Serious Problems Remain: A Complete Guide to the New Draft Amendments to the WHO International Health Regulations

Serious problems remain in the new draft amendments to the WHO International Health Regulations, say Dr. David Bell and Dr. Thi Thuy Van Dinh as they provide a full annotated guide.

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For two years, the 196 States Parties to the 2005 International Health Regulations (IHR) – composed of 194 Member States of the World Health Organisation (WHO), and Liechtenstein and the Vatican – have been submitting and discussing proposed amendments to update this agreement. Introduced in the 1960s, the IHR are intended to strengthen national capacities and improve coordination among countries in the event of a health emergency. Though a legally binding agreement under

international law (i.e., a treaty), most of the provisions have always been voluntary.

The draft of the IHR amendments and an accompanying draft Pandemic Agreement are both still under negotiation a month short of the intended vote at the World Health Assembly (WHA) in late May. Together, they reflect a sea-change in international public health over the past two decades. They aim to further centralise control of public health policy within WHO and base response to disease outbreaks on a heavily commoditised approach, rather than WHO's prior emphasis of building resilience to disease through nutrition, sanitation and strengthened community-based health care.

The changing public health environment

Public health's metamorphosis responds to the increasingly directive nature of WHO's funding and an increasing participation of the private sector in that funding. Together with a growth of commodity-based public-private partnerships including Gavi (for vaccines) and CEPI (vaccines for pandemics), this has been heavily directed by powerful privately-owned foundations with strong connections to Pharma who shape the work of these organisations through direct funding and through influence brought upon countries. This became particularly prominent during the response to COVID-19, in which prior WHO guidance was abandoned in favour of more directive and community-wide measures

including mass workplace closures and mandated vaccination. The resultant concentration of wealth within private and corporate sponsors of WHO, and increasing impoverishment and indebtedness of countries and populations, both set a precedent for such approaches and left the world more vulnerable to their imposition.

Implications of the new draft

In understanding the apparent reversals of some proposals amending the IHR in the latest draft, it is important to understand that the COVID-19 response demonstrated great success in imposing this new outbreak response paradigm under the current voluntary nature of the IHR. Pharmaceutical corporations successfully sealed highly lucrative contracts directly with states, including public funding for R&D and liability-free advance purchase agreements. This was supported with heavy sponsorship of media, health, regulatory and political sectors, enabling both the high level of compliance and the stifling of dissent. Centralising more proscriptive powers within WHO to repeat this business approach under a legally binding agreement would simplify future repetition, but also introduces an element of the unknown into a system already proven to work. These aspects of the previous drafts also presented an obvious focus for public opposition. Pharma has been aware of this reality during the negotiating process.

The latest version of the IHR amendments released on April 16th thus removes wording that would involve member states "undertaking" to follow any future recommendation from the Director General (DG) when he or she declares a pandemic or other Public Health Emergency of International Concern (PHEIC) (former New Article 13A). They now remain as "non-binding" recommendations. This change is sane, conforms with the WHO Constitution and reflects concerns within country delegations regarding overreach. The shortened review time that passed in rather *ad hoc* fashion by the 2022 World Health Assembly will apply to all but four countries that rejected them. Otherwise, the intent of the draft, and how it is likely to play out, is essentially unchanged. The World Bank, IMF and G20 have signalled an expectation that the overall plan will proceed, and rising national indebtedness further increases powers to coerce this.

States are still expected to manage dissenting opinion, and together with the accompanying Pandemic Agreement, WHO and its partners continue to set up a highly dangerous complex (from a public health, equity and human rights viewpoint) involving a massive and expensive surveillance system to identify natural viral variants, a requirement for rapid notification by countries, passage of samples by WHO to pharmaceutical manufacturers of their choice, a 100-day mRNA vaccine delivery bypassing

normal regulatory and safety trials, and then a mass-vaccination-based response that will, as seen in the COVID-19 response, be pitched as a way to get back to normal. This can still be invoked by the DG alone, simply on his or her perception of a threat rather than actual harm. The pharmaceutical companies will be supported by public funds (see discussion on the Pandemic Agreement) and receive liability-protected profits.

