidler, “The IHR is a treaty, and, under international law, treaty parties are required to implement treaty obligations within their jurisdictions. How parties execute domestic

[18] WHO document A/77/9, Annex 1.
[19] Ibid., Article 1.1.
[20] Ibid., Article 1.1 bis

implementation is a matter of national law."[21] This is reflected in article 4.2bis: "States Parties shall take measures to implement paragraphs 1, 1 bis, and 2 of this Article, including, as appropriate, adjusting their domestic legislative and/or administrative arrangements."[22]

During the negotiations, the Bureau of the WGIHR had proposed the creation of two new additional national authorities – the National IHR Authority and a National IHR Competent Authority. In addition to the agreed upon mandate of the National IHR Authority, the function of the proposed National IHR Competent Authority was to guide and oversee implementation of the IHR provisions relating to points of entry and/or conveyance operators and/or travelers, and the identification of competent authorities at points of entry in their territories. The establishment of two additional national authorities posed the risk of deep fragmentation of institutional arrangements for domestic implementation of the IHR and associated financial and technical resources.[23] Though these concerns are somewhat mitigated with the requirement of establishment of only one additional national authority, and the discretion available to States parties to vest the powers of both the national authorities in the same agency, they still remain valid.

[21] Fidler, *supra* note 15.
[22] WHO document A/77/9.
[23] K.M. Gopakumar and N. Ramakrishnan, "WHO: WGIHR Bureau's push for 2 new national institutions for IHR implementation raises concerns", TWN Info Service on Health Issues, 6 February 2024, available from https://www.twn.my/title2/health.info/2024/hi240202.htm.

III. Information And Public Health Response

III.1 Surveillance

Obligations relating to surveillance under article 5 of the IHR have been retained. Article 5 required States parties to develop, strengthen and maintain core capacities to detect, assess, notify and report events. An important addition in article 5 is an obligation of States parties to develop, strengthen and maintain core capacities for prevention, and a corresponding obligation to assist States parties to do so, upon request. While developed countries' have an interest in developing countries' core capacities on surveillance and reporting on potential or actual threats,[24] there were no commitments on supporting capacity building for surveillance in developing countries, despite the proposals made during the negotiations.

A proposal by the United States (US) to add a new paragraph 5 in article 5 to develop early warning criteria for assessing and progressively updating the national, regional, or global risk posed by an event of unknown causes or sources, and convey the risk assessment to States Parties, was not adopted in the final outcome. This would have altered the IHR approach to risk assessment by grading it into national, regional and global levels and could have potentially enabled developed countries to abdicate from their responsibilities in a PHEIC, including a pandemic, by classifying the same as a "regional" health emergency. At the same time, it could have created a trigger for additional support and temporary recommendations at an earlier stage than a PHEIC.

III.2 Notification

In article 6.1, new text has been added to require the WHO to immediately notify a competent intergovernmental organization if the notification of an event received by the WHO from a State party requires the competence of that intergovernmental organization. Before the amendment, the IHR only required a notification by the WHO to the International Atomic Energy Agency. The reference to other intergovernmental organizations has been made in the context of a proposal by the US that such notification should be also made to the Food and Agriculture Organization (FAO), the World Organization for Animal Health (OIE), the United Nations Environment Programme (UNEP), and other entities. The agreed text allows WHO to issue immediate notifications of events to these intergovernmental organizations. However, immediate sharing of information with a relevant intergovernmental organization even before assessing the information shared by State parties scientifically could have adverse economic implications for the affected countries. Hence, the WHO should prudently implement this requirement.

There is no change in the text of article 6.2 about communications between a State party and the WHO following notification of an event by that State party. A proposal by the US and EU for sharing epidemiological and clinical data, as well as microbial and genomic data in case of an event caused by an infectious agent, and genome sequencing data if available, was not adopted. The non-adoption of specific obligations on data sharing is significant because any obligation in this respect in the IHR would have prejudiced the ongoing negotiations on the establishment of a Pathogen Access and Benefit-Sharing System (PABS) in the INB under

[24] W. Aldis, "Health security as a public health concept: a critical analysis", *Health Policy and Planning*, vol.23, Issue 6, 2008, pp. 369-75, available from https://academic.oup.com/heapol/article/23/6/369/572074#google_vignette.

the pandemic treaty, where many States have stressed that benefit-sharing should be addressed on an equal footing with sharing of pathogen samples and data.[25]

III.3 Information-Sharing During Unexpected and Unusual Public Health Events

The European Union (EU) had also proposed an obligation under article 7 of the IHR for the WHO to make the information received available to all Parties in accordance with modalities to be adopted by the Health Assembly, for the purpose of fostering event related research and assessment. On the other hand, developing countries had proposed that the rules on information sharing should take into account the need for benefit-sharing. The African Group proposed that "No sharing of genetic sequence data or information shall be required under these Regulations. The sharing of genetic sequence data or information shall only be considered after an effective and transparent access and benefit sharing mechanism with standard material transfer agreements governing access to and use of biological material including genetic sequence data or information relating to such materials as well as fair and equitable sharing of benefits arising from their utilization is agreed to by WHO Member States, is operational and effective in delivering fair and equitable benefit sharing".[26]

In the final outcome, none of these proposals were adopted and article 7 of IHR remains unchanged with no new obligation on information sharing. Thus, in the event of the occurrence of an unusual or unexpected public health event which may constitute a PHEIC, a State party concerned has to provide all relevant public health information to the WHO. However, the State party will have the discretion to determine what is relevant public health information and will not have a specific obligation under the IHR to disclose the genetic sequence information of a pathogen causing the event. This issue, however, will continue to be discussed in the context of the negotiations on the pandemic treaty.

