THE WHO'S PANDEMIC LAWMAKING - NEGOTIATIONS OF INTERNATIONAL CONCERN

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The WHO's Pandemic Lawmaking: Negotiations of International Concern, October 2023
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Negotiations of International Concern at the WHO

The World Health Organisation (WHO) and its member states are currently involved in two far-reaching negotiation processes that will overhaul the international legal framework for global health emergency prevention, preparedness and response.

This document aims to thoroughly inform and open a transparent debate in WHO member states about the planned reforms and their wider implications. To this end, it attempts to give a detailed but easy-to-understand description of the eight most important building blocks of the envisaged reforms and their likely far-reaching implications for human health and the enjoyment of human rights worldwide.

Note: all links have been accessed last on the 5th of October 2023.

Contents

List of abbreviations

BWC – Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction

CEPI – Coalition for Epidemic Preparedness Innovations

COP – Conference of the Parties

COVAX – Covid-19 Vaccines Global Access

ECHR – European Convention on Human Rights

GAVI – Alliance for Vaccines and Immunization

GHS – Global Health Security

GoF – Gain of Function

ICCPR – International Covenant on Civil and Political Rights

ICESCR – International Covenant on Economic, Social and Cultural Rights

IFPMA – International Federation of Pharmaceutical Manufacturers

IHR – International Health Regulations

INB – Intergovernmental Negotiation Body

PHEIC – Public Health Emergency of International Concern

PHERC – Public Health Emergency of Regional Concern

PPP – Public-private Partnership

SCHEPPR - Standing Committee on Health Emergency Prevention, Preparedness and Response

WGIHR – Working Group on Amendments of the International Health Regulations

WHA – World Health Assembly

WHO – World Health Organisation

WHO CA+ – WHO Convention, Agreement or other International Instrument on Pandemic Prevention, Preparedness and Response

WHO-DG – Director General of the World Health Organisation

WHOC – Constitution of the World Health Organisation

Introduction

This document describes the main building blocks and functioning of the WHO's existing architecture for global health emergency prevention, preparedness and response.

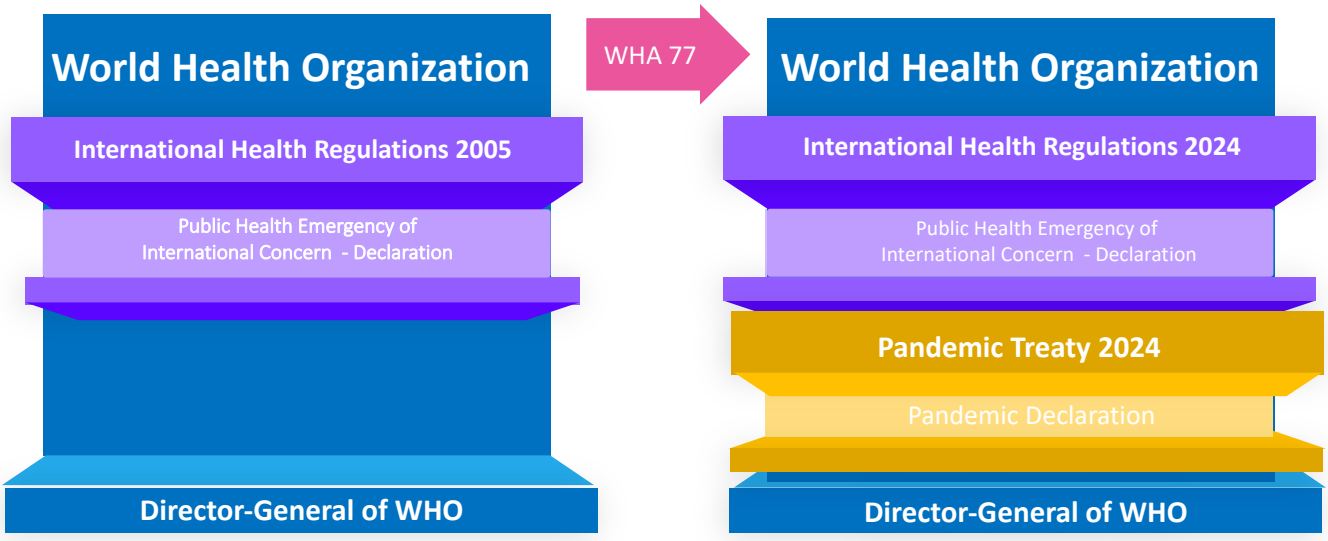
It shows how the planned reforms of the international legal framework on this architecture is likely to both greatly enlarge all building blocks of this architecture and significantly expand the WHO Director-General's (WHO-DG) executive, legislative and administrative powers during a public health emergency of international concern (PHEIC), and potentially also during a pandemic. This will likely give the WHO-DG further powers to determine health interventions and individual medical treatments (i.e. countermeasures) for every person living on the planet; to command vast funds and resources; and to activate a network of public-private partnerships (PPPs) and WHO member states that rapidly develops, gives emergency authorisation, distributes and administers investigational medicinal products to address any future PHEIC and pandemic around the world.

The analysis also briefly explores the funds and mechanisms that are being set up to finance the expanding architecture for global health emergency prevention, preparedness and response. For context, it in addition summarises the reasons that the WHO gives for these reforms, as well as the ideology that drives and shapes these reforms: the Global Health Security (GHS) doctrine.

The document further highlights some of the issues that are not or insufficiently covered by the reform proposals as well as some of their more prominent problematic aspects. Among the latter are their shaky factual basis, the considerable effects these reforms may have for human health, on the enjoyment of human rights, on the functioning of democratic states and on medical law (especially clinical trials and medicinal product authorisation), as well as the likely proliferation of dangerous gain-of-function (GoF) research that it may bring about.

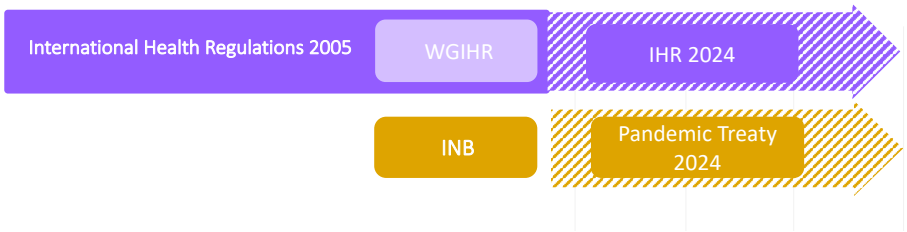
The concluding part calls for a thorough and open debate in WHO member states of the on-going negotiations and their potentially far-reaching implications. This will be an essential first step towards stopping these negotiations of international concern.

New WHO Pandemic Architecture possibly adopted at WHA 77 in 2024:



I. Two Parallel Reform Processes

For starters, it has to be made clear that two parallel reform processes of the international legal framework on the architecture for global health emergency prevention, preparedness and response are currently underway at the WHO.



I.1 New treaty on pandemic preparedness and response

The first process is the negotiation and drafting of a new WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (WHO CA+). The decision to negotiate this new treaty was taken in December 2021 at the second Special Session of the World Health Assembly (WHA).[1] The negotiation and drafting process takes place primarily in the Intergovernmental Negotiation Body (INB).[2]

This analysis uses the currently available draft of the WHO CA+, the 'Bureau's text of the WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response' (henceforth referred to as 'WHO CA+ (Bureau's text)'), dating from 2nd of June 2023.

According to its tight timeline, the INB is to produce a negotiation text of the WHO CA+ by November 2023,[3] as well as a report on the negotiation and drafting process to the 77th WHA to be held in May 2024.[4] The WHO CA+ may be opened for signature and ratification by WHO member states at the 77th WHA too.[5]

I.2 Revision of the International Health Regulations (IHR)

The second process is the process of revising and amending the existing multilateral treaty regulating global health emergencies, preparedness and response: the International Health Regulations 2005 (IHR).[6] The official decision to embark on this process was taken at the 75th WHA in May 2022,[7] and

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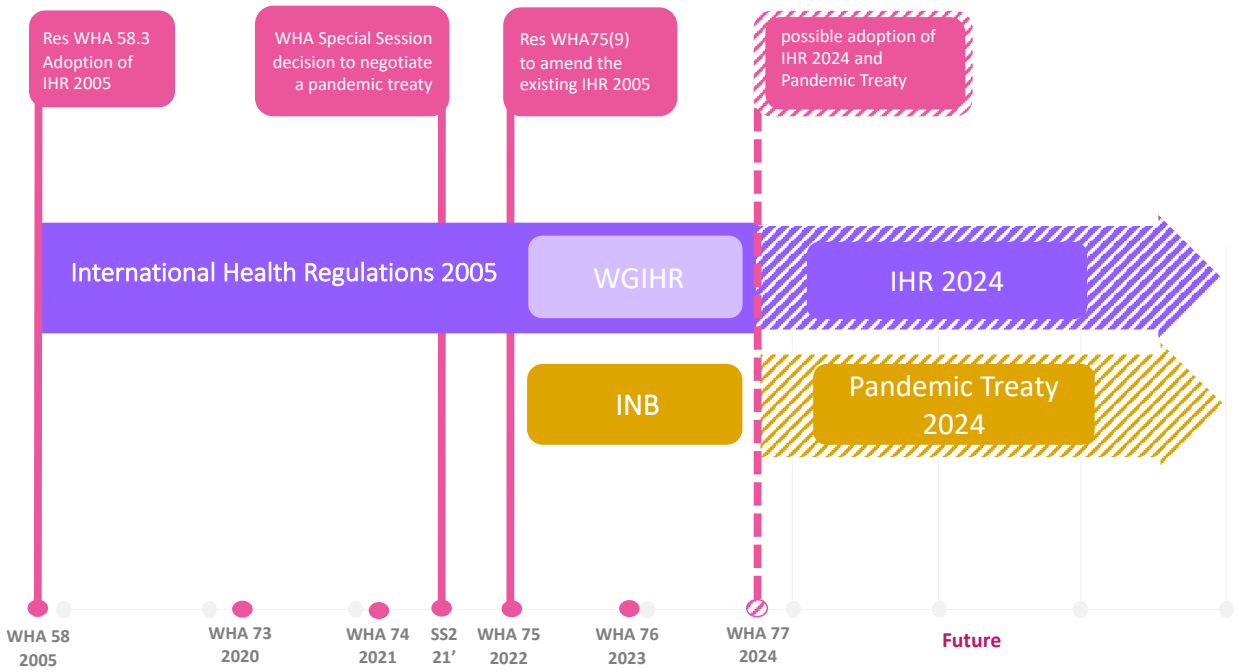
[1] WHASS, 'The World Together: Establishment of an Intergovernmental Negotiating Body to Strengthen Pandemic Prevention, Preparedness and Response', SSA2(5), 1 December 2021.
[2] Website of the INB: https://inb.who.int
[3] WHO, INB Bureau to Develop a Proposal for Negotiation Text, 13 September 2023.
[4] INB, 'Proposal by the Bureau on an Update Timeline and Deliverables, Development of the Zero Draft of the WHO CA+, and the Establishment of Drafting Group Modalities', A/INB/3/4, 25 November 2022. A new version with the negotiating text will be published around 16th of October, according to INB, Interim report of the Meeting, A/INB/DG/3, 19 September 2023.
[5] Art. 35 WHO CA+ (Bureau's text) envisages opening for signature immediately after the adoption of the treaty at the 77th WHA.
[6] International Health Regulations (IHR) 2005, 2509 UNTS 79. The treaty entered into force 15 June 2007.
[7] WHA, 'Strengthening WHO Preparedness and Response to Health Emergencies', WHA75(9), 27 May 2022; and WHO Executive Board (EB), 'Strengthening the International Health Regulations (2005): a process for their revision through potential amendment', EB150(3), 26 January 2022.

negotiation and drafting takes place via the Working Group on Amendments of the International Health Regulations (2005) (WGIHR).[8]

In the short period between May and September 2022, WHO member states and regional integration organisations like the European Union (EU) could submit their proposals for amendments to the IHR.[9] The WGIHR complied and published 300 proposed amendments to 33 of the 66 Articles of the IHR and 5 of its 9 Annexes as well as six new Articles and two new Annexes in November 2022 (referred to as 'Article-by-Article Compilation' in the following).[10] The proposed amendments were analysed and commented on in a Report by the WHO Review Committee regarding amendments of the International Health Regulations issued in February 2023.[11]

According to its timeline of work, the WGIHR will propose a package of amendments to the IHR for consideration and possible adoption by the 77th WHA in May 2024.[12]

The envisaged relationship between the two instruments remains ambiguous. In their current form, there are substantive overlaps in almost all areas regulated, and it is unclear why the WHO and its member states use considerable resources to negotiate two international instruments with overlapping scope, content and institutions.