An unfit and unready document

This system will be overseen by WHO, despite being a beneficiary of pharma funding, who in turn will be the major financial beneficiaries of the pandemic response. The DG personally selects the committee members who may advise and oversee this process (rather than the member states who are supposed to ultimately be in charge). WHO receives funding for its emergency agenda from the same organisations and private investors who stand to benefit. The conflicts of interest and vulnerabilities to corruption in this scheme are obvious. A whole international bureaucracy is already being put in place for this, whose sole reason for existence is to determine that viral variants and minor outbreaks, a natural part of existence, are a threat requiring a specific response that they must then implement. The current DG declared a global emergency over Monkeypox, after just five deaths in a clear and relatively restricted demographic group.

Lastly, the current text of the amendments discussed below looks far from complete. There are internal contradictions, such as clauses both requiring informed consent and, strangely and alarmingly, recommending that this be overridden. The definition provided of a pandemic is as much based on the response put in place as the pathogen or disease itself. By removing the shortened review period and removing overt compulsion, the prior misrepresentation of urgency and outbreak frequency seems to have been recognised.

Yet, this document, and the draft Pandemic Agreement, are still intended to be voted on before the end of May. This completely abrogates the legal requirement within Article 55 of the IHR(2005), and repeated in this draft, for a four-month review period before any vote. This is not only irrational given the unfinished nature of the text, but inequitable as it disadvantages less-resourced countries in fully assessing likely impacts on health, human rights and their economies. There are no procedural reasons to prevent WHO calling for a later WHA vote after the drafts have been properly reviewed. Member states should clearly demand this.

Significant proposed amendments and their implications.

The key changes and implications of the current draft are summarised below. The proposed

changes are found here and the existing IHR (2005) here.

The proposed amendments should be reviewed in the light of the lack of urgency, low burden and currently-reducing frequency of recorded infectious disease outbreaks and the huge financial requirements on countries – already heavily impoverished and indebted post-lockdowns – for setting up additional international and national bureaucracies and institutions. It must also be assessed in light of the accompanying draft Pandemic Agreement, the apparent conflicts of interest, the concentration of wealth among sponsors of WHO during the COVID-19 response and the persistent absence of a transparent and credible cost-benefit analysis of the COVID-19 response and proposed new pandemic measures from WHO.

(Text note: Bold text below reflects its use in the draft amendments to denote new text added in this draft.)

Article 1. Definitions

> **"pandemic" means a public health emergency of international concern, that is infectious in nature and:**
>
> **(i) has spread and is spreading to and within multiple States Parties across WHO Regions; and**

> **(ii) is exceeding the capacity of health systems to respond in those States Parties; and**
>
> **(iii) is causing social and/or economic and/or political disruption in those States Parties; and**
>
> **(iv) requires rapid, equitable and enhanced coordinated international action, with whole-of-government and whole-of-society approaches.**

It is useful to have a definition of 'pandemic' added to the draft, as it was recently noted elsewhere that without this the entire pandemic agenda is somewhat undefinable. Note the use of 'and'; all these conditions must be met.

It is, however, a technically flawed definition. While clause (i) is sensible and orthodox, (ii) will vary between states, meaning that the same outbreak may somehow be a "pandemic" in one country but not the other. It must also be causing social, economic or political disruption, and must additionally require a "whole-of-government approach".

"Whole-of-government approaches" is an undefinable but popular term in public health that can be argued to be almost nothing – what really requires a whole-of-government approach? Certainly, no infectious disease outbreak in the past few centuries would readily

confirm, as only specific arms of most governments were involved. Some countries had a quite light approach during COVID-19, with very limited government redirection, whilst attaining similar or better outcomes than neighboring states. This would mean that COVID-19 would fall outside this pandemic definition despite "spreading to and within" multiple states and also causing illness.

This definition appears insufficiently thought through, reflecting the rushed nature of this document and its unreadiness for a vote.

