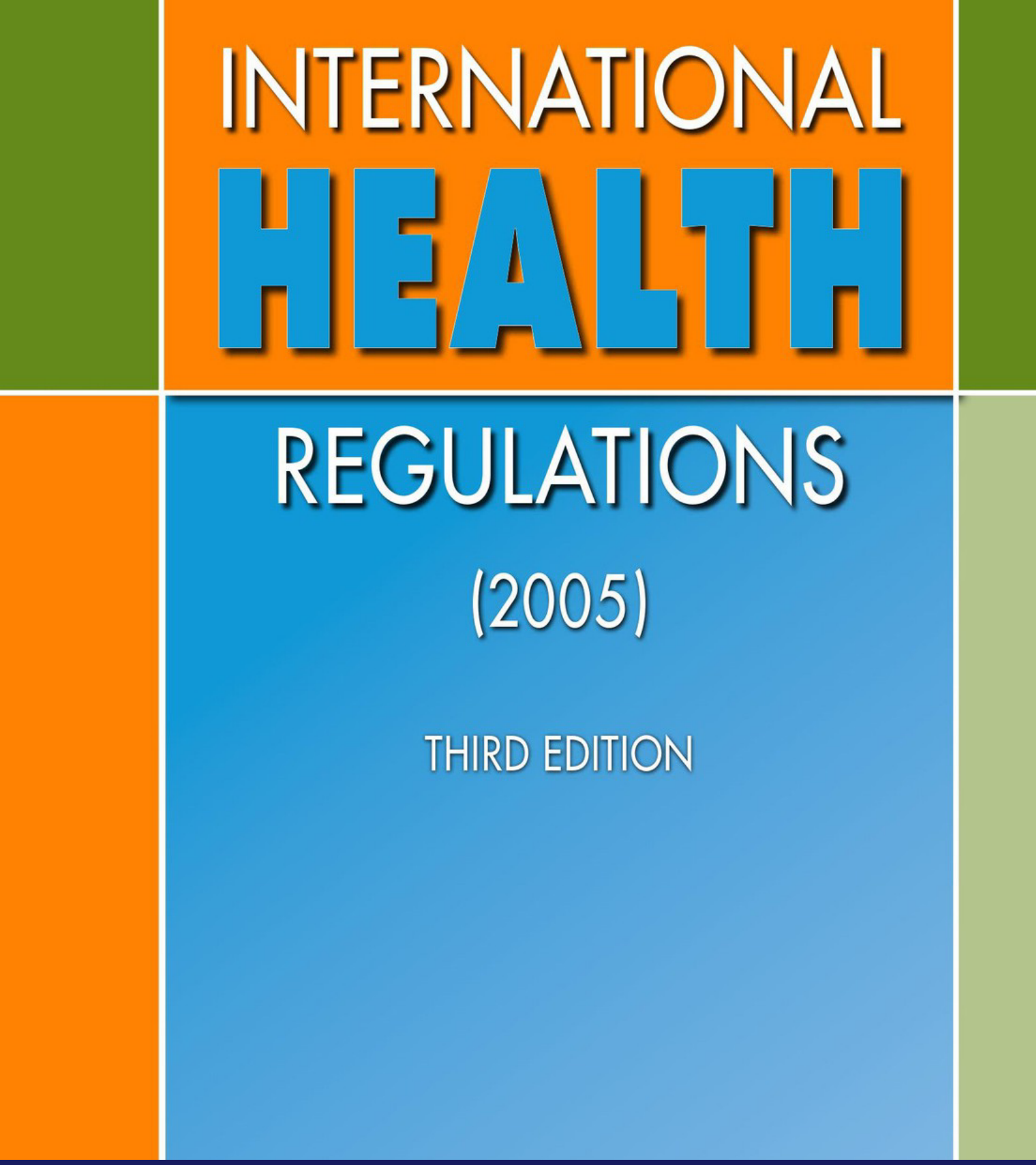

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THE NEW AMENDMENTS TO THE INTERNATIONAL HEALTH REGULATIONS (77TH WHA, 2024)

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THE NEW AMENDMENTS TO THE INTERNATIONAL HEALTH REGULATIONS (77th WHA, 2024)

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I. Introduction

During the Covid-19 pandemic, weaknesses in the international legal system's ability to prevent and respond to pandemics were revealed. Consequently, in January 2022, the World Health Organization (WHO) Executive Board urged Member States to "consider potential amendments to the International Health Regulations". Further, world leaders issued a call for a "new international treaty for pandemic preparedness and response." Thus, member states launched two concurrent reform processes at the WHO, agreeing that modifications to the International Health Regulations 2005 (IHR) and a new

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WHO Pandemic Agreement would be presented at the 77th World Health Assembly, which would take place from May 27 to June 1, 2024.

