
BRIEFING PAPER
The April 2024 Interim Draft of the IHR Amendments Package

CONTEXT

An interim draft ‘Bureau’s text’ of the proposed amendments to the International Health Regulations (IHRs), dated 17 April 2024, was released by the WHO just prior to the start of the 8th meeting of the IHR Working Group in Geneva. The document is held out as a text showing the *“additions to and deletions of the current IHR text”*, meaning the current in force version of the IHRs.

This is the first interim draft text that has been released since the original package of amendments (dated November 2022) was first published in early 2023. All of the interceding Working Group negotiations have taken place essentially in private. The original package of proposals was analysed in extensive detail in an earlier UsForThem briefing document, available on request.

We understand that it remains the WHO’s intent to finalise this package of amendments so that a final draft of the amended IHRs text can be presented at the World Health Assembly meeting taking place at the end of May 2024, and adopted by a simple majority of member states.

A number of important qualifications therefore apply to a review and analysis of the interim draft text at this stage. First, it is an interim draft which remains under negotiation, and thus the text may change before it is finalised. Second, while we currently assume that the text will be presented for adoption at the end of May, a legitimate question mark has been raised as to the legality of any adoption vote taking place within that timescale. This turns on the interpretation and application of Article 55 under the in force version of the IHRs. That question is not addressed in this briefing but we have commented on it elsewhere.¹

Nevertheless, by any measure, this latest draft reflects a material change of tone and position relative to the original package of amendments. We have seen that some

¹ <https://twitter.com/UsforThemUK/status/1767230334238708030>

commentators are continuing to flag serious concerns about this latest draft. Certainly questions remain about the significant overreach and expansionist ambitions evident in the original draft proposals, most egregiously insofar as they would have impacted on the primacy of human rights, free speech and national autonomy.

There are equally serious problems with the funding arrangements for the WHO, its increasingly corporatised mission and ethos, and – given the litany of mistakes and mis-steps made by the organisation during the Covid pandemic – its general fitness for purpose as a global public health manager.²

However, these topics are not specifically engaged in the interim draft and so they are not the subject of this briefing, which concentrates on the substantive content of the 17 April 2024 document.

It must also be recognised that the purpose of the IHR amendment exercise has only ever been to *expand* the scope of the IHRs and *strengthen* existing positions and powers; it has never been on the table to narrow the scope or powers that have been in force in various forms for decades, and most recently updated in 2005.

Overall, we view this latest development as a significant victory for those of us who have expressed deep and serious concerns about this IHRs review project. That said, we remain deeply concerned about the WHO's expansionist and anti-democratic ambitions, as well as cautious about the IHRs: regardless of what the IHRs and the Pandemic Treaty eventually say, it would be naive to assume that, in the context of the next actual or perceived international health emergency, all nation states can be relied upon to act in accordance with their international legal obligations. It may not be the case that all of the words written in the IHRs will survive first contact with the next pathogen.

This briefing has been prepared by lawyers qualified in the jurisdiction of England and Wales and credentialled at the end of this document.

HEADLINES

In most areas, and for all of those which most concerned us from a legal perspective, the interim draft reflects a major retreat by the WHO Working Group from the text of the original proposals. We address each of these important areas in turn.

² See, in particular, *The Covid Consensus*, T. Fazi and T. Green, Hurst Publishers, 2023.

- 1. *The WHO's recommendations remain non-binding. Article 13A.1 which would have required Member States to follow directives of the WHO as the guiding and coordinating authority for international public health has been dropped entirely.***

One of the most controversial proposals in the original package of amendments was to amend the definitions of WHO temporary and standing recommendations to explicitly delete reference to those recommendations being “non-binding”.

This, together with a new Article 13A.1 requiring Member States to “*recognize [the] WHO as the guid[ing] and coordinating authority of international public health response*” and to “*undertake to follow*” its recommendations, would if carried forward have transformed the WHO from a purely advisory body to a supra-national public health executive authority with power to issue legally-binding advice and directions to Member States.