> **"pandemic emergency" means a public health emergency of international concern that is infectious in nature and:**
>
> **(i) is, or is likely to be, spreading to and within multiple States Parties across WHO Regions; and**
>
> **(ii) is exceeding, or is likely to exceed, the capacity of health systems to respond in those States Parties; and**
>
> **(iii) is causing, or is likely to cause, social and/or economic and/or political disruption in those States Parties; and**
>
> **(iv) requires rapid, equitable and enhanced coordinated international action, with whole-of-government and whole-of-society approaches.**

‘Pandemic emergency’ is a new term. The definition includes “or is likely to be”, thus substituting for the change in Article 12 in the previous version that included “potential or actual” to broaden the PHEIC scope to a perceived threat rather than an event causing actual harm. i.e., the IHR proposals are unchanged on this point.

‘Pandemic emergency’ appears to be used within the text as a subset of a Public Health Emergency of International Concern (PHEIC). This may be to ensure future conformity of the accompanying Pandemic Agreement with policy on PHEICs, as this is pandemic-specific whilst the IHR addresses declared international public health emergencies of any type.

> “health products” means medicines; vaccines; medical devices including diagnostics; assistive products; vector control products, blood and other products of human origin

More restricted than previous draft, which included an option of “and other health technologies, but not limited to this”, then defining ‘health technologies’ as anything that improves “well-being”.

Standing Recommendations and Temporary Recommendations are now returned to being “non-binding advice”, with the previously deleted ‘non-binding’ wording returned to the

text (see also notes on Article 13A and Article 42 below).

Article 5 Surveillance

Paragraph 1

> Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the core capacities to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1.

This remains problematic, particularly for low- and middle-income countries. The "Core capacities" in Annex One include surveillance, laboratory capacity, maintenance of specialised staff and sample management. Many countries still struggle to develop and maintain these for high burden diseases such as tuberculosis, with well recognised mortality resulting from this lack of capacity. The Pandemic Agreement lays out these resource-intensive requirements in further detail. Low-income countries risk significant harm through resource diversion from high burden health problems to a problem predominantly perceived as a major threat by better-off Western nations with higher life expectancies.

Interestingly, the censorship expectation – "risk communication, including countering

misinformation and disinformation" – has also now been tucked away in Annex 1, but remains essentially unchanged.

Paragraph 5

> When requested by WHO, States Parties ~~should~~ **shall** provide, to the fullest extent possible within the means and resources at their disposal, support to WHO-coordinated response activities.

If this means anything, the change from 'should' to 'shall' seems to imply the state party is still expected to be under some direction from WHO. This is a return to the sovereignty issue – non-compliance could be used as a reason for enforcement such as through financial mechanisms (e.g. World Bank, IMF financial instruments).

The wording has escape clauses in "within the means and resources", but this then begs the question of why it is deemed necessary to change "should" to "shall".

Article 12 Determination of a public health emergency of international concern, including a pandemic emergency

Paragraph 1

> The Director-General shall determine, on the basis of the information received, in particular from the State(s) Party**(ies)** within

> whose territory**(ies)** an event is occurring, whether an event constitutes a public health emergency of international concern**, including, when appropriate, a pandemic emergency…**

The DG alone retains the power to declare a PHEIC or pandemic emergency (see Chapter III provisions below regarding DG power over committees).

Article 13 Public health response, including access to health products

Paragraph 1

> **Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the core capacities to prepare for, and respond promptly and effectively to public health risks and public health emergencies of international concern, including a pandemic emergency, as set out in Annex 1**

As above – this needs to be optional as appropriate in many circumstances. The alternate (bis) version following it is far more appropriate and consistent with equity:

> **1.bis. Each State Party shall, within the means and resources at its disposal, provide sustainable domestic funding to build,**

> **strengthen and maintain the core capacities required under these Regulations.**

Article 17 Criteria for recommendations

> When issuing, modifying or terminating temporary or standing recommendations, the Director-General shall consider:
>
> (a) the views of the States Parties directly concerned;
>
> (b) the advice of the Emergency Committee or the Review Committee, as the case may be;...