III.4 Consultation

For events that do not require a notification in terms of the decision instrument under Annex 2 of the IHR, a State party is given the discretion under article 8 to advise the WHO about the event, particularly if there is insufficient information to complete the Annex 2 decision instrument. This provision has been amended to encourage the State party to provide such advice to the WHO in a timely manner.

III.5 Reports from other sources and verification

Article 9 of the IHR gives discretion to the WHO to take into account reports from sources other than notifications under article 6 or consultations under article 8. If the WHO takes such other reports into account, it is mandated to assess these reports in accordance with established epidemiological principles and then communicate the information about the event to the State party in whose territory the reported event is allegedly occurring. Further, before taking any action based on such reports, the WHO is bound to consult with the State party and attempt to obtain verification from it. This verification procedure is laid down in article 10.

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[25] Malaysia had made a proposal pointing to the need for considering the capacities of States Parties in sharing genetic sequence data. See WHO, Proposed Amendments to the International Health Regulations (2005) submitted in accordance with decision WHA75(9) (2022), available from https://apps.who.int/gb/wgihr/pdf_files/wgihr1/WGIHR_Submissions_Original_Languages.pdf.
[26] TWN, "WHO: North's proposals to take centre stage in IHR working group meeting", TWN Info Service on Health Issues, 24 July 2023, available from https://www.twn.my/title2/health.info/2023/hi230704.htm.

During the WGIHR negotiations, the US had made a proposal to delete the consultation requirement under article 9. This would have empowered the WHO to proceed with actions based on the information received from other States or third parties without the mandatory consultation with the concerned State Party for verification under Article 10. However, this proposal has not been adopted and article 9 of the IHR remains unchanged.

The US had also proposed several related amendments under article 10 – a 24 hour timeframe for the WHO to request a verification of an event reported by third parties without undergoing consultations under article 9; removal of reference to article 9 in article 10.2; adding references to the proposals made under article 6.2 to provide genetic sequence information; a 24 hour timeline for WHO to offer assistance to collaborate with the concerned State party; deeming failure to respond to the WHO offer within 48 hours as rejection of the WHO offer; removing the discretion of the WHO to share the information with other States parties immediately after rejection or non-acceptance of the offer and making it mandatory for WHO to do so.

None of the amendments to article 10 proposed by the US were substantially accepted. Article 10.4 has been amended stipulating that the "WHO **should** share with other States Parties the information about the event available to it" (emphasis added). Hence, sharing the information by the part of WHO remains discretionary.

III.6 Provision of Information by WHO

The US also proposed several changes to Article 11 of the IHR regarding how the WHO shares information from State parties:

- **Automatic Sharing of Information:** The US suggested that WHO should share information received from State parties by default, unless the State party explicitly objected. This contrasts with the existing rule, where WHO needs the explicit agreement of the State party to share information.
- **Discretion for WHO:** A proposed new sub-clause (e) would have allowed WHO to share information without State party agreement if it deemed it necessary for other States to make informed, timely risk assessments.
- **Notification Instead of Consultation:** The US wanted to change WHO obligation from consulting with the State party before sharing information to merely informing them.

However, these proposals were not adopted. The only change made was to include "pandemic emergency" in the conditions under which WHO can share information, which does not significantly alter the fundamental scheme of Article 11.

III.7 Declaration of PHEIC

According to article 12, the WHO DG must consult with the affected States parties where the event is occurring which the DG considers to be a PHEIC based on the assessment under the IHR, before convening an Emergency Committee (EC) to seek its advice on the matter. Paragraphs 2 and 3 of article 12 specify that the DG has 48 hours to convene the EC after consulting with the affected State Party to reach an agreement. If the affected State Party disagrees with the WHO, the DG can still convene the EC after 48 hours.

The US had proposed several changes to this provision, including:

- Notifying all States parties about a potential or actual PHEIC concern before the EC is convened.

- Introducing new concepts such as “public health emergency of regional concern” and “intermediary health alert,” which would be determined by the WHO Regional Director or the DG.
- Removing the 48-hour period for consultation with States parties before establishing the EC.
- Consulting with all relevant States Parties, including those not affected by the disease or public health emergency, to determine when the emergency has ended.