Crucially, those key amendments have been dropped in their entirety in this interim text. This is a very significant change of position because while it does not affect the binding nature of the obligations to which Member States will commit by adopting the updated IHRs, it *does* affect the force with which the WHO can issue any future statements or advisory communications while exercising its coordinating functions under the IHRs. According to this interim draft, all such WHO communications will remain advisory only. This has a pervasively positive effect because it means that national governments cannot legally be compelled, and should not regard themselves as bound, to follow the WHO's lead (or at least, no more than they had already voluntarily bound themselves to do so – for those countries which rely on WHO funding to sustain their health services, particularly in the Global South, the distinction may continue to be moot).

The fact that this material amendment had been contemplated but is now seemingly rejected in the latest draft is helpful insofar as it should carry jurisprudential weight were any question to arise in the future as to whether a WHO advisory or recommendation issued pursuant to the IHRs should – in a domestic legal context – be considered binding.

- 2. *An egregious proposal which would have erased reference to the primacy of “dignity, human rights and fundamental freedoms” has been dropped. This proposal marked a particularly low watermark, and should never have been suggested.***

The original draft of the IHR amendments had proposed to delete from Article 3.1 of the IHRs the words *“The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons”* and to replace them with *“The implementation of these Regulations shall be based on the principles of equity, inclusivity, coherence and in accordance with their common but differentiated responsibilities of the States Parties”*.

This was an egregious change which would have cut across seven decades of international human rights norms and jurisprudence. The new interim draft now reads:

“1. The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons, and shall promote equity and solidarity among States Parties.”

The additional recognition of equity and solidarity between nation states seems inoffensive, and unsurprising given what we understand to have been the equity-focussed nature of much of the recent negotiations.

3. *Proposals to construct a global censorship and ‘information control’ operation led by the WHO have been dropped.*

The original draft text had proposed, in an extensively amended Article 44 and expanded Annex 1, to mandate that Member States collaborate with each other, and with the WHO, and that the WHO itself *“at the Global level ... strengthen capacities to ... counter misinformation and disinformation”*. The latter requirement in particular provoked controversy because it suggested that the WHO would commit to develop its own information control and censorship operations distinct from the domestic activities of Member State governments and agencies, ‘at a global level’.

Those of us already concerned by the extent of the State-sponsored censorship and information control revealed to have taken place during the Covid pandemic had regarded the implication of any supra-national (and unelected, democratically unaccountable) authority acquiring the means and the legal standing to control lawful scientific and public debate at a national or global level as a profound threat to free speech, national autonomy and democracy, and human rights. This was particular worrying when read alongside the proposed amendment to Article 3 of the IHRs explained in the previous section.

Those proposals have been scaled back significantly in the interim draft, and in particular the ambition to anoint the WHO as a global centralised censorship authority

appear to have been dropped. Amendments aimed at strengthening each Member State's "*risk communications*" operations remain by way of updates to Annex 1, which oblige Member States to develop, strengthen and maintain their capacity to counter "misinformation and disinformation". The Pandemic Treaty too contains soft obligations for Member States to promote evidence-based information, promote trust in public health and cooperate with each other to prevent mis and disinformation.

Dispassionately, however, these amount to little more than a statement of the reality of encroaching national-level censorship. While a point of concern to many of us, and a subject on which further action is certainly needed, this appears no longer to be a significant feature of the IHR amendments debate.

4. *Provisions that would have allowed the WHO to intervene on the basis of a mere 'potential' health emergency have been dropped: a pandemic must now either be happening or likely to happen, but with the safeguard that to activate its IHR powers the WHO must be able to demonstrate that a series of qualitative tests have been met and that rapid coordinated international action is necessary.*

Original proposals to modify Article 12 of the IHRs appeared to contemplate the Director General of the WHO being able to declare a public health emergency in circumstances where a perceived health threat is, in his opinion, either "actual" or merely "potential".

The legal implication of that change, when read alongside other proposals to expand the scope of the IHRs and to give the WHO binding powers of direction over Member States, were of great concern to us. Certainly it prompted legitimate commentary about the risk of the WHO pre-emptively identifying and declaring 'potential' emergencies in order to engage its more extensive powers, and access to Member State resources, under the modified terms of the IHRs.

In the interim draft, however, those modifications to Article 12 no longer appear and, as noted in the sections above, other relevant proposals including the central proposal to grant the WHO powers of direction, have also been deleted.