[8] Website of the WGIHR: https://apps.who.int/gb/wgihr/index.html.
[9] WHA75(9), *supra* n. 6, para. 2(c).
[10] WGIHR, Article-by-Article Compilation of Proposed Amendments to the International Health Regulations (2005) submitted in accordance with decision WHA75(9) (2022), A/WGIHR/2/7, 6 February 2023 (Article-by-Article Compilation).
[11] WGIHR, Report of the Review Committee regarding the Amendments of the International Health Regulations (2005), A/WGIHR/2/5, 6 February 2023; a reference document is available here https://apps.who.int/gb/wgihr/pdf_files/wgihr2/A_WGIHR2_Reference_document-en.pdf.
[12] WGIHR, Provisional WGIHR Timeline 2022-2024, A/WGIHR/2/4 Rev.1, 14 March 2023.

I.3 How will the two instruments enter into force?

The WHO CA+ is currently negotiated under Article 19 of the WHO Constitution (WHOC)[13] as a new multilateral treaty. This implies that the treaty should in principle establish its own institutions and bureaucracy through which its implementation will be monitored.[14] The WHO CA+ shall be adopted by a 2/3 majority vote of the WHA. Once it has been adopted, every WHO member state can decide if they wish to sign and then ratify in accordance with the procedures set out in domestic law. These procedures normally involve approval by the domestic legislature. In addition, the WHO CA+ (Bureau's text) envisages that regional integration organisations like the EU can also ratify the WHO CA+.[15]

It normally takes many years until a new treaty enters into force since a certain number of state ratifications are needed for entry into force. The WHO CA+ (Bureau's text) currently envisages 30 ratifications before the WHO CA+ can enter into force.[16] However, presumably to speed up implementation of the treaty, it includes a highly uncommon clause that states and regional integration organisations shall apply the WHO CA+ provisionally, i.e. *before* it enters into force.[17]

By contrast, the amendments to the IHR may enter into force much faster and through a much simpler procedure than the new multilateral WHO CA+. The amendments to the IHR can be adopted by the WHA with a simple majority vote. Within 10 months, the amendments will enter into force automatically for all state parties to the IHR in accordance with Articles 59, 61 and 62 IHR, unless a state decides to opt out by sending a notification to that regard to the WHO Secretariat in accordance with Article 22 WHOC. It is noteworthy that Articles 59, 61 and 62 IHR have been amended during the 75th WHA in May 2022.[18] Through the US-proposed amendment, the period of time during which states might reject amendments to the IHR was shortened from 18 to 10 months.

The processes for the coming into force of the WHO CA+ and the amendments to the IHR are summarised in the table.

IHR	**simple WHA quorum**	• Will enter into force *10 months* after adoption by WHA for all WHO member states (Article 59 IHR), unless states opt out within that period (Article 22 WHOC)
Pandemic Treaty	**2/3 WHA quorum**	• Negotiated under Article 19 WHOC • Will likely establish a new bureaucracy (Secretariat), separate from WHO • Open to state signature and ratification in accordance with domestic legal procedures

[13] Constitution of the WHO (WHOC) 1946, 14 UNTS 185, entered into force 7 April 1948.
[14] However, see the description of planned institutional arrangements under the WHO CA+ in part V below.
[15] Art. 36 WHO CA+ (Bureau's text).
[16] Art. 37(1) WHO CA+ (Bureau's text).
[17] Art. 38 WHO CA+ (Bureau's text).
[18] WHA Res 75.12, 28 May 2022, Annex. Note that these amendments will enter into force in November 2023 for those state parties to the IHR which have not opted out of these amendments.

II. WHO's Reasons for the Reforms

The WHO and its public-private partnerships (PPPs) give various reasons for the need for the reform of the legal framework regulating the global architecture for health emergency prevention, preparedness and response. These reasons can *inter alia* be found in the WHO's and its PPPs' reports evaluating the WHO's, its PPPs' and WHO member states' response to the Covid-19-PHEIC. These reasons shall be briefly summarised.

First, WHO documents recognise that responses to the appearance of SARS-CoV-2 were a failure.[19] This goes hand in hand with WHO's claim that around 15 million people died of Covid-19 by early 2023,[20] and the 'the virus' or 'the pandemic' caused wide-ranging economic and social disruption.[21]

As a second step, WHO documents elaborate on the alleged reasons for these failures. WHO discerns these reasons *not* in the fact that the medical and non-medical countermeasures it recommended states to take to address the Covid-19-PHEIC might have been ineffective, counterproductive or even harmful,[22] but rather, in the fact that the recommended countermeasures have not been implemented fast enough and thus not aggressively enough.[23] WHO documents concede that the world was 'not prepared'[24] for the allegedly novel Coronavirus in early 2020, that China did not notify WHO quickly enough about its appearance, and that therefore, it could spread around the world, overwhelming health systems in many countries and killing many people.[25] In addition, the WHO observes that today, the world has to cope with numerous cases of long-Covid.[26] Mis- and disinformation about Covid-19 were not combatted fast enough leading to mistrust in health authorities, non-compliance with public health and social measures and vaccine hesitancy.[27]

A related third argument one can discern in the WHO's documents justifying the push for the reforms of the legal framework concerns the development, emergency authorisation, global distribution and administration of investigational vaccines. Whilst WHO documents argue consistently that the rapid development of these vaccines was a remarkable and unprecedented breakthrough in science[28] that

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[19] The Independent Panel for Pandemic Preparedness and Response (IPPPR), 'COVID-19: Make it the Last Pandemic', 2021, (hereinafter IPPPR Report) pp. 10-11 and 15.

[20] WHO, 'World Health Statistics 2023: Monitoring Health for the SDGs', Global Report, 19 May 2023, p. 18; and WHO-DG, 'WHO Director-General's Opening Remarks at the Media Briefing – 5 May 2023', referring to 'at least 20 million' deaths from Covid.

[21] IPPPR Report, *supra* n. 19, pp. 10 and 38-40; Global Preparedness Monitoring Board, 'From Worlds Apart to World Prepared' (hereinafter GBMP Report), 2021, pp. 17-18; WHO-DG, 'WHO Director-General's Opening Remarks at the Media Briefing – 5 May 2023', *supra* n. 20. For a critical analysis of these claims, see Kevin Bardosh, 'When Will the WHO Acknowledge its Covid-19 Policy Failure?', *UnHerd*, 22 September 2023.

[22] The lack of the evaluation of WHO recommended countermeasures to respond to the Covid-19 PHEIC is surprising in particular because these measures sharply deviated from WHO's own time-tested guidelines on responses to pandemics, e.g. WHO, Non-pharmaceutical Public Health Measures for Mitigating the Risk and Impact of Epidemic and Pandemic Influenza, 19 September 2019.

[23] IPPPR Report, *supra* n. 19, pp. 10, 28 and 31-33, hailing 'aggressive containment strategies' implemented strictly and from the top-down as done e.g. by China, New Zealand, South Korea, Viet Nam, Singapore as highly effective in curtailing the spread of Covid-19; see also WHO, Report of the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme, A75/16, 11 May 2022, para. 30.

[24] IPPPR Report, *supra* n. 19, pp. 15-20; 'Covid-19 Shows Why United Action is Needed for more Robust International Health Architecture', statement by 26 heads of states, the WHO-DG and the President of the European Council, 30 March 2021.

[25] WHO-DG, 'WHO Director-General's Opening Remarks at the Media Briefing – 5 May 2023', *supra* n. 20.

[26] *Ibid*.; and WHO, Strategic Preparedness, Readiness and Response Plan to End the Global COVID-19 Emergency in 2022, p. 2.

[27] WHO, Strategic Preparedness, Readiness and Response Plan, *supra* n. 26, pp. 2, 4, 11-12 and 18.

[28] WHO, Covid-19 Research and Innovation Achievements, April 2022, p. 6; and John Cohen, '2020 Breakthrough of the Year: Shots of Hope', *Science*, 17 December 2020.

has allegedly saved millions of lives worldwide,[29] many million more lives could have been saved, had the international community been even faster in developing these vaccines, providing them with emergency authorisations and, in particular, in manufacturing them and distributing them around the globe to reach every human being, living even in the most remote areas.[30] These observations frequently go hand in hand with the observation that if the international community had been guided firmly by solidarity and equity in vaccine distribution, then the Covid-19-PHEIC would have ended much faster.[31]

Fourth, the WHO gives reasons for the need for reforms that point into the future. The WHO-DG has issued warnings that the world will face many more pandemics in the future, and that they may well be much more deadly than Covid-19.[32] The WHO and the Vaccine Alliance GAVI predict that such pandemics will emerge at the 'human-animal-environment' interface, i.e. they will be caused by zoonotic pathogens.[33] This is allegedly due to climate change and biodiversity loss, to wildlife trade, to antimicrobial resistance, to urbanisation and to increased travel of people around the world.[34] WHO documents point not only to the Covid-19-PHEIC, but also to more recent Ebola, Zika and m-pox (Monkeypox) outbreaks to confirm the trend that there will be increasingly more pandemics in the future.[35]

The vast majority of WHO documents identifies the above as the main reason for the reforms of the international regulatory framework. They are allegedly required to allow the WHO, its member states and WHO's numerous PPPs to effectively prevent future global health emergencies and pandemics, and to react faster through the top-down implementation of uniform, globally coordinated medical and non-medical countermeasures. What WHO documents do not mention is that if the global biosurveillance system is expanded as planned by the reforms,[36] including by constantly surveilling human-animal interactions, many more new, emerging or re-emerging pathogens with PHEIC/pandemic potential may be detected. This may indeed lead to a situation where the WHO declares many more PHEICs/pandemics in the future.

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[29] GAVI, 'Covid Vaccines have Saved 20 Million Lives so Far, Study Estimates', 27 June 2022. Note that these claims are based on mathematical modelling, not on real world data. WHO/ECDC, 'Nearly Half a Million Lives Saved by Covid-19 Vaccination in Less Than a Year', 25 November 2021.

[30] 'Covid-19 Shows Why United Action is Needed', statement *supra* n. 24, indicating that 'immunization is a global public good and we will need to be able to develop, manufacture, and deploy vaccines as quickly as possible'; GPMB Report, *supra* n. 21, pp. 15-21.

[31] 1. Preambular Recital, first sentence WHO CA+ (Bureau's text); IPPPR Report, *supra* n. 19, pp. 41-43, criticizing 'vaccine nationalism'; WHO-DG, 'WHO Director-General's Opening Remarks at the Media Briefing – 5 May 2023', *supra* n. 20; WHO, Report of the Independent Oversight and Advisory Committee, *supra* n. 23, paras. 35 and 39.

[32] See e.g. WHO-DG, WHO Director-General's Report to Member States at the 76th World Health Assembly, Speech, 22 May 2023; see also GAVI, 'New Study Suggests Risk of Extreme Pandemics like Covid-19 Could Increase Threefold in Coming Decades', 5 September 2022; and *WHO, Strategic Preparedness, Readiness and Response Plan, supra n. 26, p. 22.*

[33] E.g. One Health High-Level Expert Panel, 'Prevention of Zoonotic Spillover', 22 February 2023; GAVI, 'Why Human Impact on the Environment is Leading to Infections Like Covid-19', 2 April 2020.