In the final outcome these proposals were not adopted. A new paragraph 4bis has been adopted under article 12 which requires the DG upon the determination of a PHEIC to further determine whether the PHEIC also constitutes a pandemic emergency. In accordance with article 12.4, this determination must also be based on a consideration of the information provided by States parties, the decision instrument in Annex 2, the advice of the Emergency Committee, scientific principles as well as the available scientific evidence and other relevant information, an assessment of the risk to human health, the risk of international spread of the disease and the risk of interference with international traffic. By specifically laying down the process of declaring a PHEIC as a pandemic emergency, the new paragraph 4bis provides clarity on the formal construct of a pandemic in terms of the IHR. Moreover, this also renders clarity in terms of when related obligations on a pandemic under a potential pandemic treaty that is currently being negotiated in the INB would become operational.

III.8 Equitable Access to Health Products

Inclusion of equitable access to health products within the scope of the IHR was a major demand of the developing countries in the WGIHR negotiations. To this end developing countries had proposed the addition of a new article 13A specifically addressing access to health products, technology and know-how. The African Group and Bangladesh had proposed under this new article the following elements:

- mandate to the WHO DG to make an immediate assessment after a PHEIC determination of availability and affordability of required health products and make recommendations, including an allocation mechanism;
- obligation on States parties to cooperate with each other and the WHO and take measures to ensure timely availability and affordability of required health products for effective response to a PHEIC;
- obligation on States parties to provide exemptions and limitations to intellectual property (IP) rights under their IP laws and related laws and regulations to facilitate manufacture, export and import of required health products, including their materials and components;
- obligation on States parties and WHO to rapidly share regulatory dossiers on safety and efficacy, and manufacturing and quality control processes for the purpose of accelerating manufacturing and supply of products or technologies by the State parties receiving the regulatory dossiers, and also expediting regulatory approvals;
- obligations on WHO to take measures to ensure availability and accessibility of required health products through local production;
- obligations on States parties to ensure that manufacturers of health products and IP rights holders comply with the WHO allocation mechanism, donate a certain percentage of their production to the WHO upon request, publish their pricing policy transparently, share technologies and know-how for diversification of production, and submit regulatory dossiers when called for by States parties or the WHO; and

- obligation on the WHO to maintain a database containing the ingredients, components, design, know-how, manufacturing process or any other information required to facilitate manufacturing of health products required for responding to a PHEIC.[27]

However, this proposal was not substantially discussed in the WGIHR for almost one year since it was submitted at the third meeting of the WGIHR in February 2023. At the seventh meeting of the WGIHR in February 2024 developing countries reiterated the commitment made by the Bureau of the IHR at WGIHR 6 to consider the proposals and facilitate informal consultations in the intersessional period,[28] which was not done. Instead, the agenda of the seventh meeting of the WGIHR prioritized other issues.[29] Prior to the seventh session of the WGIHR, the WHO secretariat had proposed to the Bureau the deletion of the proposed new article 13A and instead include elements from that proposal in other provisions of the IHR and make cross references to the provisions in the pandemic treaty being negotiated in the INB.[30] It was agreed at the seventh meeting of the WGIHR that a dedicated session should be held to discuss the Bureau's text proposals on equity including article 13A. The Bureau's text proposed at the resumed seventh meeting of the WGIHR in March 2024 greatly diluted the article 13A as originally proposed. These dilutions included deletion of the paragraph in the proposal by African Group and Bangladesh that required States parties to provide exemptions and limitations to IP rights to facilitate the manufacture, export and import of health products, including materials and components. The Bureau proposed deletion of this clause as it considered this to be "... beyond the current and foreseeable scope" of the IHR.[31]

The Bureau's text on article 13A emphasized the role of WHO in supporting equitable access to health products during public health emergencies, detailing steps the DG will take once an emergency is declared. These included assessing and publishing availability and affordability of health products needed, establishing allocation mechanisms, and supporting local production and regulatory processes. However, the obligations for States parties to collaborate were framed in non-binding clauses, making equitable access uncertain. The text lacked clarity on key mechanisms, such as sourcing and sharing regulatory dossiers, and omitted several proposals from developing countries, like creating a product specifications database and a repository for biological materials. Thus, this draft was criticized as insufficient and somewhat speculative in ensuring meaningful equity in global health responses.[32] Moreover, developed countries tried to further dilute this text at the resumed seventh meeting of the WGIHR and also suggested shifting the discussion on health technologies and equitable access to the INB negotiations.[33]

At the eighth meeting of the WGIHR in April 2024, the Bureau submitted a consolidated Bureau's text based on the Bureau's assessment of areas of convergence on the textual proposals made by Member States. This text attempted to limit the IHR amendments to a few articles. With regard to equitable access, this text sought to accommodate some of the