The Director General retains sole authority to declare and cease a PHEIC, with the emergency committee and member states giving advice only.

Article 18 Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels

> 3. Recommendations issued by WHO to State Parties shall take into account the need to:
>
> (a) facilitate international travel, as appropriate, including of health workers and persons in life-threatening or humanitarian situations...

It is hoped this reflects some recognition of the harm done in the COVID-19 response through

the effect of international travel on economies. People starve to death in low income countries and lose their incomes and future education, especially women, when tourism is stopped. However, it appears largely confined to health staff.

Article 23 Health measures on arrival and departure

> 3. No medical examination, vaccination, prophylaxis or health measure under these Regulations shall be carried out on travellers without their prior express informed consent or that of their parents or guardians, except as provided in paragraph 2 of Article 31,...

Article 31, paragraph 2 (below) cited here actually supports mandatory vaccination, clashing with informed consent provisions above, and therefore one or other needs rewording (one hopes this is Article 31).

Using vaccination status as a criteria for right of entry, a country's sovereign right though used egregiously in the COVID-19 response, may serve a purpose when a vaccine blocks transmission of a serious disease not already prevalent in the country concerned.

Article 31 Health measures relating to entry of travellers

> 2. If a traveller for whom a State Party may require a medical examination, vaccination

> or other prophylaxis under paragraph 1 of this Article fails to consent to any such measure, or refuses to provide the information or the documents referred to in paragraph 1(a) of Article 23, the State Party concerned may, subject to Articles 32, 42 and 45, deny entry to that traveller. If there is evidence of an imminent public health risk, the State Party may, in accordance with its national law and to the extent necessary to control such a risk, compel the traveller to undergo or advise the traveller, pursuant to paragraph 3 of Article 23, to undergo:
>
> (a) the least invasive and intrusive medical examination that would achieve the public health objective;
>
> (b) vaccination or other prophylaxis; or
>
> (c) additional established health measures that prevent or control the spread of disease, including isolation, quarantine or placing the traveller under public health observation.

In other words, contrary to Article 23, informed consent will not be a requirement for a member state to perform medical examinations or inject people.

Vaccination at time of entry is of no use in preventing disease importation, as it will not stop an established infection in the traveller, so mandatory vaccination at time of entry is not a

legitimate public health measure, irrespective of human rights concerns.

Requirement of medical examinations, or isolation on refusal, would be broadly considered as a last resort in highly dangerous infectious diseases, but should not be imposed lightly.

Amendments in Part IX regarding the use of experts and conduct of committees

Chapter I – The IHR Roster of Experts

Article 47 Composition

> The Director-General shall establish a roster composed of experts in all relevant fields of expertise (hereinafter the “IHR Expert Roster”). The Director-General shall appoint the members of the IHR Expert Roster in accordance with the WHO Regulations for Expert Advisory Panels and Committees (hereinafter the “WHO Advisory Panel Regulations”), unless otherwise provided in these regulations.

This is, obviously, inappropriate for the head of an organisation directly funded by those who benefit from the countermeasures promoted, due to conflict of interest. State parties should, as owners of WHO, surely be providing experts from their own national pool. This would reduce conflict of interest and help ensure diversity and representativeness.

Article 48 Terms of reference and composition [of the emergency committee]

> 2. The Emergency Committee shall be composed of experts selected by the Director-General from the IHR Expert Roster.

See note on Article 47.

Article 49 Procedure [of the Emergency Committee]

> On determination of decisions including a PHEIC:
>
> 5. The views of the Emergency Committee shall be forwarded to the Director-General for consideration. The Director-General shall make the final determination on these matters.

As above, the DG has sole authority. This underlines the importance of keeping compliance with the IHR voluntary. The current Director General declared a Public Health Emergency of International Concern for Monkeypox, after just five deaths in a very specific demographic group. This would, under the new Pandemic Agreement and the provisions here, allow the DG to trigger the whole process of recommending lockdowns, rapid vaccine development, promotion of mandatory vaccination and resultant profits flowing to entities currently involved in funding WHO's pandemic agenda.