[34] IPPPR Report, *supra* n. 19, pp. 19-20; GAVI, '5 Reasons Why Pandemics Like Covid-19 are Becoming more Likely', 10 June 2020.

[35] E.g. IPPPR Report, *supra* n. 19, pp. 15-16.

[36] For details, see section IV.2 below.

III. Global Health Security (GHS): The Doctrine behind the Reforms

Though rarely made fully explicit,[37] the so-called Global Health Security (GHS) doctrine underlies and drives both the proposals for the amendments of the IHR and the new WHO CA+.

Overall, the GHS doctrine promotes a centralised (top-down), technocratic and biomedical approach to health emergency prevention, preparedness and response. It prioritises biological risk reduction in a biosecurity context. It thereby links two fields that have been separate before: health and national/international security, which leads it to combine biohazard and biowarfare mitigation strategies with public health. Or, more concretely: the GHS integrates classical rationales of security and defence policies and standard military operating procedures with the traditional medical field of communicable disease prevention and containment.

This is done by adopting a so-called 'all-hazards approach' which requires

a) constant global biomedical surveillance networks to detect and alert domestic, regional and global institutions to the appearance of new, emerging or re-emerging pathogens; and
b) the adoption of rapid executive emergency medical and non-medical countermeasures that are coordinated, implemented, and strictly enforced at national, regional and/or at global level to combat outbreaks, regardless of whether they have arisen naturally or are the result of biowarfare, bioterrorism or laboratory accidents.

Since it originates from the security context, standard epidemiological and medical treatment procedures are replaced with a 'health emergency' mode. The focus is on the rapid adoption of medical and non-medical countermeasures to contain and manage infectious diseases. Among the medical and non-medical countermeasures preferred by the GHS-doctrine are for example curfews, mass quarantines (also known as 'lockdowns'), mass-testing, contact tracing, so-called 'risk communication' that, among other things, involves information control, and the fast-track development, production and distribution of (emergency licensed) diagnostics, therapeutics and vaccines.

There is evidence that the GHS-agenda is driven in particular by philanthropic entities who profit from the rapid global production, distribution and administration of PHEIC/pandemic products. Among other things, these entities have sponsored public campaigns on the GHS-approach to PHEIC/pandemic prevention, preparedness and response of main-stream media outlets for many years prior to the Covid-19-PHEIC.[38]

The GHS-approach dominated the WHO's response to the Covid-19-PHEIC. This included the numerous recommendations for medical and non-medical countermeasures that the WHO-DG and his Covid-19 Emergency Committee issued to states,[39] and that states subsequently implemented at the domestic level. In many countries, the implementation of medical and non-medical countermeasures

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[37] But note the numerous references to health security on the WHO's website, for example when in the introduction of the WHO's Health Emergencies Programme: 'WHO's Health Emergencies Programme works with all countries and partners to ensure the world is better prepared for all-hazards health emergencies that threaten global health security.'

[38] E.g., *The Telegraph's* website about the GHS is sponsored by the BMGF since 2018, see *The Telegraph*, Global Health Security: About this Site; The Bureau of Investigative Journalism is funded by BMGF, see https://www.thebureauinvestigates.com/about-us/our-funding; and European Journalism Centre, How the Global Health Security Call Grantees used Inspiration to Drive their Reporting Projects, 13 September 2023.

[39] All recommendations can be accessed here: https://www.who.int/groups/covid-19-ihr-emergency-committee

was organised and executed by the military, and WHO envisages a long-term civil-military collaboration for PHEIC/pandemic prevention, preparedness and response programmes.[40]

The securitised GHS-approach to infectious disease management contrasts with more holistic, traditional and time-tested approaches that the WHO and domestic guidelines on pandemic preparedness and response advocated before the appearance of SARS-CoV-2.[41]

Still, the current international legal framework on health emergencies, the IHR in its version of 2005, already incorporates the tenets of the GHS. The GHS was integrated into the IHR during the last revision process of the IHR which took place between 1995 and 2005. This process was driven primarily by the USA – a country whose domestic legal system has long incorporated the concept of a state of a health emergency[42] – and the security aspect gained more weight in particular after 09/11 and the Anthrax attacks. The most prominent example of the securitisation of the IHR in 2005 is the inclusion of the notion of a state of global health emergency that the WHO-DG can declare under the IHR, or rather, as it is phrased in the IHR, a PHEIC. However, the entire current WHO architecture for global health emergency prevention, preparedness and response is shaped by the GHS. The eight primary building blocks of this architecture are described next.

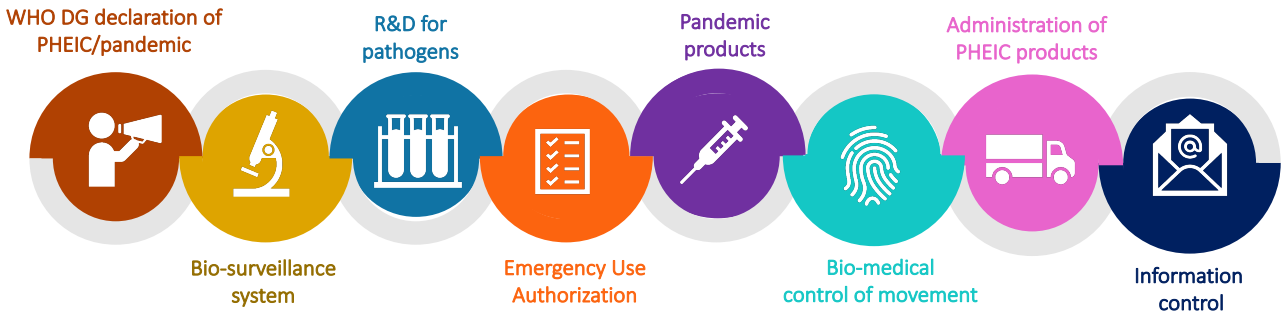
[40] WHO, National Civil-military Health Collaboration Framework for Strengthening Health Emergency Preparedness, WHO guidance document, 2021; Amir Khorram-Manesh *et al.,* 'Civilian-Military Collaboration Before and During COVID-19 Pandemic. A Systematic Review and a Pilot Survey among Practitioners' (2022) 14 *Sustainability* 624.

[41] See e.g. WHO, Non-pharmaceutical Public Health Measures for Mitigating the Risk and Impact of Epidemic and Pandemic Influenza, 19 September 2019.

[42] According to US law, the Secretary of the Department of Health and Human Services (HHS) may, under section 319 of the Public Health Service (PHS) Act determine that: a) a disease or disorder presents a public health emergency; or b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists, see Administration for Strategic Preparedness and Response, Declarations of a Public Health Emergency.

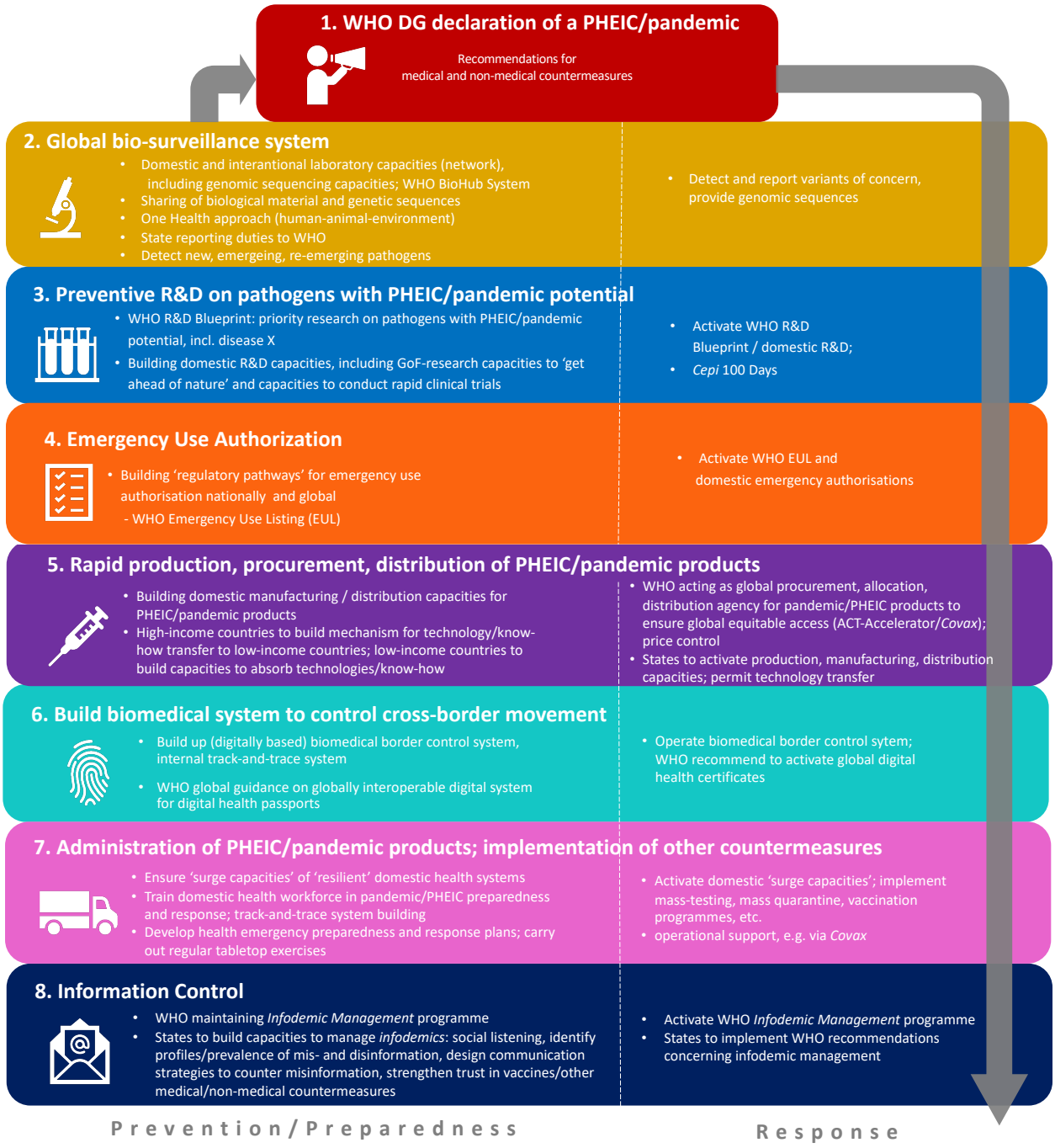
IV. The Eight Building Blocks of the WHO Architecture for Global Health Emergency Prevention, Preparedness and Response

The currently existing WHO architecture for global health emergency prevention, preparedness and response has eight primary building blocks:



1. The WHO-DG's special powers to declare a PHEIC/pandemic and to issue countermeasures
2. The global bio-surveillance system
3. Preventive research and development (R&D) on pathogens with PHEIC/pandemic potential
4. Emergency use authorisation of PHEIC/pandemic products
5. Rapid global production, procurement and distribution of PHEIC/pandemic products
6. Biomedical system to control cross-border movement
7. Administration of PHEIC/pandemic products; implementation of other countermeasures
8. Information control

All of these building blocks will be strengthened and expanded considerably should the amendments to the IHR and/or the WHO CA+ be adopted. The figure below gives an overview of the eight building blocks.



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The building blocks span institutions and programmes at the domestic and international (WHO) level which are meant to work together as a global system for the prevention, preparedness and response to new PHEICs/pandemics. At the domestic level, this involves building so-called 'core capacities'[43] for pandemic preparedness and response.