However, negotiations to finalise the pandemic agreement stalled because of considerable political differences between developed and developing countries. The draft pandemic agreement contains contentious but important provisions regarding the establishment of a pathogen access and benefit-sharing system (PABS); provisions encouraging intellectual property waivers, voluntary licensing and technology transfer to developing countries; and the integration of environmental, food, animal and human health surveillance through a One Health approach (among others). Member states have extended the International Negotiation Body's (INB) mandate to finalize the pandemic agreement by May 2025.

While the necessity of the pandemic agreement's adoption remains, the purpose of this note is to examine the IHR Amendments which were adopted by member states at the 77th WHA. Some are celebrating the IHR Amendments' adoption, claiming that it "enhance(s) transparency and strengthen(s) global health security architecture." We examine the amendments and assess whether they represent a multilateral success in boosting global health security.

Our analysis finds that, while the amendments include innovations aimed at addressing some of the IHR's key issues, the mechanisms utilized to do so are primarily soft, consultative, or voluntary in nature. Indeed, the IHR Amendments are more toned down than the proposal presented at the 8th meeting of the Working Group on Amendments to the IHR (WGIHR). As a result, some commenters may have desired tougher accountability mechanisms, but they were not included.

Furthermore, it is crucial to note that some issues which could have significantly strengthened global health security, such as the use of pathogen genomics for pandemic surveillance and the sharing of pathogen genetic sequence data, were eventually not included. This topic remains contentious in debates between the global north and the global south; hence it has been excluded from the final version.

Nonetheless, if states decide it is in their best interest to comply and devote the necessary human and monetary resources to implementing the new provisions, the changes which have been included have the potential to gradually increase core capacities while also improving a spirit of equity and solidarity in global health security. But only time will tell if this amendment has been effective in effectuating significant change.

More broadly, what one can conclude from the IHR revision process in terms of the state of

multilateralism, is that agreement is possible, on matters that are not overly contentious, and if states are not required to subject themselves to strict accountability or enforcement mechanisms.

In what follows, we lay out the main shortcomings of the IHR as identified in reviews following the Covid-19 pandemic (section II). We then address the main amendments (section III).

II. Main Shortcomings of the IHR (2005)

At the height of the Covid-19 pandemic, it became evident that the IHR, the cornerstone of the global health security system, had utterly failed in preventing the international spread of the Covid-19 pandemic.

Against this background, several reviews of the IHR and international pandemic response were carried out. In May 2020, the World Health Assembly (WHA) asked the WHO Director General to appoint an independent panel to review the international response to the pandemic. Accordingly, the Independent Panel for Pandemic Preparedness and Response was established under the leadership of Her Excellency Ellen Johnson Sirleaf and the Right Honourable Helen Clark. The Panel presented its first report in May 2021 to the World Health Assembly, making seven recommendations to prevent a future outbreak from becoming a pandemic.

Simultaneously, the Director General convened the Review Committee on the Functioning of the International Health Regulations in September 2020 at the request of the 73rd WHA. The Committee's mandate was to examine the functioning of the IHR during the Covid-19 pandemic. The Review Committee submitted its report on April 2021.

Both reports identified major shortcomings in the IHR, including its implementation. Scholars and other experts also highlighted other gaps in the international response to Covid-19. In the section below, we summarize some of the key criticisms of the IHR and the international response to the pandemic.

1. IHR (2005) Does Not Cover 'Deep Prevention'.

The IHR aimed to enable the prevention, detection and containment of health risks and threats, creating a global health alert and response system under the leadership of the WHO. The Regulations operated under the assumption that disease outbreaks could not be prevented, but only controlled during international spread of a disease. As such, the IHR did not cover more systematic surveillance, or deep prevention, of outbreaks. Deep prevention measures on the other hand, focus on prevention of disease outbreaks by addressing their driving factors and not merely containing spread of disease.

With most pandemic outbreaks being zoonotic in nature, the Independent Panel emphasized the "urgency for better detection...and more robust preparedness", that is a core function of governments and international health systems; not merely a responsibility of the health sector alone. Zoonotic disease outbreak is a consequence of climate change, biodiversity loss and chemical pollution, which necessitates a One Health approach. Deep prevention would require building and strengthening pathogen surveillance capacities of states that monitors and detects zoonotic spillover of pathogens from animals to human beings. Such surveillance capacity-building would implicate the need for financing, technical support, a One Health approach and international cooperation, that were absent in the text of the IHR.