Instead, the Working Group has modified the legal trigger for the Director General to declare a public health emergency so that it would now explicitly include a "*pandemic*" and a "*pandemic emergency*", both of which are in effect subsets of the existing concept of a public health emergency of international concern (PHEIC).

The latter concept is defined as an infectious health emergency which is already, *or is likely to be*, spreading within multiple Member States, and must additionally be *likely to* overwhelm health systems, and *likely to* cause social, economic or political disruption in Member States. Thus it does involve a pre-emptive element (i.e. a potential rather than actual emergency), but crucially, and contrary to concerns that a small number of commentators have voiced, it is not an unfettered discretionary trigger or a hair trigger.

Specifically: to establish that a pandemic emergency is occurring, the definitional provisions as now drafted would require the Director General to be satisfied that a “*rapid, equitable and enhanced coordinate international*” response is “*required*” (importantly not: ‘is likely to be required’) to an “*extraordinary event*” which constitutes “*a public health risk ... through the international spread of disease*”.

In other words, if he abides by the terms of the IHR, the Director General will need to be able to evidence that an extraordinary international infectious public health risk has emerged in sufficiently clear terms that it already “*requires*” a rapid and coordinated international response. Moreover, he will need to demonstrate not only that the risk is or is likely to be spreading but also that it necessitates a response that is likely to exceed the capacity of health systems and to cause social, economic and/or political disruption.

These function as inter-conditional tests rather than independent tests; so – as currently drafted – contrary to fears expressed by some already it would not legally be possible for the Director General to declare a pandemic emergency on the basis that, for example, NHS capacity in the UK is perennially said to be stretched to capacity in flu season.

Much therefore turns on the words used in these definitions, so we should remain alert to any last minute alterations.

While we oppose as a matter of principle that authority to declare a public health emergency, including a ‘pandemic’ or a ‘pandemic emergency’, currently rests with the Director General of the WHO, concentrating decision-making powers in the hands of a single unelected and largely unaccountable individual, we recognise that this has been the case since 2005.

For that reason it was not a feature of the existing IHRs that was ever realistically on the table for negotiation during the current process; but it can and should remain one of many challenge points in favour of reforming the architecture and balance of powers across global, national and local public health bodies.

5. ***A material dampening of the expansionist ambitions of the WHO: provisions which had proposed to expand the scope of the IHRs to include “all risks with a potential to impact public health” (e.g. climate change, food supply) have been deleted. The scope now remains essentially unchanged, focussed on the spread of disease.***

The original IHR amendments had, via Article 2, purported to expand the scope of the IHRs so that it would apply to “*all risks with a potential to impact public health*”. This was a significant amendment which, allied with the proposed power to give binding directions to Member States, many believed was intended to open the door to the WHO expanding its remit into areas such as climate change and food supply management.

In the interim draft, Article 2 is left essentially unchanged from its original form – the proposal seemingly rejected – save for the addition of an unsurprising reference to the purpose of the regulations including preparation for future pandemics.

6. ***A climb-down on mandatory funding for pandemic-related infrastructure and subsidies, and implicit recognition that public spending is a matter for national governments to determine.***

When the original proposals were first released they were published alongside the first (CA+) draft of the Pandemic Treaty. Those drafts together proposed substantial public spending commitments for Member States including a commitment to allocate at least 5% of its national health budget and an unspecified additional percentage of GDP to pandemic prevention and response initiatives. In addition, the Treaty and the draft IHR proposals included provisions which anticipated Member States participating in pandemic funding arrangements designed primarily to support Member States whose infrastructure and health systems needed to be upgraded to meet presumed IHR standards.

These granular and prescriptive commitments have disappeared from the IHR text (and indeed had already been removed from the draft Treaty text). In their place, Articles 4 and 13.1.bis of the revised IHRs would enshrine a softer commitment for each Member State simply to maintain internal (i.e. national-level) capacities sufficient to meet their commitments under the IHRs, including by using the financial resources “*at its disposal*” (i.e. recognising that it is for Member State governments to determine their own public spending capacities).