[27] WHO, Proposed Amendments to the International Health Regulations (2005) submitted in accordance with decision WHA75(9) (2022).
[28] P. Patnaik and T. Jager, "Developing Countries Seek to Retain Equity Provisions in the amendments to the IHR", *Geneva Health Files*, 7 February 2024, available from https://genevahealthfiles.substack.com/p/wgihr-equity-who-2024-february-pandemic-pheic.
[29] N. Ramakrishnan and K.M. Gopakumar, "WHO: WGIHR 7 agenda proposes inequitable treatment for equity proposals", *TWN Info Service on Health Issues*, 5 February 2024, available from https://twn.my/title2/health.info/2024/hi240201.htm.
[30] TWN, "WHO: Bureau rejects Secretariat's proposal to delete equity-related IHR amendment proposals", *TWN Info Service on Health Issues,* 8 February 2024, available from https://twn.my/title2/health.info/2024/hi240203.htm.
[31] P. Patnaik and T. Jager, "Ëquity"in the International Health Regulations, Makes it to the Negotiating Table", *Geneva Health Files*, 11 March 2024, available from https://genevahealthfiles.substack.com/p/equity-who-ihr-geneva-ip-access-tech-pheic-amend.
[32] N. Ramakrishnan and K.M. Gopakumar, "WHO: Developed countries push to dilute WGIHR Bureau's half-hearted equity text", *TWN Info Service on Health Issues*, 11 March 2024, available from https://twn.my/title2/health.info/2024/hi240305.htm.
[33] Ibid.

proposed amendments under article 13A within article 13. It proposed adding "including access to health products" to article 13 and introduced new clauses that obligate the WHO to coordinate responses during emergencies, assess and ensure the availability of health products, assist States in accessing them, support production and diversification efforts, facilitate regulatory approvals, and strengthen local production and technology transfer.[34]

Despite this diluted version of the proposal made by the African Group and Bangladesh, developed countries proposed further dilutions at the eighth meeting of the WGIHR. These included qualifying the reference to health products as "relevant", conditioning technology transfer to be "voluntary" in addition to it being based on "mutually agreed terms" as proposed in the Bureau's text; deletion of references to the mandate for the DG to use existing WHO coordination mechanisms to facilitate access to health products and replacing the same with a general coordination role; and deletion of obligations on States parties to support WHO efforts to facilitate equitable access.[35] On the other hand, developing countries such as Bangladesh and Nigeria still attempted to reintroduce a clause that requires States parties to provide under their IP laws and regulations exemptions to the exclusive rights of IP holders to facilitate the manufacturing, import and export of health products, including materials and components.[36]

As the negotiations moved to the resumed eighth meeting of the WGIHR in May 2024, — barely days before the World Health Assembly— developing countries had compromised to accept a number of the proposed amendments to article 13 that incorporated some of the elements from the African Group and Bangladesh proposal for a new article 13A. However, developing countries still insisted on deleting references to "voluntary" technology transfer on "mutually agreed terms". The developed countries insisted on retaining these wordings. The US even suggested that unless this wording was retained all references to technology transfer and know-how should be removed from the text. At best, the US proposed a footnote to explain that the reference to mutually agreed terms is without prejudice to the flexibilities available under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) – which was essentially stating the obvious and not adding anything new.[37]

The issue of technology transfer in the context of equitable access to health products remained unresolved at the end of the resumed eighth meeting of the WGIHR. This matter was finally left to the drafting group negotiations during the World Health Assembly. In the final text that was approved, references to technology transfer in article 13.8 (e) were replaced with a generic reference to "other measures".

Thus, article 13 has been amended to ensure international support for equitable access to health products like diagnostics, vaccines, and treatments during public health emergencies of international concern (PHEICs) and pandemic emergencies. The heading of the article itself has been expanded to include reference to equitable access to health products, making it clear that this is fully within the scope of the IHR. Three new paragraphs have been added to article 13 to provide this support.

The new paragraph 7 mandates that the WHO assist IHR States parties during PHEICs, including pandemics, by coordinating international response efforts.[38]

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[34] K.M. Gopakumar, "WHO: WGIHR Bureau's text recognizes equity without effective implementation means", *TWN Info Service on Health Issues,* 22 April 2024, available from https://twn.my/title2/health.info/2024/hi240405.htm.
[35] TWN, "WHO: Developed countries push for dilution of WGGIHR Bureau's text proposal on equity", *TWN Info Service on Health Issues*, 24 April 2024, available from https://twn.my/title2/health.info/2024/hi240407.htm.
[36] Ibid.
[37] P. Patnaik, "Close, But Not Yet: Consensus Pending on the Amendments to the International Health Regulations", *Geneva Health Files,* 19 May 2024, available from https://genevahealthfiles.substack.com/p/wgihr-geneva-may-2024-pandemic-emergency-pheic.
[38] Ramakrishnan and Gopakumar, *supra* note 9.