2. Slow response

The international alert system to declare a public health emergency does not operate with sufficient speed when faced with a fast-moving respiratory pathogen. Precious time was lost to IHR processes as the SARS-CoV-2 virus spread rapidly, across international borders. The WHO Review Committee found that "early alert, notification and response" was a major area of failure. Accordingly, there were suggestions to establish a new global system of surveillance, based on full transparency and authority of the WHO to publish information about public health risks without requiring prior approval of national governments (recommendation 4 of the Independent Panel). The IHR Review Committee suggested a key message for "early alert, notification and response" to trigger timely action and enable the WHO Secretariat to use its full powers under the IHR.

3. Notification of Public Health Events

One of the main problems in the case of an outbreak is that states are disincentivized to notify the WHO or other states, as they are concerned it may lead to economic sanctions, such as closing of national borders – causing a backlash to their trade and travel. For these reasons, China likely hesitated in notifying the WHO about the Covid-19 outbreak, and South Africa suffered reputational and economic loss after detecting the Omicron variant. While the IHR seeks to create a balance between public health and international trade (resulting, in the WHO Director General advising against application of trade and travel restrictions after declaring the Covid-19 public health emergency of international concern), in practice, states have strong incentives to delay notification about outbreaks.

4. Declaration of a PHEIC Does Not Give Proper Warning

Under the IHR, the WHO Director General (DG) has the power to declare a Public Health Emergency of International Concern (PHEIC), on advice of an Emergency Committee comprised of experts. The

criteria to determine whether a PHEIC has occurred are whether the event: (i) is extraordinary; (ii) a public health risk to other states; and (iii) possibly requires a coordinated international response. Many considered this binary (yes/no) approach ineffective. The PHEIC declaration mechanism under IHR is the "public face of WHO's IHR response", but should have a tiered approach that warns the international community *before* a disease outbreak becomes an emergency. As such, scholars and experts have called to adopt a gradual, tiered-approach, which would warn states ahead of a full-blown PHEIC declaration, through 3 levels of assessment.

Level 1 PHEIC would indicate a high-risk outbreak in a **single** country, with the **potential of international spread.** Level 2 would reflect that **multiple countries** have had **limited spread** of the disease. Level 3 would denote **large clusters** of disease in **multiple countries**, with evidence of **ongoing local transmission**.

5. Inadequate IHR Implementation/Compliance

There is widespread consensus that many countries had failed to implement their core capacity obligations, which led to public health systems being overwhelmed and unable to cope with pandemic proportions of an infectious disease outbreak. Covid-19 exposed severe inadequacies in health emergency preparedness and response. According to the Global Health Security (GHS) Index of 2019, collectively, international preparedness was weak, with an average overall index score among 195 countries assessed at a meagre 40.2 out of a possible 100. 60 high income countries averaged a GHS score of 51.9. Further, the Review Committee found that the lack of IHR compliance in preparedness was a major cause for the failure of international response to Covid-19. Accordingly, the Committee emphasized that IHR implementation responsibility should be elevated to the highest level of government; and a robust accountability mechanism with provisions for **implementation and compliance** with IHR should be established, to strengthen preparedness, international cooperation and timely notification of public health events.

6. Lack of Political and Financial Commitment

Effective IHR implementation requires robust and sustainable financing at the national and international level. The failure to implement and comply with IHR was due to a dearth of financial and political commitment on part of WHO member states. Moreover, the absence of dedicated funding at the scale required, resulted in unequal access to medical equipment, diagnostics, therapeutics and vaccines. Further, uncoordinated and divided global leadership contributed to the undermining of multilateral institutions like WHO, and distrust amongst national leaders. To address this issue, the

Independent Panel recommended increasing WHO funding, while the Review Committee recommended strengthening collaboration, coordination, and financing.

7. The IHR Does Not Cover Access to Medicines

The IHR's scope is limited to preventing the international spread of disease, but it does not cover access to medicines in the case of an outbreak. The Independent Panel made a set of three immediate recommendations to help end the pandemic. They proposed that major vaccine producing countries meet under the auspices of the WHO and WTO to agree on voluntary licensing and technology transfer, with intellectual property rights waived if a voluntary agreement is not obtained within three months.

