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Far-reaching U.S. Proposals to Amend the International Health Regulations at the Upcoming 75th World Health Assembly: A Call for Attention

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The upcoming 75th World Health Assembly (WHA) to be held in Geneva from 22-28th May 2022 will potentially adopt far-reaching amendments to the 2005 International Health Regulations (IHR). The IHR is currently the most important multilateral treaty regulating the global architecture for health emergency, preparedness, response and resilience (HEPR architecture). The extensive amendments to the IHR have been initiated by the United States (US), listed as agenda item WHA75/18 for the 75th WHA. The amendments are already backed by 19 co-sponsor states and the EU.

As of yet, there has been almost no public awareness or debate of the substantial amendments to the IHR although the WHO Secretariat circulated the US initiative first in January 2022 to state parties. The US initiative contradicts the gist of a report by the WHO Director-General issued in November 2021 which sketched out some of the amendments now tabled by the US, but which also indicated that the IHR will not be renegotiated, raising a number of concerns about amending the IHR. Attention to the US amendments was further drowned by the stir made around the launch of the negotiations to draft a new treaty on pandemic preparedness and response by 2024 with a hitherto uncertain scope, content and outcome, as well as an uncertain relationship to the existing legal framework of the IHR. The scope of the proposed US amendments might therefore come as a surprise to a number of delegations to the 75thWHA.

The following is a brief comment on the extensive amendments proposed by the US that, if adopted, will lead to a considerable extension of WHO's emergency powers.

Increasing the WHO General Director's executive emergency powers

and its implications

Under Article 12(1) of the current IHR, read in conjunction with Article 1(1) IHR, the WHO Director-General already has the broad executive power to declare a public health emergency of international concern (PHEIC) when faced with an 'extraordinary event' in one state which is determined 'to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response'. In this process, the Director-General shall *inter alia* enter into extensive consultations with the state party in whose territory the 'event' occurs and come to a mutual conclusion within 48 hours on whether the event indeed constitutes a PHEIC (Article 12(2) IHR). The proposed US amendments to Article 12 IHR will both considerably extend the executive powers of the WHO Director-General to declare global emergency-like situations and centralise this power further by removing the need to consult and find agreement with the respective state party.

The former is achieved first via the introduction of a new category of an 'intermediate public health alert' that requires 'heightened international awareness' of a hitherto undefined low threshold (proposed new Article 12(6) IHR). Second, the US amendments suggest granting new overlapping layers of executive emergency powers to the six WHO Regional Directors to declare a 'public health emergency of *regional* concern' (PHERC) (proposed new Article 12(7) IHR). There is no indication as to the division of powers between the regional and international levels to declare health emergencies, nor are there any proposals as to how the increase in the WHO Director-General's and Regional Directors' executive powers is to be safeguarded against abuse. The importance of these questions becomes clear when practical and legal consequences of PHEIC/PHREC/'intermediate public health alert' declarations are considered: the powers of Emergency Committees (see Articles 15-17 and 48-49 IHR) set up by the WHO Director-General in response to such emergencies to issue recommendations to states to adopt medical and non-medical countermeasures, which, as has become clear with regard to the responses to Covid-19, can have far-reaching implications for the livelihoods, lives, health and human rights of individuals around the world. In addition, WHO emergency declarations can trigger the fast-track development and subsequent global distribution and administration of unlicensed investigational diagnostics, therapeutics and vaccines. This is done via the WHO's Emergency Use Listing Procedure (EULP). The introduction of an 'intermediate public health alert' in particular will also further incentivise the pharmaceutical industry's move to activate domestic fast-track emergency trial protocols as well as for advance purchase, production and stockpile agreements with governments before the existence of a concrete health threat to the world's population has been detected, as is already the case under WHO's EULP via the procedures developed for a 'pre-public health emergency phase' (see here, pp. 10-15).

As indicated, the proposed US amendments to Article 12 IHR also increase WHO's powers towards the state in whose territory an 'event' occurs, i.e. on whose territory a new, emerging or re-emerging pathogen is detected. This, in turn, further restricts states' 'sovereign rights to legislate and to implement legislation in pursuance of their health policies' as set out in Article 3(4) IHR, should they disagree with the assessment of WHO's Director-General and the Emergency Committee. This would be so even if the legislation is adopted and implemented in line with the respective states' obligations under international human rights law as specified in Article 3(1) IHR. The US amendment proposals to Articles 9 and 10 IHR moreover strengthen WHO's powers to assess alleged global health risks by relying on information received *outside* official channels, giving the respective states only

24 hours to verify such information, and to accept WHO's 'offer' to collaborate in 'assessing the potential for international disease spread, … and the adequacy of control measures'. The rejection of such an 'offer' results in the disclosure of the health information, giving the respective state no possibility to express its views on the matter, including on potentially unjustified allegations. The US proposals also do not envisage WHO consultations with the respective state parties concerning information indicating the potential existence of an 'intermediate public health alert' or a PHREC. Given the substantive economic consequences (especially concerning tourism and international trade) WHO declarations of such emergency situations can have for affected states, these provisions are unlikely to promote friendly relations between governments, and between WHO and its member states.