Chapter III – The Review Committee

Article 50 Terms of reference and composition

> 3. The Members of the Review Committee shall be selected and appointed by the Director-General.

As above. A review committee must be independent to function properly, and therefore cannot be selected by the same people it is reviewing. All the more so here, as conflicts are so likely as private beneficiaries of the proposed approach also sponsor part of the process..

Article 51 Conduct of business

> The Director-General shall invite Member States, the United Nations and its specialised agencies and other relevant intergovernmental organisations or nongovernmental organisations in official relations with WHO to designate representatives to attend the Committee sessions. Such representatives may submit memoranda and, with the consent of the Chairperson, make statements on the subjects under discussion. They shall not have the right to vote.

It is extraordinary for a review committee that only those appointed by a person whose actions are a subject of the review would have a right to vote and make any determination. However, this

has crept in here, and there is no attempt by Member States to provide a mechanism for serious oversight.

Article 54 Reporting and review

> 3. WHO shall periodically conduct studies to review and evaluate the functioning of Annex 2. [the decision tree for declaring a pandemic emergency or PHEIC]

More of WHO reviewing itself, but then:

Article 54bis Implementation and Compliance Committee for the International Health Regulations (2005)

> 2. The IHR Implementation and Compliance Committee shall be comprised of [number] State Party members, [number] from each WHO Region represented by individuals possessing appropriate qualifications and experience. State Party members shall serve for [number] years.

This alternate Article 54 seems an attempt by some Member State(s) to wrest some oversight back from the DG, ensuring member states nominate committee members with an actual decision-making role. If so, it may benefit from tightening of the wording.

Article 55 Amendments

> The text of any proposed amendment shall be communicated to all States Parties by the Director-General at least four months before the Health Assembly at which it is proposed for consideration.

This is, of course, completely incompatible with a vote on these proposed amendments in May 2024.

Time to review implications is essential. Four months is short for this, four weeks would be ridiculous.

Article 59 Entry into force; period for rejection or reservations

> 1. The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, these Regulations or an amendment thereto, shall be 18 months from the date of the notification by the Director-General of the adoption of these Regulations or of an amendment to these Regulations by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.
>
> 2. These Regulations shall enter into force 24 months after the date of notification referred to in paragraph 1 of this Article, except for:... States who reject or file reservations...

This article will be modified based on the resolution accepted previously by most states at the WHA in 2022 (excepting those who rejected it prior to the end of 2023), reducing the review time.

This is clarified in a report from the DG: "27. The amendments to Articles 55, 59, 61, 62 and 63 of the Regulations, adopted by the 75th World Health Assembly through resolution WHA75.12 (2022), will enter into force on May 31st 2024. As communicated to all States Parties, the Islamic Republic of Iran, the Kingdom of the Netherlands, New Zealand and Slovakia notified the Director-General of their rejection of the above-referenced amendments."

The new articles now come into force 12 months after a vote (Article 63).

For States that reject any amendment during the review period, prior versions of these articles apply. As before, however, active rejection is required, within 10 months (or 18 for the four countries above), or these legally binding articles automatically apply (Article 61).

(*This note is revised from original version.)*

Other issues

A general note on terminology.

"Developed" and "developing" countries. It is perhaps time that WHO moved on from the assumption that some countries are more 'developed' than others. Perhaps 'high income', 'middle-income' and 'low income', reflecting World Bank custom, are less colonialist. Have 'developed' countries attained all that progress and technology can provide? This would of course mean that they were 'undeveloped' 20 years ago, and that technology is the only measure of development, rather than culture, art, political maturity or a preference for not bombing less powerful countries. WHO considers countries such as India, Egypt, Ethiopia and Mali, with thousands of years of written history and civilisation, less 'developed'. Words matter. They promote, in this case, an impression of a hierarchy of countries (and therefore people) in terms of attainment or importance, based in a very materialistic world view.

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