In the section follows, we address the main amendments that have been adopted at the 77th WHA.

III. Main Amendments

To address these gaps in the IHR, the IHR review and amendment process began in 2022 under the leadership of the Working Group on Amendments to the International Health Regulations 2005 (WGIHR) and came to a close at the 77th Meeting of the World Health Assembly, held from 27 May 2024 to 1 June 2024. The IHR Amendments were adopted by member states at the closure of the WHA77. We analyse some key provisions of the IHR as amended, to examine how they improve the status quo and to what extent they address the gaps identified.

1. Spirit of the IHR: From Functionality to "Equity and Solidarity"

The nature of the IHR has historically been functional, creating a global alert and notification system whose purpose is to prevent and contain the international spread of disease. IHR Amendments introduce a change to the spirit of global health coordination in preventing, detecting and responding to public health emergencies. Notably, the amendments have changed the IHR's basic principles to declare that the IHR will not only be implemented in line with dignity and human rights, but also "shall promote equity and solidarity among State Parties" (Article 3(1)). The change to the basic principles of IHR is an affirmation of the fundamental role of the principles of equity and solidarity in interpreting state obligations under the amended Regulations.

The IHR, however, does not define the terms equity and solidarity. Thus, our general understanding of the concepts and their consequences can be derived from other sources of international law. Solidarity is a concept in international human rights law. It is a "fundamental human rights principle that is legally defined as promoting unity among individuals, communities, states and international organizations to achieve common goals." Solidarity would necessitate collaboration and cooperation at an international

level, to implement the IHR amendments in strengthening health emergency prevention, preparedness and response.

According to the WHO, equity is the "absence of unfair, avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically or by other dimensions of inequality (e.g. sex, gender, ethnicity, sexual orientation)." Health equity is achieved when everyone can attain their fundamental right to health. Leaving inequalities behind would mean that world leaders need to "equalize access to rights, equalize access to services, equalize access to the best science and medicine."

While not defined in the IHR, the operationalization of the equity and solidarity concepts is reflected in new provisions that seek to advance equitable outcomes (which we address in detail below).

- Article 13 has been amended to regulate "**equitable access** to relevant health products".
- Article 44 has been amended to address financing support to developing countries, including the establishment of a Coordinating Financial Mechanism (Article 44bis), to **equitably** address the needs of developing countries for developing, maintaining and strengthening their core capacities.
- Annex 1 on Core Capacities and Article 44, create a mutually supportive duty for States to **collaborate** with one another in developing, maintaining and strengthening core capacities.

It remains to be seen whether and how the principles of "equity" and "solidarity" will influence the *de facto* application of the IHR (2024) in practice.

2. Definition of and Determination of a Pandemic Emergency

Whereas the IHR (2005) covers PHEICs, IHR (2024) introduces a new category of PHEIC: a "pandemic emergency". Article 1 defines a pandemic emergency as a PHEIC caused by a communicable disease that has or is at a high risk of having (i) wide geographical spread, within multiple States; (ii) exceeding health system capacities to respond in those States; (iii) causing substantial social and/or economic disruption (including to international traffic and trade); (iv) and requires rapid, equitable and enhanced coordinated international action with whole-of-government and whole-of-society approaches.[3]

[3] A whole-of-government approach envisions higher coordination amongst relevant sectors of public administration or public service agencies in a domestic jurisdiction, and an integrated government response to health. Such increased cohesion would

The power to determine the existence of a pandemic emergency and issue respective recommendations rests with the DG and follows the same rules and procedures as those for determining a PHEIC (Articles 12, 15). In other words, the DG does not need to follow different or additional procedures before determining that a PHEIC amounts to a pandemic emergency. Notably, the DG is not required or entitled to receive additional sources of information towards making such a determination.

Consequences for Member States, WHO and Director General

What are the consequences of adding the category of pandemic emergencies?

First, states are now under an obligation to develop and maintain core capacities for pandemic emergencies. Article 13 determines that state parties need to develop and strengthen "core capacities to prevent for, prepare for and respond promptly and effectively to…PHEICs, including a pandemic emergency…" The details are set out in Annex 1.

Second, the Director-General's determination of a PHEIC now extends to determining if a pandemic emergency has occurred (Article 12). The WHO must coordinate international response activities during PHEICs and pandemic emergencies. It is also tasked with facilitating timely and equitable access to health products (Article 13(8)).