The various building blocks moreover include both prevention/preparedness *and* response programmes and measures, where the latter spring into action once the WHO-DG has declared a PHEIC. At the same time, many of the building blocks interact and relate to each other in one way or another, spanning prevention, preparedness and response programmes and institutional set-ups.

[43] As set out in Arts. 5, 13, 19, 21, 44 and Annex 1 IHR.

What follows is a short description of all eight building blocks, covering their current shape as well as the most likely ways in which they are to be expanded and strengthened further through the planned new WHO CA+ and the proposed amendments to the IHR.

IV.1 The WHO-DG's special powers to declare a PHEIC/pandemic and to issue countermeasures

The first building block concerns the WHO-DG's increasing special powers to declare global health emergencies in various forms. These powers give great discretion to the WHO-DG, and declarations have far-reaching legal and practical consequences. Under the current Article 12 IHR, the WHO-DG already has the power to declare a PHEIC, advised by the Emergency Committee[44] that the WHO-DG can set up and administer.

As of September 2023, there is a proposal for an Article 15(2) WHO CA+ (Bureau's text) which indicates that the WHO-DG shall gain a new power to also declare a 'pandemic' under the new WHO CA+.[45] Draft Article 1(1)(b) WHO CA+ (Bureau's text) offers a definition of a 'pandemic',[46] but otherwise, the scope of this power is unclear, as are its legal and practical consequences. It is also unclear how a declaration of a PHEIC by the WHO-DG with its numerous legal and practical consequences shall relate to the declaration of a pandemic by the same WHO-DG, presumably with overlapping and additional legal and practical consequences.

Returning to the proposed IHR amendments, it is clear that at least three of the proposed amendments aim at widening considerably the definition of a PHEIC, and with it the powers of the WHO-DG to declare a PHEIC. Under the current 1(1) IHR, a PHEIC is defined as an 'extraordinary event' in one state which is determined to '(i) constitute a public health risk to other States through the international spread of disease' and '(ii) to potentially require a coordinated international response'.

The first proposed amendment indicates that the WHO-DG shall be empowered to declare an 'intermediate public health alert' where a public health event does not meet the criteria of a PHEIC but 'requires heightened international awareness and preparedness activity'.[47] It is unclear by what criteria an 'intermediate public health alert' is to be determined.

Second, another proposal suggests that the WHO-DG and/or one of the WHO's six Regional Directors should be able to declare a Public Health Emergency of *Regional* Concern (PHERC).[48] The proposals make no indications as to what constitutes a PHERC, and what criteria Regional Directors should apply when evaluating a public health event.

Third, there are proposed amendments to the decision instrument in Annex 2 to the IHR which shall, among other things, guide the WHO-DG and the Emergency Committee in their decision as to whether

[44] Arts. 12(4)(c) and 49 IHR.
[45] Option 15 B.2 for Art. 15(2) WHO CA+ (Bureau's text).
[46] Art. 1(1)(d) WHO CA+ (Bureau's text) defines "pandemic" as 'the global spread of a pathogen or variant that infects human populations with limited or no immunity through sustained and high transmissibility from person to person, overwhelming health systems with severe morbidity and high mortality and causing social and economic disruptions, all of which require effective national and global collaboration and coordination for its control.'
[47] Article-by-Article Compilation, proposed amendments to Art. 12, new para. 6 IHR (p. 10), and proposed amendments to Art. 11(2)(a) IHR (p. 8).
[48] Article-by-Article Compilation, proposed amendments to Art. 12, new para. 7 IHR (pp. 10-11), and proposed amendments to Art. 11(2)(a) IHR (p. 8).

an event can be classified as a PHEIC. The proposals to amend that decision instrument suggest extending the list of events that *by default* activate reporting obligations via the global bio-surveillance system (by National Focal Points within states) to the WHO to include a) 'clusters of severe acute pneumonia of unknown cause' and b) 'clusters of other severe infections in which human to human transmission cannot be ruled out'.[49]

If all or some of these amendments were adopted, this would significantly extend the types of situations which the WHO-DG can classify as a PHEIC. The current flaws in the IHR's definition of a 'PHEIC' – the absence of a clear 'severe' or 'life-threating' disease benchmark to ensure that PHEIC declarations are only issued if we are indeed facing a severe health hazard deserving the highest level of alert and justifying the far-reaching legal and practical consequences such a declaration can have on a global scale – are aggravated by the proposed amendments. No attempts are made to address the existing flaws, e.g. by developing severity benchmarks in Article 12 IHR and/or in Annex 2 to the IHR, to be applied in accordance with the principles of necessity and proportionality.

It is important to note that if the types of situations that the WHO-DG and/or one of the six Regional Directors can categorise and declare as a state of (global or regional) health emergency increases, then the types of situations increase too to which the numerous legal and practical consequences of such a declaration apply.

Among the most important legal consequence of the declaration of a PHEIC is that the WHO-DG and the Emergency Committee can adopt temporary and standing recommendations for medical and non-medical countermeasures that states shall take to address the PHEIC.[50] Under the current version of the IHR, these recommendations are indeed recommendations, i.e. they are not legally binding on WHO member states. However, there are some proposals for amendments to the IHR that suggest changing the legal character of these recommendations into instructions that are indeed *legally binding* on states.[51]

Adopting these amendments would convert the WHO-DG and the Emergency Committees he can set up into a *global health emergency legislator* once this very same WHO-DG and his Emergency Committee exercised their discretionary powers to declare a PHEIC. Apart from the UN Security Council acting under chapter VII of the UN Charter on matters of international peace and security,[52] there is no other UN organ or specialised UN agency that has such global legislative powers, let alone one of their DGs. Given the content of the temporary and standing recommendations the WHO-DG and his Emergency Committee have issued during the Covid-19-PHEIC,[53] it is highly likely that potentially binding 'recommendations' will lead to conflicts between these 'recommendations' and states' human rights duties under international and regional human rights treaties as well as under domestic constitutional law.

[49] Article-by-Article Compilation, proposed amendments to decision instrument in Annex 2, p. 42.
[50] In line with Arts. 12(2), 17, 48 and 49 IHR.
[51] Article-by-Article Compilation, proposed amendments to Art. 1 (p. 2) and proposed new Art. 13A(1), p. 13; and similarly, proposed new Art. 13A(4) and (5), p. 13, and the alternative proposal for a new Article 13A(2), p. 14.
[52] Art. 25 UN Charter.
[53] See *infra* ns. 108 and 182-187.

IV.2 A global bio-surveillance system

The second building block of the WHO architecture for global health emergency prevention, preparedness and response is the global bio-surveillance system. This surveillance system has domestic and international (WHO) components.

In short, the idea is that each state builds up laboratory capacities that then work together as a global network through which they can identify emerging and re-emerging pathogens, determine and share the genetic sequence data of these pathogens and inform the WHO and other member states about them. Such networks shall be built and strengthened through various proposals for amendments of the IHR and through draft provisions of the WHO CA+.

Proposed IHR amendments suggest that states build domestic surveillance capacities, that is 'laboratory networks including that for genomic sequencing and diagnostics to accurately identify pathogens/other hazards'[54] so that they can effectively report information on 'microbial, epidemiological, clinical and genomic data' through all levels of domestic health systems[55] and thus 'support timely exchange of biological materials and genetic sequence data to WHO, entities under WHO and other State Parties subject to equitable sharing of benefits therefrom'.[56] Similar provisions can be found in the WHO CA+ (Bureau's text).[57] Article 6(3) for instance obliges states

> to establish[…], or build[…] on existing, genomics, risk assessment, and laboratory networks in order to conduct epidemiological genomic surveillance and the global sharing of emerging pathogens with pandemic potential, and drug-resistant pathogens.

In addition, the so-called 'One Health' concept is central to the proposals surrounding the building of a bio-surveillance system in both the proposed amendments to the IHR and WHO CA+ (Bureau's text). Draft Article 5(6) WHO CA+ (Bureau's text) is most detailed here, asking states to

> commit to strengthening multisectoral, coordinated, interoperable and integrated One Health surveillance systems, and to strengthening the laboratory capacity to identify and assess the risks and emergence of pathogens and variants with pandemic potential, in order to minimize spillover events, mutations and the risks associated with zoonotic neglected tropical and vector-borne diseases, with a view to preventing small-scale outbreaks in wildlife or domesticated animals from becoming a pandemic.[58]

It thus implies a constant bio-surveillance of the 'human-animal-environment' interface on a global scale, including the building up extensive genomic sequencing capacities, in line with the so-called 'One Health' concept.

In fact, WHO already established a *de facto* requirement for its member states to build domestic genomic surveillance systems in its 'Global Genomic Surveillance Strategy for Pathogens with Pandemic

[54] Article-by-Article Compilation, proposed amendments to Annex 1 IHR, A(new5)(b), p. 36; and proposed amendments to Annex 1 IHR, A(5)(d)(i), p. 35.
[55] Article-by-Article Compilation, proposed amendments to Annex 1 IHR, A(4)(b), p. 34; and proposed amendments to Annex 1 IHR, A(new5)(e), p. 35.
[56] Article-by-Article Compilation, proposed amendments to Annex 1 IHR, A(6)(g), p. 37. Similarly, Article-by-Article Compilation, proposed amendments to Art.6(2), p. 5; and to 7(2), p. 6.
[57] E.g. Art. 4, option 4.B.(5) and (6), Art. 6(3) and (4)(d) WHO CA+ (Bureau's text).
[58] Art. 5(6) WHO CA+ (Bureau's text). Article-by-Article Compilation, proposed amendments to Annex 1 IHR, A(new5)(a), p. 36, go into a similar direction.

and Epidemic Potential, 2022–2032'[59] and its related national[60] surveillance and sharing[61] strategies that are already implemented at the national level. The envisaged provisions on genomic surveillance in the WHO CA+ and the IHR amendments serve to expand and create a legal basis for these existing WHO policies.

With regard to international sharing and access of biological materials and their genetic sequence data, the WHO CA+ (Bureau's text) envisages setting up a 'WHO Pathogen Access and Benefit Sharing System' which should ensure that there is timely global access to pathogens with pandemic or PHEIC potential.[62] There are few details on how the system shall work, and the WHO CA+ (Bureau's text) suggests that these should be clarified through the Conference of Parties to the WHO CA+ at a later point in time.[63] It can be noted, however, that the WHO has already began to build a global system – the WHO BioHub System[64] – through which it collects biological materials with PHEIC or pandemic potential and their genetic sequence data.

The 'WHO Pathogen Access and Benefit Sharing System' furthermore mirrors WHO's existing Pandemic Influenza Preparedness (PIP)[65] model, which, however, has not been implemented so far.[66] If established, such mechanisms can potentially interfere with intellectual property rights. This is the main reasons why the International Federation of Pharmaceutical Manufacturers (IFPMA) raised fierce objections against giving these mechanisms a firm legal basis in the new WHO CA+ and/or the amended IHR.[67]

Another considerable danger of such systems is that they actively encourage highly dangerous GoF-research. This is discussed further section VII.6 below.

[59] WHO, Global Genomic Surveillance Strategy for Pathogens with Pandemic and Epidemic Potential – 2022–2032, 28 March 2022.
[60] WHO, Considerations for Developing a National Genomic Surveillance Strategy or Action Plan for Pathogens with Pandemic and Epidemic Potential, 2023.
[61] WHO, WHO Guiding Principles for Pathogen Genome Data Sharing, November 2022.
[62] Art. 12, option 12.B(2) WHO CA+ (Bureau's text).
[63] Art. 12, option 12.B(3) and (4) WHO CA+ (Bureau's text).
[64] WHO, WHO BioHub System.
[65] WHO, the Pandemic Influenza Preparedness (PIP) Framework; the benefit sharing mechanism is included in the WHO, Standard Material Transfer Agreements (SMTA2).
[66] Concerns about the lack of practical experience of the PIP model have been voiced in the report of the Review Committee, A/WGIHR/2/5, *supra* n. 11, p. 70.
[67] See IFPMA, Joint Plenary Meeting of the Intergovernmental Negotiating Body (INB) and the Working Group on Amendments to the International Health Regulations: Agenda item 3, 24 July 2023.