The new paragraph 8 elaborates on the role of WHO role in ensuring timely and equitable access to health products for States Parties. WHO is tasked with removing barriers to access, periodically assessing public health needs, and evaluating the availability, accessibility, and affordability of health products. These assessments will inform WHO recommendations under articles 15-18.[39]

Additionally, paragraph 8 mandates WHO to work on removing barriers to timely and equitable access by State parties to relevant health products during a PHEIC, including a pandemic emergency, based on public health needs and risks. To that end the DG is mandated to conduct, periodically review and update assessments of public health needs, availability and accessibility, including affordability, of relevant health products for the public health response. WHO is also required to use WHO-coordinated and other mechanisms and networks for the equitable allocation and distribution of health products. WHO will also support States parties in scaling up and geographically diversifying the production of these products, promoting research and development, and enhancing local production of safe, effective health products, and facilitate other measures relevant for the full implementation of article 13. WHO is also required to share product dossiers with States parties to aid in regulatory evaluation and authorization.[40]

This obligation is reinforced by the amended Paragraph 2(d) of Article 44, which now states: "WHO shall collaborate with, and assist, States Parties, upon their request, to the extent possible, in... (d) the facilitation of access to relevant health products, in accordance with paragraph 8 of Article 13." This amendment aims to help States parties overcome barriers to equitable access.[41]

Paragraph 9 adds that States parties are also required, within their legal and resource capacities, to support WHO in implementing the actions specified in Article 13. They must engage with and encourage stakeholders within their jurisdictions to facilitate equitable access to health products during PHEICs and pandemics. Furthermore, they are obligated to disclose the terms of their research and development agreements related to promoting equitable access to these products during such emergencies.[42]

In spite of incorporating issues relating to equitable access to health products to a limited extent in article 13, there is lack of clarity in the IHR with regard to the means of implementing these obligations. The mandate that is given to the DG to undertake specific actions under article 13.8 such as assessing the public health needs, availability and affordability of health products, scaling up and geographically diversifying production, enhancing local production, etc., will be triggered only upon the determination of a PHEIC or a pandemic emergency. Hence, these obligations are only designed as response measures and not preparatory actions. This is in contrast to what the developing countries had proposed with a focus on preparedness, e.g., mandating the WHO to prepare a database with details of the ingredients, components, design, know-how, manufacturing process, or any other information required to facilitate manufacturing of health products required to respond to a potential outbreak of a PHEIC, based on all PHEICS declared so far. Similarly, while the WHO is mandated under article 13.7 to coordinate international response activities, there is no guidance on how this should be done, leaving the modalities of coordination at the discretion of the WHO Secretariat.[43] While references to transfer of technology have been replaced with a broader phrase that mandates the DG to facilitate other measures relevant for the full implementation of article 13, this does not mandate States parties to ensure transfer of technology upon the recommendation of the WHO. As experienced during the COVID-19 pandemic, the WHO had

[39] Ibid.
[40] Ibid.
[41] Ibid.
[42] Ibid.
[43] Gopakumar, *supra* note 33.

attempted to facilitate technology access through the COVID-19 Technology Access Pool (C-TAP). Still, the model was not attractive for proprietary technology owners to waive their commercial interests and share the technologies through C-TAP.[44] The C-TAP has now been replaced by the Health Technology Access Pool (HTAP).

In summary, developed countries succeeded in avoiding any direct obligation to ensure equitable sharing of pandemic-related products and technologies, while putting on the WHO the burden of acting in many fields, though with limited powers. For instance, WHO would have no authority to ensure that the objectives in article 13. 8 ("WHO shall facilitate, and work to remove barriers to, timely and equitable access by States Parties to relevant health products...") are achieved. What authority would the WHO have to oblige a State party to remove national IP or trade barriers? Hence, matters relating to the equitable access to health products and technologies will have to be further elaborated in the pandemic treaty negotiations, and their implementation must be monitored through the States parties implementation committee established under the IHR (see below).

[44] Syam, *supra* note 1.

IV. Temporary and Standing Recommendations

Article 15.2 has been amended to include relevant health products among the list of topics on which the WHO DG may issue temporary recommendations upon the determination of a PHEIC, including a pandemic emergency. A new clause 2bis has been added that obligates the DG when issuing, modifying or extending temporary recommendation, to provide available information on any WHO coordinated mechanism(s) concerning access to, and allocation of, relevant health products, as well as on any other allocation and distribution mechanisms and networks.

Similar amendments have also been introduced in article 16 which allows WHO to make standing recommendations of appropriate health measures. Pursuant to the amendments, the WHO can make standing recommendations relating to relevant health products, and provide States parties with available information on any WHO coordinated mechanism concerning access to, and allocation of, relevant health products.

As the definition of relevant health products includes health technologies, the reference to WHO coordinated mechanism concerning access can be construed to include WHO programmes like the Health Technology Access Pool (C-TAP), the mRNA Hub, the international coordination group (ICG) on Vaccine Provision, as well as any future WHO initiatives aimed at facilitating equitable access to health products in a PHEIC, including a pandemic emergency.

Moreover, article 17 has been amended to include a new clause (d bis) that states that when issuing, modifying or terminating temporary or standing recommendations the DG shall consider, inter alia, the availability of, and accessibility to, relevant health products. Further, a new paragraph 3 has been added to article 18 which states that the WHO recommendations (temporary or standing recommendations) shall, as appropriate, take into account the need to maintain international supply chains, including for relevant health products and food supplies.[45]

The implication of these amendments is that in future PHEICs, including pandemic emergencies like COVID-19, the WHO temporary and standing recommendations on the emergency can include recommendations of access to relevant health products such as vaccines, medicines, diagnostics, personal protective equipment, etc. as well as allocation of these products between States parties. Although these recommendations will carry the authority conferred under the IHR to temporary or standing recommendations, they are not legally binding on States.[46] This is, hence, an important but limited outcome for developing countries.