Early Alert System

As mentioned above, a common criticism has been the absence of an early alert system that could warn States regarding public health risks that do not constitute a PHEIC yet. Thus, before the eighth meeting of the WGIHR, the text of the IHR proposed amendments consisted of an "early action alert" system, that was defined as "information and non-binding advice issued by the Director General to States Parties on an event which, at the time of the consideration pursuant to paragraph 4 of Article 12 [determination of PHEIC and pandemic emergency], he or she has determined does not constitute a public health emergency of international concern." The proposal imposed a potential obligation upon the DG to issue an early action alert comprising of advice to states on preparing for and responding to

be unified across governmental structures such as departments/ministries concerning health, trade or commerce and enforcement of law and order. A whole-of-society approach does not delineate between public and private sector functions, and would include profit-making entities working together with policy-making actors.

a public health risk that was determined to **not** constitute a PHEIC as yet (Article 12 (4ter))). However, this proposal was eventually dropped and not included in the adopted text of IHR.

Had this proposal for an early action alert system been included, it would have increased transparency and information gathering by the WHO; and facilitated its dissemination globally. Despite the Independent Panel on Pandemic Preparedness and Response's recommendation for the WHA to give "WHO the explicit authority to publish information about outbreaks with pandemic potential immediately without requiring the prior approval of national governments", states are hesitant about being obligated to share information with the WHO. Fear of reputational loss or premature trade sanctions that disproportionately impact economies of reporting countries (as seen with South Africa and Omicron) are reasons that disincentivize prompt and full disclosure of information concerning outbreaks.

Article 43 on health measures is the only safeguard for incentivizing disclosure of information, by precluding States from imposing measures that are "more invasive or intrusive" than reasonable alternatives. All health measures imposed in addition to WHO recommendations, must be scientific and evidence-based (Article 43(2)(a)(b)). A modest amendment to Article 43 now allows a state that "deems itself" subject to additional health measures, to directly consult with the state imposing the measures. Alternatively, the Director General can be asked to mediate between the two states to arrive at a mutually agreeable solution that clarifies the public health rationale and scientific information underlying the additional measure(s).

3. Core capacities: New obligations to Prevent and Prepare for PHEICs, Including Pandemic Emergencies.

IHR was designed to be a global warning system, concerned primarily with mitigating the spread of international disease. To this end, Article 5 and 13 of the IHR (2005) sets out the state's obligations to have core capacities to detect, assess, notify and report PHEICs (Article 5), and to respond to them (Article 13). Annex 1 details these core capacities.

However, as highlighted above, Covid-19 revealed that many states were ill-prepared for the pandemic and that they lack tools for preventing outbreaks. Hence, IHR (2024) seeks to expand the scope of the core capacity obligations. Under the amended IHR, states must also have core capacities to prevent (Article 5, 13) and to prepare for (Article 13) PHEICs and pandemic emergencies. This expansion is also reflected in Annex 1 which sets out the details regarding Core Capacities. There, it sets out "**Core**

Capacities requirements for Prevention, Surveillance, Preparedness and Response", and sets our core capacity requirements at the local, intermediate and national levels.

- At the local community level or primary health care, the core capacity to **prepare for immediate implementation** of preliminary control measures is expected. **Access to health care services** and **engagement of local stakeholders** is also a core capacity to successfully prevent and respond to public health risks.
- In what used to be a primarily reporting of information function, the intermediate level of public health response, is now additionally obligated to **coordinate with and support the local level** in **prevention, preparedness and response** to public health risks. Such support would include the fields of **surveillance, on-site investigations, lab diagnostics, implementation of control measures, access to health services and products, risk communication that addresses misinformation and disinformation,** and **logistical assistance** such as **transportation of medicines and equipment.**
- At the national level, obligations have expanded in the realm of prevention, preparedness and response (PPR). PPR core capacities include the obligations to **rapidly determine** what control measures are required to prevent domestic and international spread of disease; **surveillance**; **deploy** specialized staff for PPR purposes; **develop and disseminate guidance for clinical case management, infection prevention and control;** ensure **access to health services and products**; and **risk communication.** The national level public health response must also serve a coordinating and supportive function for the local and intermediate levels in PPR.

Th expansion of these core capacities can be viewed as an opportunity to integrate emergency preparedness, surveillance and response within essential public health functions to make national health systems more resilient.

Finally, Annex 1 has now added a new provision in paragraph 4, mandating compliance with Article 44 that prioritizes addressing financial needs of developing countries, in the spirit of solidarity, and equitable access to relevant health produces as an obligation upon state parties [Article 44(1)(c) & (2)(d)). It says, "pursuant to Article 44, State Parties shall undertake to collaborate with each other, to the extent possible, in developing, strengthening and maintaining core capacities."