IV.3 Preventive R&D on pathogens with PHEIC/pandemic potential

The third building block of the WHO architecture for global health emergency prevention, preparedness and response concerns programmes and activities on the (preventive) R&D on pathogens with PHEIC/pandemic potential. This building block is primarily covered in the WHO CA+ (Bureau's text), and in particular in its draft Article 9.

As many draft Articles, it is a very lengthy Article. In essence, it obliges states to build, strengthen and sustain capacities and institutions for research and development for pandemic-related products,[68] to 'increase clinical trial capacity and strengthen clinical trials policy frameworks [...] in order to enable a greater number of clinical trial sites that can conduct well-designed and well-implemented clinical trials';[69] and to sustainably finance such activities.[70]

Concerning WHO's own pre-emptive R&D activities in relation to pathogens with PHEIC- or pandemic potential, one can observe that the WHO has been very active in this area already since 2014 through its Research and Development Blueprint for Emerging Pathogens (R&D Blueprint) Programme. The programme 'allows [for] the rapid activation of research and development activities during epidemics [or rather: PHEICs]' aiming to 'fast-track the availability of effective tests, vaccines and medicines that can be used to save lives and avert large scale crisis,'[71] and to thus 'reduce the time between the declaration of a PHEIC and the availability of effective tests, vaccines and medicines'.[72] It does so not only through activating a rapid R&D plan once a PHEIC has been declared but also by commissioning R&D on pathogens with PHEIC-potential *before* a PHEIC occurs under the pretext of R&D preparedness. The latter happens through establishing a priority list of pathogens that may in future cause a PHEIC and/or a pandemic, including the placeholder disease X,[73] and by developing and adopting R&D roadmaps for each priority pathogen, and, where relevant, target product profiles and generic protocols.[74] R&D activities are frequently conducted via WHO's public-private partnerships, in particular CEPI – the Coalition for Epidemic Preparedness Innovations. On its website, CEPI indicates that it will in future be able to develop a vaccine within 100 days that can be deployed globally once the WHO has declared a PHEIC/pandemic.[75]

This building block boosts global investment and business opportunities for pandemic products enabled by vast philanthropic and targeted public funding – with immense profits awaiting the pharmaceutical sector in particular. The sector is tightly involved in WHO programmes, including through PPPs like CEPI[76] and GAVI,[77] and philanthropic foundations like the Bill and Melinda Gates Foundation,[78] as well as through direct contribution to the WHO's biannual budgets.[79]

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[68] Art. 9(1) and (9) WHO CA+ (Bureau's text).
[69] Art. 9(7) WHO CA+ (Bureau's text).
[70] Arts. 9(2)(c)and (d) and 9(3)(c) WHO CA+ (Bureau's text).
[71] WHO, R&D Blueprint, About Us.
[72] WHO, 'An R&D Blueprint for Action to Prevent Epidemics', Plan of Action 2016, p. 11.
[73] WHO, 'WHO R&D Blueprint for Epidemics. Updating the WHO List of Pathogens with Epidemic and PHEIC Potential – Concept Note', 2022, p. 2; and WHO, Prioritizing Diseases for Research and Development in Emergency Contexts.
[74] WHO, WHO R&D Blueprint – Background.
[75] CEPI, 100 Days.
[76] See CEPI Investment Case.
[77] See GAVI, Investment here.
[78] See e.g. Annabelle Littoz-Monnet and Ximena Osorio Garate, 'Knowledge Politics in Global Governance: Philanthropists' Knowledge-making Practices in Global Health' (2023) *Review of International Political Economy*, published online August 2023.
[79] WHO's Programme budget webportal is available here; For GAVI's contribution to WHO, see here.

IV.4 Emergency listing (authorisation) of PHEIC/pandemic products

The fourth building block of the WHO architecture for global health emergency prevention, preparedness and response concerns the emergency listing (authorisation) of PHEIC/pandemic products which the WHO identifies as relevant to address a PHEIC/pandemic. Emergency authorisation is required to subsequently distribute and administer PHEIC/pandemic products all over the world.

Draft provisions in the WHO CA+ (bureau's text) and proposals to amend the IHR aim at both ensuring that states have the regulatory framework in place to grant fast-track emergency authorisation for medicinal products during a PHEIC/pandemic and that WHO itself can issue *de facto* global emergency authorisations (so-called 'emergency listings') for investigational – that is, experimental – PHEIC/pandemic products.

Proposed amendments to the IHR suggest that WHO should 'develop appropriate regulatory guidelines for the rapid approval of health products of quality'[80] facilitating fast-track emergency authorisation of investigational pandemic/PHEIC products in domestic legal systems. Article 14 WHO CA+ (Bureau's text) on 'regulatory strengthening' goes into great detail to ensure that states set up the regulatory framework for granting rapid emergency authorisation for investigational pandemic-related products during a pandemic. To achieve this, Article 14 *inter alia*[81] calls on states to

- strengthen the capacity of their regulatory authorities to regulate pandemic-related products, including 'with the aim of expediting regulatory approvals and authorisations and ensuring the quality, safety and efficacy of pandemic-related products';[82]
- make public any information on national processes 'for authorising or approving use of pandemic-related products during a pandemic, and any additional relevant regulatory pathways that may be activated during a pandemic to increase efficiency';[83] and to
- 'take steps to ensure that it has legal, administrative and financial frameworks in place to support emergency regulatory approvals for the effective and timely regulatory approval of pandemic-related products during a pandemic.'[84]

In effect, this would mean that all states shall set up procedures at the domestic level that are comparable to the US Food and Drug Administration's (FDA) emergency use authorisation procedure,[85] or the European Medical Agency's (EMA) conditional marketing authorisation procedure for pandemic/PHEIC-products.[86]

Concerning WHO, we can observe that the organisation already has in place a procedure for granting *de facto* emergency authorisations for investigational medical products during a PHEIC: the Emergency Use Listing (EUL) procedure.[87] Once the WHO-DG declared a PHEIC, or in cases where the DG is of the opinion that it is in the best interest of public health to use the procedure in a public health emergency

[80] Article-by-Article Compilation, proposed new Art. 13A 'Access to Health Products, Technologies and Know-How', para. 6(c), p. 14.
[81] Note that Art. 14 WHO CA+ (Bureau's text) is – like many other draft Articles of the WHO CA+ – a very long Article with numerous specificities and nuances which cannot be reproduced here in full.
[82] Art. 14(2) WHO CA+ (Bureau's text).
[83] Art. 14(3) WHO CA+ (Bureau's text).
[84] Art. 14(5) WHO CA+ (Bureau's text).
[85] US Food and Drug Administration, Emergency Use Authorization.
[86] EMA's conditional marketing authorisation process explained: https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/conditional-marketing-authorisation.
[87] WHO, Emergency Use Listing Procedure.

(PHE) situation that does not meet the criteria of a PHEIC,[88] the EUL procedure can be activated. In the words of the WHO, the

> EUL is a special procedure for [assessing and listing] unlicensed vaccines, medicines and in vitro diagnostics in the event of a PHE when the community/public health authorities may be willing to tolerate *less certainty* about the efficacy and safety of products, given the morbidity and/or mortality of the disease and the lack or paucity of treatment, diagnosis/detection or prevention options.[89]

Its aim is to 'expedit[e…] the availability of these [medical] products to people affected by public health emergency'90 on a 'time limited [preliminary] basis while further data is being gathered and evaluated'.[91]

During the Covid-19-PHEIC, the WHO granted EULs to all known investigational vaccines against Covid-19.[92] Among other things, this enabled WHO to promote, distribute and administer these vaccines worldwide through its public-private partners, especially GAVI and COVAX.[93]

IV.5 Rapid production, procurement and distribution of pandemic-products

The fifth building block of the WHO architecture for global health emergency prevention, preparedness and response concerns the rapid production, procurement and distribution of pandemic/PHEIC-products which the WHO considers are needed to address a PHEIC/pandemic.

There are numerous and far-reaching proposals in both the WHO CA+ (Bureau's text) and for amendments of the IHR that in essence aim to convert the WHO into a global procurement and distribution agency for pandemic/PHEIC products which would also have the power to order states with manufacturing capacities to produce such products for global distribution. To give one example from the WHO CA+ (Bureau's text): Article 13 on 'supply chain and logistics' proposes to establish a 'WHO Global Pandemic Supply Chain and Logistics Network'[94] through which global access to pandemic products shall be achieved. According to draft Article 13, 'the network shall

(a) determine the types and size of products needed for robust pandemic prevention, preparedness and response, including the costs and logistics for establishing and maintaining strategic stockpiles of such products;

(b) assess the anticipated demand for, map the sources of, and maintain a dashboard of manufacturers and suppliers, including surge capacities, for the sustainable production of pandemic-related products;

(c) identify the most efficient multilateral and regional purchasing mechanisms, including pooled mechanisms;

(d) promote transparency in cost, pricing and all other relevant contractual terms along the supply chain;

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[88] WHO, 'Emergency Use Listing Procedure', Version of 9 August 2022, p. 6. It is unclear based on what criteria the WHO-DG shall make this decision when no PHEIC exists.

[89] *Ibid*., p. 7 (emphasis added).

[90] WHO, Emergency Use Listing Procedure.

[91] WHO, 'Emergency Use Listing Procedure' (2022), *supra* n. 88, p. 7.

[92] WHO, Status of COVID-19 Vaccines within WHO EUL/PQ Evaluation Process.

[93] Obtaining an EUL from WHO is a precondition for a product to then be distributed globally via COVAX, see WHO, Product Eligibility under the COVAX Facility, 29 December 2020. This indicates that EUL designations can have de facto regulatory consequences.

[94] Art. 13(2), option 13.A, WHO CA+ (Bureau's text).

(e) develop a mechanism to ensure the fair and equitable allocation of pandemic-related products based on public health risks and needs;

(f) map existing delivery and distribution options;

(g) establish or operationalize, as appropriate, international or regional consolidation hubs and staging areas; and

(h) establish appropriate measures to reduce the unnecessary waste of government-procured pandemic-related products, including through considering the sharing of products in order to maximize their use.'[95]

Similarly, proposed amendments to the IHR suggest that the WHO should build its institutional capacities to carry out an 'assessment of the availability and affordability of the health products' required for responding to PHEICs, 'including the potential increase in supply resulting from the surge and diversification of production.'[96] And, 'in cases of expected shortage of supply', the WHO should have the capacities to 'develop an allocation plan for health products so as to ensure equitable access to people of all States Parties'[97] including by identifying and prioritising 'recipients of health products, including health workers, frontline workers and vulnerable populations, and determine the required quantity of health care products for effective distribution to the recipients across States Parties'.[98] Another amendment suggests that the WHO 'develop[s] and maintain[s] a database containing details of the ingredients, components, design, know-how, manufacturing process, or any other information required to facilitate health products required for responding to the potential PHEICs'[99] as well as a 'repository of cell-lines to accelerate the production of similar biotherapeutics products and vaccines'.[100]

Converting the WHO into a global procurement and distribution agency for pandemic/ PHEIC products will only work if states are obliged to build manufacturing and distribution capacities at the domestic level too. And indeed, there are many proposals in the WHO CA+ (Bureau's text) and for amendments to the IHR that aim to achieve this. For example, proposed amendments to the IHR suggest that once the WHO-DG has declared a PHEIC, the WHO-DG and the Emergency Committee should be able to issue recommendations to 'states parties with production capacities … [to] undertake measures to scale up production of health products' and 'supply the requested quantity of health products to WHO or other State Parties as directed by WHO in a timely manner in order to ensure effective implementation of the allocation plan';[101] as well as recommendations to all states to permit for technology transfer to low-income countries,[102] and to waive intellectual property (IP) protection for pandemic/PHEIC products to 'facilitate the manufacture, export and import of the required health products, including their materials and components.'[103] Proposals to pose similar duties on states are found in Article 11 on 'co-development and transfer of technology and know-how' of the WHO CA+ (Bureau's text).