WHO deployment missions as default option during PHEICs

A related US proposal for the amendment of Articles 13(3) and (4) IHR has a similar effect of increasing WHO powers in relation to member states' freedom to determine their own health policies during a PHEIC in light of local circumstances and preferences. By deleting the phrase 'at the request of the State Party', and replacing 'may' with 'shall', assistance offered by WHO to a state in the response to public health risks becomes the default option. If a state does not accept such offers for assistance within two days, it must justify this by declaring the 'public health rationale for the rejection' to all other WHO member states, potentially resulting in far-reaching economic and financial consequences for the rejecting state. WHO assistance offered includes 'mobilisation of international assistance', including on-site assessments, supported further by suggested amendments to Article 15(2) IHR, allowing the WHO Director-General and the Emergency Committees set up by him/her to recommend 'the deployment of expert teams' to states experiencing a PHEIC.

The proposal to grant WHO – and the US Centre for Disease Control and Prevention (CDC) which is closely associated with WHO due to its technical skills in epidemiological investigations – the right to carry out on-site assessments/send expert teams that the state party in question cannot easily reject, should be carefully analysed also in light of similar US proposals made in 2004 during the then thorough revision process of the IHR (lasting from 1995-2005). At the time, some WHO regions rejected the proposal as they suspected a US' intention behind them to gain access to biodefence research facilities around the world, thus fearing espionage. This appeared against the background of the Iraq war which started in 2003 under the pretext of the existence of Iraqi bioweapons that UN investigators had been unable to find (see more here at p. 24).

Issues not considered: detection of SARS viruses automatically constituting PHEICs and default end to PHEICs

US proposed amendments miss the opportunity to question the fact that the detection of a SARS virus automatically leads to the declaration of a PHEIC in accordance with current Annex 2 of the IHR without there being a requirement that the actual severity of the illness caused by the new respiratory virus is assessed. Considering the experiences with SARS-CoV-2, it can rightly be questioned as to whether such an approach is justified. The SARS-CoV-2 PHEIC declared by WHO on 30 January 2020 resulted in the adoption of unprecedented medical and non-medical countermeasures around the world having extensive second and third order effects (analysed e.g. here, here and here), despite the fact that the Infection Fatality Rate (IFR) for Covid-19 is low, in particular for persons under the age of 70.

In light of the fact that the SARS-CoV-2 PHEIC should – in accordance with Article 12(4) IHR – have been terminated by now (May 2022), amendments could have suggested the inclusion of an automatic expiry date for PHEICs, similar to the expiry of temporary recommendations after a three months period issued by the Director-General and Emergency Committees (according to Article 15(3) IHR). This would also terminate the global distribution of investigational EUL diagnostics, therapeutics and vaccines, transferring them back into regular clinical trial procedures to ensure their full safety and effectiveness.

Compliance Committee and Universal Peer Review Mechanism

The US amendments include a proposed new chapter IV to the IHR on a Compliance Committee tasked to monitor state compliance with their obligations under the IHR. Consisting of six government experts from each WHO region, it shall *inter alia* be authorised to request information from state parties, undertake information gathering in state parties (with their consent), seek services of experts and advisers (including a wide range of non-state actors), and recommend how states shall improve compliance, including by offering financial and technical assistance. Questions can be asked as to whether a group of nominated 'governmental experts' are suitable to independently judge whether a state party violated their obligations under international law. Proposed amendments to Article 5 IHR furthermore envisage the introduction of a Universal Peer Review Mechanism to review states' capacities to detect, assess, notify and report new, emerging and re-emerging pathogens. If implemented, these mechanisms are likely to contribute to restructuring of domestic health systems and allocation of domestic health budgets away from primary health care centred around the implementation of the core human right to health towards pandemic surveillance, preparedness and response activities, regardless of how disease burdens are spread locally.

Adoption and entry into force of the amendments

Finally, the US amendments propose to reduce the time during which state parties to the IHR can reject, or enter reservations to, future IHR amendments that were adopted by a simple majority of the WHA from 18 months to six months (proposed US amendments to Article 59 IHR). Thus, in future, if states do not opt out within six months, amendments enter into force for them automatically in line with Article 22 WHO Constitution and the amended Article 59 IHR. This leaves states rather limited amount of time thoroughly evaluate the legal and practical implications of IHR amendments, including for their domestic health policies and budgeting.

Concluding remark

This short review of the US proposals to amend the IHR would like to end with a call on members of the WHA to discuss and carefully consider the implications of the proposed amendments before endorsing and adopting them. Have technocratic, biomedical approaches, developed and implemented from the top down primarily through executive action, worked well in response to Covid-19, justifying a further extension and centralisation of global emergency powers at WHO? And, if WHO's powers are extended in this way, is there a need to also answer the question *quis custodiet ipsos custodes* (who guards the guards?), and to thus set up mechanisms ensuring that WHO complies with its obligations under the IHR and its Constitution, as well as its responsibilities for human rights deriving from customary international human rights law?

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