4. Implementation Mechanisms

As highlighted above, inadequate implementation of core capacities has been one of the main problems with the IHR (2005). To strengthen implementation, the amendment establishes two new

institutional measures: a new Committee for Implementation and a National IHR Authority. While these measures introduce more institutional oversight, they lack teeth and are largely soft accountability mechanisms. The amendments also include provisions on strengthening financing to improve implementation (which we address in the next section). Besides these soft mechanisms, compliance mechanisms introducing stricter accountability have not been added. Thus, it remains to be seen whether these soft implementation mechanisms will be successful in ensuring improved implementation of the IHR.

A. Committee for Implementation of the IHR

Article 54 *bis* establishes a state parties' Committee for Implementation of the IHR. This Committee is designed to be consultative and non-adversarial. It is adopted with the aim of promoting the exchange of best practices on implementation of the IHR amongst state parties and mandates the appointment of a Subcommittee to provide technical advice to the Committee. Its modalities include meeting once biennially and it must be headed by a Chair and Vice-Chair, appointed by the Committee on a regional basis, for a term of two years.

The adopted Implementation Committee lacks reference to a previously proposed Compliance Mechanism that was included in the draft proposal for an "Implementation and Compliance Committee" and presented at the 8th meeting of the WGIHR. In fact, all mentions of "compliance"—including in Article 42, which had proposed a new obligation on states to engage with non-state actors in **complying** with and implementing health measures taken under IHR—have been deleted in the adopted text.

As a result, the Implementation Committee lacks teeth due to the erasure of a compliance obligation under the final text of amendments. In that regard, the outcome is likely disappointing for some who had hoped that members states would agree on stricter accountability mechanisms. This result is not surprising given that states have historically been hesitant about introducing accountability measures which could potentially interfere with their domestic affairs, or which could increase reputational costs in case of non-compliance. That said, the Implementation Committee introduces more discourse and exchange of best practices among members and could potentially strengthen capacity over time.

B. National IHR Authority

Article 4 of IHR (2024) requires state parties to designate a National IHR Authority in accordance with its laws, to coordinate the **implementation** of the IHR within state jurisdiction (Article 4(1bis)). The National IHR Authority can be an entity designated or established at the national level and is an

additional authority that works alongside the National IHR Focal Points (whose primary purpose is to make urgent communications and disseminate information from relevant state administration and sectors, to WHO IHR Contact Points). While the National IHR Focal Points continue to notify the WHO of public health information on behalf of their state, the National IHR Authority's primary purpose is to ensure implementation of the IHR within the state.

5. Financing

The urgency for creating financing mechanisms that incentivize countries' preparedness funding is not new. Article 44 IHR (2005), concerning collaboration and assistance was considered a "weak obligation on financial assistance". Additionally, with nearly 80% of WHO's budget being voluntary, there is lesser incentive for global solidarity without a dedicated financing mechanism in the IHR.

Further, the new and expanded core capacities necessitate sustainable financing. While the implementation mechanisms addressed above may incentivize compliance, ultimately, the costs associated with building and bolstering health systems are the main barrier to effective preparedness. Hence, all the reviews highlighted the need to find financing solutions towards regional and domestic capacity-building, including in LMICs.

To this end, Article 44 is renamed to cover not only collaboration and assistance, but also "financing". States are now under an obligation to "maintain or increase their domestic funding as necessary" for the implementation of the IHR (Article 44 (2bis)). Moreover, new financing obligations and mechanisms—which are focused on developing countries' needs—have been included, thereby reflecting the integration of the principle of solidarity into the new IHR.

First, states' obligation to cooperate with each other now also include the mobilizing of financial resources, "including through relevant sources and funding mechanisms" that "address the needs of developing countries". States are also encouraged to make "funding mechanisms…regionally representative and responsive to needs and national priorities of developing countries in the implementation of these Regulations" (Article 44 (2ter)).

Second, Article 44 2*bis* establishes a Coordinating Financial Mechanism (CFM) with the primary purpose of promoting the implementation of the Regulations through a sustainable financing mechanism, and develop, strengthen and maintain core capacities of developing States to deal with PHEICs, including pandemic emergencies. The objectives of the CFM are to carry out funding gap analyses, identify sources for funding and leverage voluntary monetary contributions for organizations supporting the development of core capacities in states.