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[95] Art. 13(*2bis*), option 13.A, WHO CA+ (Bureau's text).

[96] Article-by-Article Compilation, proposed new Art. 13A 'WHO Led International Health Response', para. 2, p. 13; similarly: Article-by-Article Compilation, proposed new Art. 13A 'Access to Health Products, Technologies and Know-How', paras. 1 and 6(a), (b) and (d), pp. 13-14.

[97] Article-by-Article Compilation, proposed new Article 13A 'WHO Led International Health Response', para. 2, p. 13.

[98] Article-by-Article Compilation, proposed new Art. 13A 'WHO Led International Health Response', para. 3, p. 13.

[99] Article-by-Article Compilation, proposed new Art. 13A 'WHO Led International Health Response', para. 6, p. 13.

[100] Article-by-Article Compilation, proposed new Art. 13A 'Access to Health Products, Technologies and Know-How', paras. 6(e), p. 14.

[101] Article-by-Article Compilation, proposed new Art. 13A 'WHO Led International Health Response', para. 5, p. 13; similarly: proposed amendments to Art. 13, new para. 7, p. 12.

[102] Article-by-Article Compilation, proposed new Art. 13A 'WHO Led International Health Response', para. 4, p. 13.

[103] Article-by-Article Compilation, proposed new Art. 13A 'Access to Health Products, Technologies and Know-How', para. 4, p. 14.

Last but not least, we can observe that the WHO and its public-private partners are already running a global procurement and allocation mechanism for EUL medical products during PHEICs today on which many of the proposed amendments to the IHR and new WHO CA+ provisions may build if adopted and implemented. Most prominently in this context is the work of the Access to Covid-19 Tools (ACT-Accelerator)[104] and, in particular, its vaccine pillar COVAX,[105] the Vaccine Delivery Partnership[106] and the Dubai Logistics Hub[107] that have been in operation during the Covid-19-PHEIC (and continue to operate today).

IV.6 Building a biomedical system to control cross-border movement (and beyond)

A sixth building block of the WHO architecture for global health emergency preparedness, prevention and response is the building of a biomedical system to control borders during a PHEIC. Proposals to strengthen such a system build on recommendations that the WHO-DG and the Covid-19-Emergency Committee gave to states during the Covid-19-PHEIC to introduce digital Covid-19-vaccine passports that can be 'implemented on [internationally] interoperable digital platforms'.[108]

Proposed amendments to the IHR thus suggest that states should build their core capacities to control their borders during a PHEIC, *inter alia* by requiring health documents from travellers that contain information 'in digital or physical format … on a laboratory test for a pathogen and/or information on vaccination against a disease'.[109] In addition, proposals suggest that states shall cooperate towards developing 'requirements that … documents shall fulfil with regard to the interoperability of information technology platforms, technical requirements of health documents as well as safeguards to reduce risk of abuse and falsification and to ensure the protection and security of personal data contained in such documents'.[110]

If adopted and implemented, these changes would further promote the building of globally interoperable digital health passport systems. A number of WHO initiatives towards this end are already in operation or under development. In the words of the WHO-DG, the WHO has already developed 'a technical interoperability standard for Covid-19 certificates, which are now in use by over 120 countries, enabling over three billion people to use digitally augmented vaccine and test results.'[111] WHO

[104] WHO, ACT-Accelerator.
[105] WHO, ACT-Accelerator, COVAX.
[106] WHO, Covid-19 Vaccine Delivery Partnership.
[107] 'Visiting the WHO's Covid Logistics Hub', *EuroNews*, 20 May 2020, updated 1 June 2023.
[108] WHO-Covid-19-EC, Statement on the Sixth Meeting of the International Health Regulations (2005) Emergency Committee regarding the Coronavirus Disease (COVID-19) Pandemic, 15 January 2021, recs. 9 and 10 to the WHO Secretariat; Statement on the Seventh Meeting of the International Health Regulations (2005) Emergency Committee regarding the Coronavirus Disease (COVID-19) Pandemic, 19 April 2021, rec. 16 to the WHO Secretariat; Statement on the Eighth Meetings of the International Health Regulations (2005) Emergency Committee regarding the Coronavirus Disease (COVID-19) Pandemic, 15 July 2021, rec. 3 to the WHO Secretariat.
[109] Article-by-Article Compilation, proposed amendments to Art. 23(a)(ii), p. 19.
[110] Article-by-Article compilation, proposed amendments to Art. 23, new para. 6, pp. 19-20; and proposed amendments to Art. 35(2), p. 22.
[111] WHO-DG, Remarks at the 152nd Session of the WHO Executive Board, 30 January 2023.

has, moreover, issued technical guidance in that area,[112] and adopted, together with its Global Outbreak and Alert and Response System (GOARN)[113] partners, the Go.Data tool[114] for public health emergencies, which includes features for digital contact tracing, contact follow-up and visualising (alleged) chains of transmission. These partnerships have been aligned with the WHO Global Health Strategy on Digital Health 2020-2025, that envisions to 'improve health for everyone, everywhere by accelerating the development and adoption of person-centric digital health solutions to prevent, detect and respond to epidemics and pandemics'.[115]

IV.7 Administration of PHEIC/pandemic products, implementation of other WHO countermeasures

A seventh building block of the WHO architecture for global health emergency preparedness, prevention and response concerns primarily the building of domestic capacities to administer WHO-recommended PHEIC-/pandemic products and to implement other WHO-recommended medical and non-medical countermeasures to address a PHEIC/pandemic.

Whilst a number of provisions in the WHO CA+ (Bureau's text) and proposed amendments to the IHR to build domestic capacities have been mentioned already that shall enable states to indeed implement the medical and non-medical countermeasures recommended by the WHO-DG and the Emergency Committee during a PHEIC,[116] other WHO CA+ Articles and proposed IHR amendments suggest that states shall be obliged to

- build resilient health systems with 'surge capacities' that can be relied on during a pandemic and to build public health emergency operating centres at the domestic level;[117]
- train health workers 'with the aim of increasing and sustaining capacities for pandemic prevention, preparedness and response, while maintaining quality essential health services and essential public health functions, during pandemics';[118] and
- develop various emergency plans and strategies to ensure efficient responses to PHEICs and pandemics. This includes duties to carry out national and 'multi-country or regional multisectoral tabletop exercises no less than every five years, with technical support from the WHO Secretariat'.[119]

[112] WHO, Digital Documentation of COVID-19 Certificates: Vaccination Status – Technical Specifications and Implementation Guidance, 27 August 2021; WHO, Digital Documentation of COVID-19 Certificates: Test Result – Technical Specifications and Implementation Guidance, 31 March 2022.
[113] https://goarn.who.int
[114] See https://worldhealthorganization.github.io/godata/ and https://www.who.int/tools/godata
[115] WHO, Global Strategy on Digital Health, 2020-2025, 18 August 2021, p. 10.
[116] See sections IV.2 – IV.6 above.
[117] Art. 6(4)(b) WHO CA+ (Bureau's text); Article-by-Article Compilation, proposed amendments to Annex I to the IHR, para. A(new5)(c), p. 36.
[118] Art. 7(1) WHO CA+ (Bureau's text); Article-by-Article Compilation, proposed amendments to Annex I to the IHR, para. A(new5)(d), p. 36.
[119] Art. 8(2) and (3) WHO CA+ (Bureau's text).

IV.8 Information control

The last and eighth building block of the WHO architecture for global health emergency preparedness and response is the building block of information control during a PHEIC or pandemic.

Proposals for amendments to the IHR for instance suggest that during a PHEIC, the WHO-DG should explicitly be able to recommend all states that they 'counter [...] the dissemination of false and unreliable information about public health events, preventive and anti-epidemic measures and [counter] activities in the media, social networks and other ways of disseminating such information'.[120]

The WHO CA+ (Bureau's text) contains a draft Article 18 on 'communication and public awareness' which goes into a similar direction but addresses states directly and gives further details. It obliges states to '... combat the infodemic, and tackle false, misleading, misinformation or disinformation, including through the promotion of international cooperation.'[121] To this end, states shall adopt domestic legislation to enable so-called infodemic management;[122] and they shall

> conduct regular community outreach, social listening, and periodic analysis and consultations with civil society organizations and media outlets in order to identify the prevalence and profiles of misinformation, which will contribute to design communications and messaging strategies for the public to counteract misinformation, disinformation and false news, thereby strengthening public trust and promoting adherence to public health and social measures.[123]

Draft Article 18 further suggests that states shall

> conduct research and inform policies on factors that hinder adherence to public health and social measures in a pandemic, including confidence, the uptake of and demand for vaccines, the use of appropriate therapeutics, the use of non-pharmaceutical interventions, and trust in science and government institutions.[124]

The WHO CA+ (Bureau's text) also shows how 'infodemic' is defined:

> "infodemic" means too much information, including false or misleading information, in digital and physical environments during a disease outbreak. It causes confusion and risk-taking behaviours that can harm health. It also leads to mistrust in health authorities and undermines the public health response.[125]

With this, the draft text of the WHO CA+ adopts the definition of 'infodemic' that one can find on WHO's website where it informs about the Infodemic Management programme[126] which has been active during the Covid-19-PHEIC. Through the programme, the WHO in collaboration with Big Tech companies, media and fact-checking organisations and governments 'pre-bunk', 'de-bunk' and censor health information that the WHO regards as mis-, dis- or false information.

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[120] Article-by-Article Compilation, proposed amendments to Art. 44(1) new (h), p. 25; similarly, proposed amendments to Art. 44(2) new (e), p. 26.
[121] Art. 18(1) WHO CA+ (Bureau's text).
[122] Art. 18(1)(a) WHO CA+ (Bureau's text).
[123] Art. 18(1)(b) WHO CA+ (Bureau's text).
[124] Art. 18(2) WHO CA+ (Bureau's text).
[125] Art. 1(b) WHO CA+ (Bureau's text).
[126] WHO, Infodemic.

V. New Institutions

Both the new WHO CA+ and the amendments to the IHR propose to set up numerous new institutions. It is not only unclear how the new bodies under the revised IHR and WHO CA+ will interact and relate but also how they will relate to the countless already existing WHO bodies, committees, expert panels, advisory groups, etc. including those already set up to supervise the implementation of the IHR.[127]

Central to the proposals for the amendments to the IHR and provisions in the WHO CA+ are proposals to set up new compliance and reporting mechanisms that shall ensure states' compliance with their obligations under the amended IHR and the new WHO CA+.

First, IHR amendments suggest establishing a Universal Health Periodic Review mechanism. It will apparently include regular reporting activities of states to a WHO committee.[128] But so far, the proposal is lacking detail. Draft Article 21 WHO CA+ (Bureau's text) goes into a bit more detail, suggesting that each party to the new treaty shall send periodic reports to the Conference of the Parties (COP) on their implementation of the WHO CA+. It further specifies that such reports shall be made public,[129] and shall include

> (a) information on legislative, executive and administrative measures, good practices or other measures taken to implement the WHO CA+;
>
> (b) information on any constraints or difficulties encountered in the implementation of the WHO CA+ and on the measures taken or under consideration to overcome them;
>
> (c) information on implementation support received under the WHO CA+; and
>
> (d) other information as required by specific provisions of the WHO CA+.[130]

Second, IHR amendments and the WHO CA+ (Bureau's text) each propose to set up a Compliance or Implementation Committee. Amendments proposed to the IHR suggest that a new Compliance Committee should *inter alia* consider information submitted to it by the WHO and state parties related to compliance with obligations under the IHR, be authorised to request information from state parties, undertake information gathering within state parties' territories (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.[131] Similar proposals can be found in Article 22 WHO CA+ (Bureau's text).