[45] WHO document A/77/9, Article 18.3 (b).
[46] Nannini, C. and Burci, G.L. (2024). Standing Recommendations under the International Health Regulations (2005). *ASIL Insights*, Vol.28(4). Available from https://www.asil.org/insights/volume/28/issue/4.

V. PUBLIC HEALTH MEASURES AND HEALTH DOCUMENTS

V.1 Special Provision for Conveyance and Conveyance Operators

Article 24 and Annex 4 of the IHR have been amended to make conveyance operators explicitly responsible for compliance on board, as well as during embarkation and disembarkation, with health measures recommended by the WHO and adopted by a State party.

V.2 Health Documents

Article 35 and Annex 6 of the IHR have been amended to provide States parties the discretion to issue health documents under the IHR in digital or non-digital formats. The WHO has been mandated to develop and update technical guidance including specifications or standards for issuance and authentication of health documents. Annex 6 has been amended to specify that health certificates must bear the signature and name of the clinician or authority responsible for issuing the certificate or overseeing the administering centre.

VI. Collaboration, Assistance and Financing

The scope of article 44 of the IHR has been expanded to include financing, in addition to collaboration and assistance. This is reflected in the heading of article 44 itself. The text of article 44 has been amended with the aim of increasing international collaboration and assistance including for mobilization of additional financial resources. States parties, however, are required to collaborate “to the extent possible” (article 44.1, chapeau).

On collaboration, article 44.1(a) has been amended to clarify that States parties have to collaborate not only with regard to event detection, assessment and response, but also on preparedness. Article 44.1(b) has been amended to specify that the undertaking of States parties to collaborate extends to facilitation of technical cooperation and logistical support for development, strengthening and maintenance of core capacities required under Annex 1 of the IHR. The existing undertaking under article 44.1 (c) to collaborate on mobilizing financial resources has been elaborated with a clarification that such mobilization should be particularly to address the needs of developing countries.

Under article 44.2, the WHO mandate to collaborate with States parties has been enhanced by requiring the WHO to also assist States parties upon request in the evaluation of their core capacities, facilitation of technical cooperation and logistical support, mobilization of financial resources to support developing countries for developing, strengthening and maintaining core capacities, and as mentioned above, for facilitation of access to relevant health products.

A new paragraph 2bis has been added to article 44. This requires States parties, subject to applicable law and available resources, to maintain and increase domestic funding as necessary, and collaborate, including through international cooperation and assistance, to strengthen sustainable financing to support IHR implementation. Under the new article 44.2quater, the DG is required to report to the Health Assembly on the outcomes of this collaboration. However, no concrete obligation regarding financing was incorporated and it is not clear how frequently that report must be submitted.

These amendments should be seen in conjunction with the amendments to Annex 1 of the IHR on core capacities. A new paragraph 4 in Annex 1, declares that States parties undertake to collaborate with each other pursuant to article 44 to develop, strengthen and maintain the IHR core capacities. Elaborating the core capacity requirements for prevention, surveillance, preparedness and response, new paragraph 1 (d) of section A of Annex 1 mentions core capacities to prepare for the provision of health services necessary for responding to public health risks and events, and access to those services, at the local and community level. New paragraphs 2(d) and (h) also mention access to health products and health services needed for response as a core capacity need at the intermediate and national levels.

In addition, a new paragraph 2ter has been added, wherein States parties have undertaken to collaborate to encourage governance and operating models of existing financial entities and funding mechanisms to be regionally representative and responsive to the needs and national priorities of developing countries in the implementation of the IHR, and identify and enable access to financial resources that are necessary to address the needs and priorities of developing countries equitably, including in relation to core capacities. The identification and enablement of access to financial resources to meet the needs and priorities of developing countries are to be done through a Coordinating Financial Mechanism established under the new article 44bis.

These amendments to article 44 constitute another important outcome for developing countries in terms of the gap in support for implementation of IHR. However, in the absence of specific binding provisions beyond collaborating "to the extent possible", it remains to be seen whether these amendments actually change the *status quo* as the language is not direct on commitments of financial resources.

VI.1 Coordinating Financial Mechanism

A major demand of the developing countries in the Working Group on Amendments to the International Health Regulations (2005) (WGIHR) negotiations was to establish a fund under the WHO to provide financing to develop, strengthen and maintain IHR core capacities. However, developed countries were not supportive of establishing a new WHO fund but instead preferred that States parties should seek funds from external financing institutions. The alternative proposal from developed countries was to establish a Coordinating Financing Mechanism to increase efficient utilization of **existing** financial instruments and work towards mobilizing further financial resources.[47] A Coordinating Financial Mechanism to support implementation of the pandemic treaty and the IHR was also proposed in the pandemic treaty negotiations in the INB.