While these financing provisions seek to promote solidarity with developing countries, the CFM is a soft mechanism, and falls short of creating a binding obligation upon states, to contribute funds to the CFM. Contributions are voluntary – making funding unpredictable and unreliable. It raises the question of whether the lessons from WHO's financial crisis due to a similar model of voluntary contributions and the severe depletion of funding post Covid-19 are bound to be repeated. Thus, only time will tell whether and how these financial measures will work.

6. Equitable Access to Relevant Health Products

As noted above, the IHR (2005) did not address access to medicines. While this topic is being negotiated under the pandemic agreement (whose negotiation period has been extended by one year until 78th WHA in May 2025), in the context of the IHR, members have revised Article 13 to regulate "equitable access to relevant health products", thereby reflecting their desire to include the spirit of global equity and solidarity into the response to PHEICs.

Relevant health products are defined as "health products needed to respond to PHEICs, including pandemic emergencies, which may include medicines, vaccines, diagnostics, medical devices, vector control products, personal protective equipment, decontamination products, assistive products, antidotes, cell and gene-based therapies, and other health technologies" (Article 1).

Article 13.8 instructs that during a PHEIC, the "WHO shall facilitate, and work to remove barriers to, timely and equitable access by states to relevant health products…based on public health risks and needs". To this end, the Director-General (DG) is given additional duties:

- To conduct assessments of public health needs and regarding availability and accessibility and affordability of relevant health products (13.8(a)). It is interesting to note that the criteria of affordability, accessibility and availability of health products operationalizes the language of the General Comment 14 to the International Covenant on Economic, Social and Cultural Rights' right to health. Thereby, integrating international human rights and access to health products under the IHR.
- To make use of WHO coordinated mechanisms and other allocation and distribution mechanisms and networks systems that facilitate timely and equitable access to relevant health products (13(8)(b))
- To support states in scaling up and geographically diversifying the production of relevant health products (through WHO coordinated and other networks and mechanisms (13(8)(c))
- To share relevant health product dossiers with state parties (13(8)(d)

- To support the promotion of research and development (13(8)(e))

The text of the IHR Amendments, submitted to the 77th WHA, contained a proposed provision in Article 13(8)(e) that obligated the DG to "facilitate **voluntary transfer of technology** and know-how and expertise **on mutually agreed terms**, including for research and development purposes." This provision was dropped from the adopted text and the IHR amendments no longer hold a mention of technology transfer, even if voluntary.

7. Digital Health Documents

In a welcome move, the amendments have created new provisions for acceptance of growing digitization of health. Health documents may now be issued in a digital format, if they comply with conditions of Annex 6 (on vaccination and prophylaxis certificates) and their authenticity is ascertainable (Articles 35(2) & 35(3)). Moreover, the WHO is also obligated to develop necessary technical guidance—in consultation with States—regarding specifications and standards for issuing and authenticating health documents in a digital format (Article 35(4)). These health documents are used by travellers in international traffic.

8. Sharing of Pathogen Genetic Sequence Data (GSD)

Finally, we want to address a topic which had been negotiated, but which was ultimately removed from the final version: the sharing of pathogen genetic sequence data (GSD).

The sharing of pathogen genetic sequence data-sharing was initially proposed by States and consolidated by the WGIHR in their article-by-article compilation of amendments. Pathogen genomics is a technology which is gaining ground as an effective technology to rapidly detect outbreaks and foresee epidemics and pandemics. Member states of the European Union and United State delegation proposed a mandatory obligation for states to share genetic material with WHO upon notification of a public health event (Article 7). Genetic/genomic sequencing data also found mentions under proposed amendments to Article 6 (notification), and Article 44 (collaboration and assistance). This proposal was contested strongly by the Africa Group, who staunchly argued against a mandatory obligation to share genetic data under the IHR, unless WHO member states agreed to a transparent access and benefit-sharing mechanism (Article 6).

Consequently, in February 2023, the Review Committee regarding amendments to the IHR made a technical recommendation on inclusion of genetic sequence data (GSD) to the WGIHR. The Committee recommended that member states need to "outline a coherent, principled, efficient and pragmatic

multilateral mechanism for GSD and benefit-sharing." But recognized that the imposition of this additional information request "may impose an additional burden on reporting, and thereby hinder feasibility".