Third, WHO CA+ (Bureau's text) envisages the establishment of a COP which should be integrated into the WHA as a new main committee.[132] The establishment of such a new main committee, namely a 'Committee C', through a WHA resolutions would seriously blur the administrative boundaries be-

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[127] For an overview of all WHO bodies, see: https://www.who.int/groups/; and https://www.who.int/about/collaboration/expert-advisory-panels-and-committees

[128] Article-by-Article Compilation, proposed amendments to Art. 5(1), p. 4.

[129] Art. 21(4) WHO CA+ (Bureau's text).

[130] Art. 21(1) WHO CA+ (Bureau's text).

[131] Article-by-Article Compilation, proposed new chapter IV (Article 35 bis-quarter): The Compliance Committee, paras. 1 and 2, pp. 30-31.

[132] Art. 20(3) WHO CA+ (Bureau's text). As of now, the WHA prepares its resolutions and the decisions to be taken by the plenary in two main committees: Committee A deals with programme matters, and Committee B with budget and managerial concerns, as established under Rule 33 of the World Health Assembly's Rules of Procedure. In addition, the planned COP suggests to integrate public and private observers 'qualified in matters covered by the WHO CA+' upon application. This will further the integration of private unaccountable profit-seeking entities into the COP and WHA.

tween the WHO and the new WHO CA+. This would likely amount to a violation of the WHO's constitutional 'advisory' functions[133] particularly by creating a *de facto* universal application of the WHO CA+ for all WHO member states, including states that decide not to become parties to the WHO CA+.[134]

The COP will be the future legislative body under the WHO CA+, and for the purpose of implementation and oversight of the new treaty, set up additional bodies, namely,

- A Panel of Experts to Provide Scientific Advice,[135]
- A Pandemic-related Products Expert Committee,[136]
- A Benefit-sharing Expert Committee,[137] and
- A Secretariat.[138]

There are inconsistencies in the current WHO CA+ (Bureau's text) on how the expert committees are nominated. The Heads of the Quadripartite Organisations[139] shall nominate the panel of experts to provide scientific advice[140] whilst the other Committees are nominated by the COP.[141] All committees will create their own rules of procedures[142] which may lead to confusion over mandates and responsibilities.

Overall, in institutional terms, the envisaged attachment of the COP and its subsidiary bodies to the WHA is a concerning development for both the WHO and the state parties to the treaty. Whilst the relationship between the new institutions established under the IHR amendments as well as the WHO CA+ (Bureau's text) remains unclear, an additional layer of complexity is added by work of the 'Standing Committee on Health Emergency Prevention, Preparedness and Response' (SCHEPPR) at the WHO's Executive Board. The WHO Executive Board established SCHEPPR in May 2022,[143] with SCHEPPR holding meetings twice a year.[144] Compliance with draft Article 27 WHO CA+ (Bureau's text) seems impossible against this background. Draft Article 27 demands that all provisions of the WHO CA+ and other relevant international instruments, including the IHR, should be interpreted in a complementary fashion, and that the provisions shall not affect the rights and obligations of any Party under other existing international instruments and shall respect the competencies of other organisations and treaty bodies.

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[133] Art. 2(c) and (d) WHOC.
[134] The establishment of a Committee C was already proposed in 2008 by Gaudenz Silberschmidt *et al.,* 'Creating a Committee C of the World Health Assembly' (2008) 371 *The Lancet* 1483.
[135] Art. 23 WHO CA+ (Bureau's text).
[136] Art. 24 WHO CA+ (Bureau's text).
[137] Art. 25 WHO CA+ (Bureau's text).
[138] Art. 26 WHO CA+ (Bureau's text).
[139] The Quadripartite organisations are made up of the UN Food and Agriculture Organisation (FAO), UN Environment Programme (UNEP), the WHO and the World Organisation for Animal Health (WOAH).
[140] Art. 23(3) WHO CA+ (Bureau's text).
[141] Arts. 24(3) and 25(3) WHO CA+ (Bureau's text).
[142] Arts. 23(4) and 25(4) WHO CA+ (Bureau's text).
[143] WHO Executive Board, Standing Committee on Health Emergency Prevention, Preparedness and Response, decision EB151(2) (2022), 30 May 2022.
[144] See *ibid*., and terms of reference of SCHEPPR, Annex 1 of EB151(2) (2022).

VI. Financing Global PHEIC/Pandemic Preparedness and Response

Any political call to expand the legal framework of the architecture for global health emergency prevention, preparedness and response inherently demands new, long-term financial commitments and investments by states in the development of health and bio-medical surveillance technologies and of PHEIC/pandemic products. The most recent example is WHO's backing of the outcome of the UN General Assembly High-Level Meeting on health in September 2023, promising to increase pandemic investments.[145] According to the philanthropic sponsors of global GHS-informed health emergency preparedness and response programmes, only long-term investments and financial commitments can save the world from future pandemic/PHEIC shocks.[146]

To achieve this, draft Article 19 WHO CA+ (Bureau's text) proposes to establish two separate funds, one for obligatory contributions and another with voluntary contributions.[147] Contributions will not only come from the state parties to the WHO CA+ but also from 'pandemic-related product manufacturers' and 'other stakeholders'.[148] Details as to how this should be effected and how conflicts of interests should be avoided are not provided.

The funds will provide resources to low-income countries to support the implementation of the WHO CA+ and finance the planned treaty Secretariat.[149] As of yet, it is unclear if low- and middle-income countries shall be called on to negotiate 'dept swap' agreements that 'convert dept repayment into pandemic prevention, preparedness, response and recovery investments' under the new WHO CA+.[150] In general, such arrangements would undoubtedly interfere considerably with low- and middle-income countries' rights to determine the allocation of their national health budgets, taking account of their countries' specific disease burden and the health priorities of their local populations.

Proposed IHR amendments also strife to establish a new Financial Mechanism for Equity in Health Emergency Preparedness and Response, giving the WHA the power to arrange the details of this funding mechanism.[151] This proposal is once more likely to come into conflict the WHO's Constitution, as the Assembly is competent to only decide on matters that are covered by its functions listed in Article 18 WHOC.

Apart from new funding mechanisms planned under the WHO CA+ and the amended IHR, the G20 has put in place an additional fund outside the WHO for financing PHEIC/pandemic prevention, preparedness and response activities: The World Bank Pandemic Fund.[152] The fund was launched in November 2022 by the G20 Presidency of Indonesia. It intends to invest in pandemic prevention, preparedness and response programmes in low- and middle-income countries in order to 'strengthen the capacity of these countries to mitigate the risks of future global health threats … providing a dedicated stream of long-term financing.' The Pandemic Fund also aims to 'incentivise countries to prioritise [… pandemic prevention, preparedness and response financing] and increase their own efforts.'[153] The

[145] WHO, WHO Welcomes Historic Commitment by World Leaders for Greater Collaboration, Governance and Investment to Prevent, Prepare for and Respond to Future Pandemics, 20 September 2023.
[146] See The Global Fund, Global Health Security; Bill and Melinda Gates Foundation, Commits up to US$125 Million to Help End the Acute Phase of COVID-19 and Prevent the Next Pandemic, 12 May 2022.
[147] Art. 19(3)(a) and (b) WHO CA+ (Bureau's text).
[148] Art. 19(3)(a)(i)-(iii) WHO CA+ (Bureau's text).
[149] Art. 19(3)(c) WHO CA+ (Bureau's text).
[150] Art. 19(6), Option A, WHO CA+ (Bureau's text).
[151] Article-by-Article Compilation, proposed new Art. 44A, p. 27.
[152] See World Bank, The Pandemic Fund.
[153] World Bank, G20 Holds Official Launch of The Pandemic Fund, Press Release, 13 November 2022.

total contributions to the Pandemic Fund currently amount to $1.664 million[154] of the $1.4 billion in seed funding committed in 2022.[155]

Though urgently needed, it is beyond the scope of this document to go into the details of the financial architecture of PHEIC/pandemic prevention, preparedness and response and to provide an overview of how 'philanthropic' and industry funding and profiteering often go hand-in-hand.

[154] The US and the EU are the main funders so far, see: https://fiftrustee.worldbank.org/en/about/unit/dfi/fiftrustee/fund-detail/pppr.

[155] World Bank, G20 Holds Official Launch of The Pandemic Fund, Press Release, 13 November 2022.

VII. Problematic Aspects and Open Questions

A discussion follows of problematic aspects and open questions arising from the current reform processes of the international regulatory framework for global health emergency prevention, preparedness and response.

VII.1 The shaky factual bases for the reforms, or: why more of the same that did not work during the Covid-19-PHEIC?

First of all, questions can be asked about the validity and veracity of the factual basis that – according to numerous WHO reports[156] – justify these reforms and the allocation of enormous resources to pandemic/PHEIC preparedness, prevention and response programmes.

For example, is it in fact reasonable to expect many more pandemics/PHEICs in the future, caused in particular through zoonotic spill-overs and climate change?[157] And, even if such increase were scientifically well established, would the exclusively biomedical GHS-informed approach promoted by the WHO that is to be formalised and cemented by the proposed amendments to the IHR and the new WHO CA+ be effective in preventing and addressing them? In other words, will the global biomedical surveillance system through which emerging and re-emerging pathogens are to be detected, their genomic sequence data shared with the WHO and its member states, and development of new vaccines in record speed, their emergency authorisation and global administration be an appropriate approach to addressing such real or alleged risks of humankind facing ever more pandemics and PHEICs in the future? Why are traditional, holistic approaches to infectious disease outbreaks left behind entirely at the advantage of this new, exclusively biomedical approach? Why is there nothing in the proposed amendments to the IHR and the new WHO CA+ on these traditional approaches or on mechanisms that will help to rapidly identify repurposed drugs that address the symptoms caused by an infectious disease outbreak?

Similarly, questions can be asked as to whether further centralisation of pandemic/PHEIC preparedness, prevention and response programmes driven by the GHS-doctrine is effective in addressing disease outbreaks, and thus justified. Given the vast differences between the 195 states and the health profiles of their populations, let alone the individual health profiles of each and every person living in these countries, is it reasonable to expect that a *global one-size-fits-all medical response* determined by the WHO-DG and a few experts on the Emergency Committee he can set up to the outbreak of an infectious disease is effective from a medical point of view? Moreover, given that the implementation of the pandemic/PHEIC preparedness, prevention and response activities will require substantial resources and the setting of rather one-sided priorities in national health policies and health system building on infectious disease surveillance, prevention and response, questions can be asked as to whether this is in line with the prevailing health needs and priorities of the local populations. In particular in resource poor settings, investing large chunks of the limited health budget in the pandemic/PHEIC preparedness, prevention and response activities may well ignore the most prevalent health needs of the general population. In addition, the centralised one-size-fits-all approach conflicts with individualised medicine and doctor-patient relationships.

These questions can be asked in particular against the background of the clear failure of the many medical and non-medical countermeasures that the WHO recommended states to adopt in response

[156] See WHO's Reasons for the Reforms, part II above.

[157] On these questions, see e.g. David Bell *et al.,* 'COVAX – Time to Reconsider the Strategy and its Target' (2023) 4 *Health Policy OPEN* 1.

to the Covid-19-PHEIC, causing untold suffering.[158] There is no indication that the WHO or its DG are ready to conduct a thorough and independent[159] investigation into the effectiveness and socio-economic and health effects of WHO-recommended medical and non-medical countermeasures during the Covid-19-PHEIC.[160]

VII.2 Human rights

These points bring us to the second problematic aspects of the proposed reforms: the danger that if adopted, both the amendments to the IHR and the WHO CA+ will undermine the enjoyment of human rights of individuals around the world. More concretely, provisions in the revised IHR and the WHO CA+ as well as potentially legally binding 'recommendations' issued by the WHO-DG to address a PHEIC/pandemic may conflict with states' obligations under international or regional human rights treaties and/or under domestic constitutional law.