The issue of establishing a new WHO fund was not resolved at the end of the WGIHR meetings, and was finally resolved in the drafting group discussions at the World Health Assembly. The compromise agreement was the establishment of a Coordinating Financial Mechanism, transposed into the IHR from the proposed article 20 of the draft pandemic treaty.[48] The final outcome substantially reflects the approach preferred by developed countries.

The Coordinating Financial Mechanism has been accorded three functions:

- provision of timely, predictable and sustainable financing for implementation of the IHR to develop, strengthen and maintain the core capacities under annex 1 of the IHR;
- seek to maximize the availability of financing for the implementation needs and priorities of States parties, particularly developing countries; and
- work to mobilize new and additional financial resources (without any concrete obligation on levels of financing), and increase efficient utilization of existing financial instruments relevant to the effective implementation of the IHR.

In furtherance of these objectives, the mechanism shall use or conduct needs and funding gap analysis, promote harmonization, coordination and coherence of existing financial instruments, identify all sources of financing that are available for implementation support and make this information available to States parties, provide advice and support to States parties, upon request, in identifying and applying for financial resources for strengthening core capacities, and leverage voluntary monetary contributions for organizations and other entities supporting States parties to develop, strengthen and maintain core capacities.

This mechanism will function under the authority and guidance of the World Health Assembly and is accountable to it. The terms of reference of this mechanism, and modalities for its operationalization and governance are yet to be decided. A newly formed States Parties

[47] TWN, "WHO: Drafting group starts negotiations on IHR amendments", TWN Info Service on Health Issues (May 24/18), 30 May 2024, available from https://www.twn.my/title2/health.info/2024/hi240518.htm.
[48] P. Patnaik, ""The Art of the Possible": Unpacking the Negotiations on the Amendments to the International Health Regulations", *Geneva Health Files*, 25 June 2024, available from https://genevahealthfiles.substack.com/p/wgihr-bloomfield-asiri-june-2024-wha77-consensus.

Committee for the Implementation of IHR 2005 is mandated to adopt the same under Article 54bis of the Regulations.

The amended IHR provisions on collaboration, assistance, and financing, including the Coordinating Financial Mechanism, recognize existing asymmetries and the need for equity in the architecture of the IHR, but fall short of imposing concrete obligations to provide financial or technological resources to developing countries for PHEIC preparedness and response. Instead, they delegate certain responsibilities to the WHO to just facilitate resource access for developing countries. The Coordinating Financial Mechanism can allow States parties to ensure that existing funding mechanisms are better matched to meet the needs of developing countries, and to look into new or additional financing, if required.[49] If States parties adequately support the WHO in these roles, the amendments can contribute to some extent to achieve equity. Moreover, as the WHO Member States have been unable to reach an agreement on establishing a specific fund under the IHR, this remains a key issue to be negotiated under the pandemic treaty in the INB.

[49] Ibid.

VII. INSTITUTIONAL MECHANISMS

VII.1 The Emergency Committee

Article 48 has been amended to modify the terms of reference and composition of the Emergency Committee (EC), which is now specifically empowered to provide its views on whether an event constitutes a PHEIC, including an international pandemic, and the termination of a PHEIC including a pandemic emergency. A new paragraph 2bis has been added which deems the EC as an expert committee and shall be subject to the WHO Advisory Panel Regulations. In terms of composition, the EC must have at least one expert nominated by States parties in whose territory the event being considered occurs.

Article 49 was amended, inter alia, to stipulate that the DG shall communicate to all States parties any supporting evidence for the temporary recommendations and the composition of the EC.

VII.2 States Parties Committee for IHR Implementation

A States Parties Committee for the Implementation of the International Health Regulations (2005) has been established under the new article 54bis. Article 54bis was adopted after negotiations were held on a number of proposals relating to compliance and implementation. These were: 1) proposal to establish an implementation committee under article 53A; 2) proposal by the US for a new chapter with three articles on the establishment of a compliance committee; 3) amendments to article 54 on reporting and review; and 4) proposal for a new article 54bis on implementation. During the WGIHR negotiations the US and EU proposed creating a compliance committee comprised of government experts from each Region. Developed countries envisaged a limited-member expert committee with quasi-judicial powers such as requesting information and conducting fact-finding missions in affected states.[50] Conversely, developing countries advocated for an inclusive implementation committee comprising all States parties that will regularly monitor IHR functions, capacity building, international assistance, and equity.[51]

The African Group had proposed the establishment of a committee of all Member States to discuss implementation and functioning of IHR annually, under a new article 53A. The proposal was equivalent to an annual conference of parties, that can monitor and review both the implementation of IHR (2005), as well as a new international instrument ensuring better coherence and complementarity between the implementation of two instruments.[52]

The US proposed a new chapter to establish a compliance committee of six experts from each WHO region. This committee would handle information on IHR compliance, monitor and advise States on compliance issues, and address concerns raised by States about IHR obligations.The compliance committee would be authorized to request further information, gather information from the territory of a State party with its consent, consider any relevant information submitted to it, seek the services of experts and advisers including representatives of NGOs and members of the public, and make recommendations to the State party concerned