A new Article 44.2.bis provides an even softer commitment for Member States to “*undertake to collaborate*” with each other to mobilise financing for supporting the implementation of pandemic-related activities. In legal terms an undertaking to collaborate in practice probably amounts to little more than an agreement to discuss in good faith.

The draft Pandemic Treaty makes provision for Member States both to collaborate to strengthen financing mechanisms for health emergencies, as well as pandemic prevention, preparedness and response (PPR), and to the extent possible within the means and resources at its disposal to “*maintain or increase*” domestic funding for pandemic PPR, “*without undermining other domestic public health priorities*”.

Member States will also “*promote*” innovative financing measures, and a ‘Coordinating Financial Mechanism’ to support pandemic PPR in developing countries in particular. These provisions are clearly intended to imply some level of new and additional financial commitment, but leave the quantification of those commitments for another day and, presumably, another negotiation among national governments.

7. *Explicit recognition that Member States not the WHO are responsible for implementing the IHRs, and bold plans for the WHO to police compliance with all aspects of the regulations have been materially watered down.*

In the interim draft a new Article 4.1.bis expressly acknowledges that national-level authorities have responsibility for implementing the updated IHRs within their respective countries. In one sense this is an unnecessary legal truism, but in light of the intensity of the criticism of the potential impact of the original proposals on national sovereignty, it is plausible to think that this addition implicitly acknowledges the legitimacy of that earlier criticism.

Whereas the original proposals had contemplated an Implementation Committee and a separate Compliance Committee being formed to oversee implementation and ongoing compliance with the amended IHRs, in the new interim draft Article 54 bis envisages a Member State-led ‘IHR Implementation and Compliance Committee’ to facilitate and oversee implementation and compliance. Notably, and again perhaps with a nod to the earlier criticisms, that committee will be expressly directed by the IHRs to be “*facilitative in nature*” and to be “*transparent, non-adversarial and non-punitive*”. In other words, it can seek to persuade but shall have no sticks – an advisory rather than a directive body.

In any event, provided that any temporary or standing recommendations issued by the WHO under the amended IHRs remain advisory only (as seems now to be the case, explained in section 1 above) the practical significance of any committee for supervising compliance with the IHRs is materially allayed. Under the original proposals, the Compliance Committee concept envisaged a proactive body established to police, among other matters, compliance with WHO's binding recommendations, and granted powers to investigate instances of non-compliance and to make recommendations to *the WHO* for how those Member States could achieve compliance (Article 53 bis).

In this aspect, the interim draft reflects a material scaling back from the original proposals.

8. *Many other provisions have been diluted, including: surveillance mechanisms that would have installed the WHO at the pinnacle of a global system of surveillance identifying thousands of potential new pandemic threats on which it could act; provisions which could have expedited regulatory approvals for new medicines including vaccines; provisions which would have encouraged and favoured digital health passports; provisions requiring forced technology transfers and diversion of national resources.*

Public health commentators have questioned the WHO's desire seemingly to prioritise pandemic surveillance and prevention at the expense of competing health priorities, including hygiene and healthcare initiatives in developing countries that have historically saved millions of lives each year.

Though on paper the surveillance-related proposals which remain in the interim draft fall far short of the expansive original proposals under which the WHO would have coordinated a global system of local, regional and national surveillance operations (Article 44, Annex 1 and New Annex 10), the original ethos that it will be desirable – continuously – to seek out new pathogens and variants evidently has not abated, and remains reflected both in the IHRs text and, particularly, in the draft Pandemic Treaty text.

In the new interim draft text, Member States will still commit to develop, strengthen and maintain pathogen surveillance capacity, with supporting obligations to “*progressively strengthen*” surveillance activities also still appearing in the Pandemic Treaty; but by itself and absent detailed amendments to Annex 1 and the addition of New Annex 10 this obligation is essentially just a more granular restatement of commitments already in force under Article 5.1 of the IHRs. That existing Article already obliges all Member

States to develop, strengthen and maintain their capacity to assess, notify and report public health emergency events, including pandemics. So in legal terms at least, the position is not materially altered.