Finally, in April 2024, the WGIHR proposed a Bureau's text on IHR amendments which dropped any mention of GSD (as well as access and benefit sharing). After a second joint plenary session of the INB (responsible for leading negotiations of the pandemic agreement) and WGIHR, issues in common were divided between the bodies, leading to public health surveillance falling under the scope of IHR. Nevertheless, pathogen GSD as a surveillance technology – and the sharing of GSD among member states – has been entirely removed from the final version of the IHR. The topic of access and benefit sharing is included in the draft pandemic agreement, and is being discussed under a provision on Pathogen Access and Benefit-Sharing System.

In sum, while pathogen GSD has the potential to improve public health surveillance and response, due to its association with the access and benefit sharing debate, any mention to pathogen GSD surveillance and sharing has been omitted from the IHR.

9. Discussion and Conclusion

Are the IHR amendments a multilateral success or a failure? Are the celebrations on multilateral conclusion of the amendments justified?

The answer depends on what one expects from multilateralism. If one expects states to agree on highly contentious topics and subject themselves to more strict legal accountability mechanisms ("sticks"), the IHR (2024) results are disappointing.

However, if one takes a more pragmatic approach to what multilateralism can achieve in today's global environment—with the number of stakeholders and countries with different and sometimes conflicting interests, as well as the recognition that states are hesitant to grant international organizations or other states power to influence their domestic affairs—then the IHR is a reasonable outcome.

Two main points need to be made. First, the amendments seek to address key problems identified in the IHR. However, the measures they have adopted to address them are soft, consultative, or voluntary. They are "carrots", seeking to encourage implementation, rather than "sticks", seeking to sanction for non-compliance. Second, there are subjects that have been negotiated but ultimately excluded because they were too contentious to agree on, particularly compliance mechanisms and

data-sharing.

Here are some main examples:

- **Implementation monitoring and compliance mechanisms**: The amendments develop new mechanisms for coping with implementation, notably an Implementation Committee and national IHR authorities. Despite earlier proposals to give this committee more teeth, the scope of the Committee does not extend to ensuring compliance with the IHR but instead, serves as a venue for exchange of best practices. By exchanging experiences and practices, this soft mechanism could eventually lead to better implementation. However, there is no compliance mechanism which measures states' progress towards implementation of IHR core capacities, nor does it impose sanctions for non-compliance.
- **Financial support to developing countries**: The Coordinating Financial Mechanism seeks to mobilize funds towards more equitable outcomes. However, it does not set out a specific obligation for states to provide funding.
- **Declaration of a Pandemic Emergency**: It establishes a higher level of alert, but it does not give the WHO any new powers since determination of a PHEIC implicates determination of whether the PHEIC rises to the higher threshold of a pandemic. This declaration will have a greater impact if the pandemic agreement is adopted with new obligations concerning pandemic preparedness and response. However, efforts to construct a tiered early warning system—before an outbreak becomes a PHEIC—have been unsuccessful, and it appears states are reticent to agree on obligations that would require disclosing information in early stages of an outbreak.
- **Equity and solidarity**: The IHR consider these two concepts to be new, foundational principles. On the one hand, they are not legally binding or enforceable measures. On the other hand, they have declarative power and member states will be expected to comply with the IHR in the spirit of equity and solidarity. This could be a useful tool for advocates seeking to influence states' response in a manner that supports equitable access to health and international solidarity in responding to future public health crisis.
- **Health Products:** Outlines the DG's responsibility in coordinating or facilitating equitable access to health products, but does not impose any definite obligations on states in terms of contentious topics such as designated percentage of vaccines to be contributed in case of a PHEIC, waivers on intellectual property, technological transfer, or transfer of skills and know-how.
- **Disincentives to notify in case of an outbreak:** States may request a consultation with another state (or ask the DG to mediate between them), if they deem themselves subjected to additional health measures (like restrictions on travel and trades). However, this conciliatory provision is

unlikely to discourage states from imposing such additional measures.

- **WHO Powers:** The amendments do not grant the WHO or the DG any new interventionist powers (such as the ability to investigate the origins of an outbreak or to get information about outbreaks from additional sources). Their primary function remains facilitating and coordinating international response.
- **Pathogen GSD sharing:** Despite attempts to include an obligation to strengthen surveillance through pathogen genomics and an obligation to share pathogen GSD, these provisions have been removed. Data sharing is of critical importance for global health security, but it is a divisive issue, making agreement difficult.

More broadly, the IHR amendment process suggests that multilateral agreement is feasible—on non-contentious matters, and provided states are not subjected to strict accountability or compliance/enforcement measures. There appears to be little appetite for stringent accountability measures. Time will tell whether the IHR Amendments 2024's soft measures, will result in stronger global health security.