[50] N. Ramakrishnan and K.M. Gopakumar, "WHO: Member States to engage in equity proposals on IHR 2005 amendment", *TWN Info Service on Health Issues,* 8 May 2023, available from https://twn.my/title2/health.info/2023/hi230502.htm.
[51] Ibid.
[52] WHO, *supra* note 26.

and /or WHO on how compliance may be improved and recommend technical assistance and financial support.[53]

Malaysia had proposed addition of a new paragraph 4 under article 54 requiring the WHO to maintain a webpage/dashboard to provide details of activities carried out under various provisions of the IHR.[54]

The EU had proposed a new article 54bis on implementation. Under this proposed article, the Health Assembly was to be responsible to oversee and promote the effective implementation of IHR, and meet in this regard in a dedicated segment during the annual sessions of the Health Assembly every two years. The Health Assembly was proposed to have the power to recommend or decide on matters related to strengthening IHR implementation and compliance. It would review reports from States and the WHO DG, assess IHR implementation, establish a review mechanism, provide technical and financial support to low-income countries, promote strategy development, cooperate with relevant organizations, oversee WHO secretariat functions, and consider further actions.It was also proposed to establish a Special Committee on the IHR as an expert committee, with members appointed on the basis of equitable geographical representation, to aid and assist the Health Assembly in the discharge of the functions under this new article.[55]

These proposals were discussed in informal consultations at the third session of the WGIHR and thereafter at the seventh session of the WGIHR it was agreed to undertake further intersessional consultations. However, no agreement was reached on this at the end of the eighth session of the WGIHR in May 2024. Final agreement on article 54bis was reached after discussions in the drafting group during the World Health Assembly.

Developed countries also proposed the establishment of a sub-committee to provide technical advice and support that would report directly to the Health Assembly. Developing countries were concerned that such a sub-committee could bypass the implementation committee. Finally, it was agreed that the sub-committee will report to the implementation committee.

The committee's purpose, as agreed under article 54bis, is to facilitate the effective implementation of the IHR provisions, particularly those on collaboration, assistance and financing under article 44 and the Coordinating Financial Mechanism under article 44bis. It would aim to promote and support learning, exchange of best practices, and cooperation among States Parties. The work of the Committee will also be aided by a sub-committee to provide technical advice. The committee is also specifically mandated to adopt by consensus the terms of reference of the Coordinating Financial Mechanism under article 44bis at its first meeting.

The new States parties committee could provide a much-needed forum within the IHR to discuss in detail the challenges, strengths and weaknesses in the implementation of the IHR 2005. It should be noted, however, that the committee only has consultative powers and does not have any decision-making power. Hence, it can only make recommendations which would only come into effect if adopted by the Health Assembly.

[53] Ibid.
[54] Ibid.
[55] Ibid.

VIII. CONCLUSION

The amendments to the International Health Regulations (IHR) are a useful step forward in strengthening global health security and ensuring a more robust and equitable response to future public health emergencies of international concern (PHEICs) including pandemic emergencies.

The negotiation process for the IHR amendments has highlighted the critical need for equitable access to health products and technologies essential for public health emergency preparedness and response, including for pandemic emergencies. Proposals from developing countries aimed at creating legal obligations and mandates for States parties and WHO to ensure this equity have significantly influenced the final amendments. Although these proposals have not been fully adopted, the amendments represent a positive stride towards enhancing equity within the IHR framework. They have also strengthened the role of the WHO as the global public health agency by providing it more tools to act in PHEICs including pandemic emergencies, one important achievement for developing countries

However, the current provisions fall short of establishing concrete obligations to provide financial or technological resources directly to developing countries, and to ensure that the principle of equity (now formally recognized) is effectively implemented and not merely proclaimed. Instead, they allocate specific functions to WHO to facilitate access to these resources, particularly for developing nations, and to remove obstacles but the WHO's capacity to do this is limited. The effectiveness of the amendments in delivering equity will heavily depend on the support WHO receives from Member States in fulfilling its newly entrusted functions. Adequate backing for WHO is crucial to ensure that these amendments can truly bridge the equity gap in global health emergency preparedness and response.

In this context, the successful conclusion of the INB negotiations on a pandemic treaty are important to complement the IHR. Upon the adoption of the IHR amendments there was a shared sense among the negotiators from both developed and developing countries that this outcome should inspire and contribute to the momentum to conclude negotiations on the pandemic treaty as early as possible.[56]

In accordance with this shared understanding, it will be critical for WHO Member States to successfully conclude the negotiations on a pandemic treaty that achieves agreement on issues that have not been addressed in the IHR. These include critical issues such as establishing a pathogen and benefit-sharing system (PABS), and access to technology and know-how. In the WGIHR negotiations, as noted, consensus could not be achieved on these issues. It will also be important to ensure that the pandemic treaty instrument contains the essential binding provisions to make it an effective tool to address future pandemics and do not repeat the catastrophic experience with the management of COVID-19.

[56] N. Ramakrishnan, "WHO: Member States term amendments to international health regulations as 'historic'", *TWN Info Service on Health Issues*, 7 June 2024, available from https://www.twn.my/title2/health.info/2024/hi240602.htm.

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