Nevertheless, as other respected critics such as Dr David Bell have pointed out, what is written down may be only part of the story, and the strength of the WHO's ambition in this area is undeniable. The advent of a new Pandemic Treaty may well set the stage, as feared, for a proliferation of self-serving pandemic risk flags being raised by the WHO and private pharmaceutical organisations. We agree that the heavily skewed focus of the WHO on pandemic risks, and the role of pharmaceutical-associated funding for the WHO in driving that focus, remains a serious and significant problem to which further efforts must be addressed, albeit we suggest this is now less so a feature of the IHRs debate.

Meanwhile, provisions in the original IHR amendment proposals which appeared to lay the groundwork for expedited regulatory approvals for novel medicines (Articles 13A.5 and 6) have been dropped. A swathe of legacy IHR provisions relating to, inter alia, border control measures of questionable efficacy deployed during the Covid pandemic remain untouched in the interim draft (Articles 18 and 23), including quarantines, isolations, testing and requirements for vaccination, but a proposal originally to have been inserted as a new Article 23(6), which controversially would have created a presumption in favour of mandating digital health passports, has been dropped.

Unsurprisingly, it appears that provisions which could have forced transfers and licensing of drug and other medical technology IP rights have been removed from the interim draft, presumably under pressure from global pharmaceutical groups. The Pandemic Treaty contains soft provisions intended to prompt relevant Member States to encourage pharmaceutical groups within their influence to be helpful and benevolent with their patents, particularly for the benefit of developing countries, but these are now couched as barely-enforceable commitments to discuss.

IN CONCLUSION

The unexpected extent of the scaling back of the ambitious original proposals revealed by this long-overdue interim draft unquestionably marks a significant victory for all who have resisted those ambitions.

That is not to say that the crumbling, conflicted and corrupted public health artifice that the WHO and its corporate supporters have become is in any sense now 'fixed'. But if

this latest draft holds, the most serious and imminent threats to human rights, free speech and democratic autonomy will have been averted, for now at least.

If resistance to bold attacks on democratic norms such as this is to be sustained, and to be successful in future rounds, we must not only accept the wins, such as this, we must also be sanguine about the impact of remaining imperfections which are materially less consequential in the broader context. Devoting energy to every last imperfection, or indeed to fighting ghosts, damages collective credibility and risks drawing public and political attention away from other dangers.

It is legitimate to say that the Pandemic Treaty and the IHRs are still intended by the WHO and its Member States to form a strengthened global framework agreement for pandemic management as part of a longer-term transfer of public health decision-making away from community and national levels; and it seems self-evident that the WHO aspires to play a more-than-advisory role in that global framework. We remain opposed to this anti-democratic direction of travel.

It would equally be legitimate to say that the expansionist ambitions implicit in the WHO's One Health ideology, and the presumption that a 'whole-of-society' approach to managing health emergencies including pandemics is always desirable, pose a threat for those who believe the role of the WHO, if it exists at all, should be to promote 'the highest attainable standard of health' for the many. At present, the WHO appears to many of us to be most focussed on promoting the interests of pharmaceutical manufacturers, influential governments and the many officials who enjoy employment by self-seeding bureaucracies.

This interim draft of the IHRs is – understandably – already being viewed through a lens of suspicion and scepticism. These are legitimate feelings given the WHO's terrible handling of the IHR negotiations and its seemingly duplicitous communications strategy. Indeed, that sceptical sentiment speaks to the grave damage done by the WHO, and particularly its Director General, to the trust and confidence of a substantial proportion of the global populace it purports to serve.

In light of that, and the well-documented mis-steps and overreach of the WHO since 2020, we must question whether the IHRs remain an appropriate framework instrument, and whether the WHO in its current form, with its current funding arrangements, remains an appropriate organisation to play any role in the management of future pandemics. That is a part of a wider debate which must now happen.

As our analysis above indicates, however, and unless the interim draft text of the proposals changes materially before its eventual adoption, the text of the IHRs – we suggest – is not now the best vehicle for moving that critical and much-needed broader debate forward.

THE AUTHORS

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Molly and Ben produced UsForThem’s earlier authoritative guide to the original IHR amendment proposals, which was widely relied upon and cited by parliamentarians and politicians, academics, journalists and other commentators in the UK, US and elsewhere.

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