For instance, there is a proposal for amending the IHR that suggests removing 'respect for dignity, human rights and fundamental freedoms of persons' as an implementing principle of the IHR as currently set out in Article 3(1) IHR.[161] The current Article 3(1) IHR reminds states that they must comply with their duties under the IHR in a way that they do not violate their obligations under international human rights law;[162] and reminds the WHO that it can neither issue recommendations to states for medical and non-medical countermeasures during a PHEIC nor take any other measures towards the implementation of the IHR that conflict with the WHO's responsibilities for human rights. An amendment that removes this reminder in Article 3(1) IHR will unquestionably be a considerably step back for the protection and promotion of human rights. However, it does not release states and the WHO from having to comply with their human rights obligations and responsibilities for human rights respectively when they take any measures to implement the (revised) IHR.

WHO CA+ (Bureau's text) contains a draft Article 3 indicating that

> The implementation of the WHO CA+ shall be with full respect for the dignity, human rights and fundamental freedoms of persons, including the right to the enjoyment of the highest attainable standard of health, and each Party shall protect and promote such rights and freedoms ...[163]

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[158] See e.g. Jonas Herby et al., 'A Literature Review and Meta-Analysis of the Effects of Lockdowns on Covid-19 Mortality' (2022) Studies in Applied Economics No. 200; Paul Elias Alexander, 'More Than 400 Studies on the Failure of Compulsory Covid Interventions (Lockdowns, Restrictions, Closures)', Brownstone Institute, 30 November 2021; Kevin Bardosh, 'How Did the Covid Pandemic Response Harm Society? A Global Evaluation and State of Knowledge Review (2020-2021)', available at SSRN: https://ssrn.com/abstract=4447806, 14 May 2023; and the work of Collateral Global. On the harms caused by the investigational Covid-19 vaccines, see *infra* n. 166.

[159] Conflict of interests regarding the Chair (Professor Lothar Wieler who was President of the Robert-Koch-Institute, Germany's national IHR focal point) and other experts (who occupied official public health positions or are otherwise related to national governments) were evident in the WHO-Covid-19 review of 2021, see WHO, Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response, April 2021. For a critique, see also Bardhosh (2023), *supra* n. 21.

[160] WHO evaluations of Covid-19-countermeasures never question WHO's own GHS-informed policies but only the extent to which member states have implemented and complied with them, see e.g. WHO After and Intra-Action-Reviews.

[161] Article-by-Article Compilation, proposed amendments to Art. 3(1) IHR, p. 3.

[162] E.g. the human rights set out in the International Covenant on Civil and Political Rights (ICCPR), (1966) 999 UNTS 171; the International Covenant on Economic, Social and Cultural Rights (ICESCR), (1966), 993 UNTS 3; and the European Convention on Human Rights (ECHR), CETS No. 5 (1950).

[163] Art. 3(1) WHO CA+ (Bureau's text).

This is a positive provision in that it reminds states once more that they must implement the new WHO CA+ in a way that this implementation does not violate their obligations under international, regional and domestic human rights (constitutional) law.

However, more broadly, many amendments to the IHR and many proposed provisions in the new WHO CA+ introduced above will ensure that the WHO-led, GHS-inspired responses that the world has experienced in relation to the appearance of SARS-CoV-2 will become the norm in future. Moreover, given the proposed expanding definitions of a PHEIC/intermediate public health alert/PHERC and thus growing scope of application of the revised IHR,[164] such responses will apply to a growing number of situations that the WHO-DG and his Emergency Committee can qualify as PHEIC/intermediate public health alert/PHERC.

There is no question that many of these responses adopted to address the Covid-19-PHEIC have led to far-reaching interferences with human rights, with numerous severe consequences for human life, health and wellbeing.[165] To name but three examples: first, as indicated above, both the WHO CA+ (Bureau's text) and the amendments to the IHR will likely make the rapid development, emergency authorisation, promotion, distribution and administration of investigational vaccines to the entire global population a routine measure during WHO-declared PHEICs/pandemics, issued as a (potentially legally binding) recommendation of the WHO-DG to all states. The rapid development, emergency authorisation, continuous global promotion, distribution and administration of investigational Covid-19 vaccines as recommended by the WHO-DG and the Covid-19-Emergency Committee to address the Covid-19-PHEIC has caused an unprecedented number of adverse effects (many of which severe).[166] Their (aggressive) promotion and administration as 'safe and effective' by the WHO, its COVAX facility and almost all WHO member states following WHO recommendations has thus led to violations of the human rights to life[167] and to health,[168] with the latter encompassing the right to physical and mental integrity, the principle of informed consent and access to safe and effective medicines. Moreover, it is very likely that due to the investigational – that is experimental – status of the EUL-vaccines, the right not to be subjected without free consent to medical or scientific experimentation,

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[164] See section IV.1 above.

[165] See *inter alia* the literature listed *supra* n. 158. And the analysis by Silvia Behrendt and Amrei Müller, 'Do We Need to Protect the Entire World Population from Health Threats Through One Global Biomedical Surveillance and Response System? A Human Rights-Based Comment on the Proposed WHO Treaty on Pandemic Preparedness and Response' (2021) 64 *German Yearbook of International Law* 41.

[166] There are numerous peer-reviewed studies on Covid-19 vaccine injuries. Among some of the most recent, see e.g. Joseph Fraiman *et al*., 'Serious Adverse Events of Special Interest Following mRNA COVID-19 Vaccination in Randomized Trials in Adults' (2022) 40 *Vaccines* 5798, finding 1 serious adverse event for each 800 vaccinees. Stephanie Seneff *et al.*, 'Innate Immune Suppression by SARS-CoV-2 mRNA Vaccinations: The Role of G-quadruplexes, Exosomes, and MicroRNAs' (2022) 164 *Food and Chemical Toxicology* 113008; Aseem Malhotra, 'Curing the Pandemic of Misinformation on Covid-19 mRNA Vaccines through Real Evidence-based Medicine – Part 1' (2022) 5(1) *Journal of Insulin Resistance* a71 and Aseem Malhotra, 'Curing the Pandemic of Misinformation on Covid-19 mRNA Vaccines through Real Evidence-based Medicine – Part 2' (2022) 5(1) *Journal of Insulin Resistance* a72; Mark Skidmore, 'The Role of Social Circle COVID-19 Illness and Vaccination Experiences in COVID-19 Vaccination Decisions: An Online Survey of the United States Population' (2023) 23 *BMC Infectious Diseases* 51; Vladimir Uversky *et al.*, 'IgG4 Antibodies Induced by Repeated Vaccination May Generate Immune Tolerance to the SARS-CoV-2 Spike Protein' (2023) 11 *Vaccines* 991; Max Schmeling *et al.*, 'Batch-dependent Safety of the BNT162b2 mRNA Covid-19 Vaccine' (2023) 53 *European Journal of Clinical Investigation* e13998; Gretchen Vogel and Jennifer Couzin-Frankel, 'Studies Probe Covid-19 Shots' Link to Rare Symptoms. Details Emerge for Uncommon Cases of Neurologic Complications, Blood Pressure Swings, and Other Side Effects' (2023) 318 *Science* 18; Fadi Nahab *et al.*, Factors Associated with Stroke after Covid-19 Vaccination: A Statewide Analysis' (2023) 24 *Frontiers in Neurology* 1199745; Josef Finsterer, 'Neurological Adverse Reactions to SARS-CoV-2 Vaccines' (2023) 21(2) *Clinical Psychopharmacology* 222. For a collection of over 1000 peer-reviewed studies see: https://drtrozzi.org/2023/09/28/1000-peer-reviewed-articles-on-vaccine-injuries/.

[167] Art. 6 ICCPR; Art. 2 ECHR.

[168] Art. 12 ICESCR.

which forms part of the absolute prohibition of torture under international human rights law, has been violated. If, in future, the implementation of an amended IHR and/or a WHO CA+ will speed up the development, emergency authorisation, global promotion, distribution and administration of investigational vaccines (and other medicinal products) even further, the violations of the mentioned human rights are likely to be repeated and intensified. In this context, it can be observed that neither the proposed amendments to the IHR nor the WHO CA+ (Bureau's text) contain proposals as to who is to ensure that the investigational medical products that are developed, emergency-authorised, distributed, promoted and administered by the WHO, its PPPs and its member states to address a PHEIC/pandemic are properly tested and are thus indeed safe and effective.[169]

A second example are the interferences with the human rights to freedom of expression and to receive and impart information, including health information,[170] and to science[171] which were (and still are) widespread during the Covid-19-PHEIC due to WHO's global 'infodemic management'. This had led to pre-bunking, de-bunking and outright censorship of all information about Covid-19[172] that was and is not in line with the (changing) determinations of the WHO as to what is right, wrong or mis-leading health information on Covid-19.[173] The plans to give the WHO's infodemic management programmes a clear legal basis in both the amended IHR and the new WHO CA+ means that also the violations of these human rights will likely be repeated with greater force in future PHEIC/pandemic preparedness, prevention and response programmes and activities of the WHO, its PPPs and its member states. Both the proposed amendments to the IHR and the WHO CA+ (Bureau's text) are silent about the human right to freedom of expression, opinion and information as well as the human right to science.

A third example are the interferences with the human right to privacy,[174] and in particular the strict protection that this right offers to health data,[175] that we observed in the WHO-led responses to the Covid-19-PHEIC, be it through contact tracing, excessive testing (including of perfectly healthy people) and the use of digital health/vaccine passports. Given that these measures were probably at best very expensive but not effective,[176] the far-reaching interferences they constitute with the human right to privacy can neither be considered lawful, necessary nor proportionate under international human

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[169] Note, however, that under Art. 10 WHO CA+ (Bureau's text), the parties to the new treaty shall be obliged to set up a 'regional or international vaccine injury compensation scheme(s) for injuries resulting from the use and/or administration of vaccines developed for response to pandemics'.

[170] Art. 19 ICCPR; Art. 10 ECHR.

[171] Art. 15(1)(b) ICESCR.

[172] On WHO's infodemic management programmes, see e.g. Tina Purnat *et al.* (eds), *Managing Infodemics in the 21st Century. Addressing New Public Health Challenges in the Information Ecosystem* (Springer, 2023); and Ritu Gill and Rebecca Goolsby (eds), *COVID-19 Disinformation: A Multi-National, Whole of Society Perspective* (Springer, 2023).

[173] On the effects of the WHO's infodemic programme, see e.g. Yaffa Shir-Raz *et al*., 'Censorship and Suppression of Covid-19 Heterodoxy: Tactics and Counter-Tactics' (2023) 61 *Minerva* 407; Paul Thacker, 'The Journal *Vaccine* Publishes Study Finding Serious Side Effects of COVID-19 Vaccines, Despite Three Dodgy Fact Checks and Facebook Censoring', *Substack – The DisInformation Chronicle*, 6 September 2022; Kamran Abbasi, 'Covid-19: Politization, "Corruption" and Suppression of Science' (2020) 371 *British Medical Journal* m4425; Laurie Clarke, 'Covid-19: Who Fact Checks Health and Science on Facebook?' (2021) 373 *British Medical Journal* n1170; Fiona Godlee and Kamran Abbasi, 'Open Letter from the BMJ to Mark Zuckerberg', Rapid Response to: Covid-19: Researcher Blows the Whistle on Data Integrity Issues in *Pfizer's* Vaccine Trial (2021) 275 *British Medical Journal* n2636.

[174] Art. 17 ICCPR; Art. 8 ECHR.

[175] See e.g. UN Special Rapporteur on the Right to Privacy, Recommendations on the Protection and Use of Health-Related Data, UN Doc A/74/277, 5 August 2019; and Task Force on Privacy and the Protection of Health-related Data, Explanatory Memorandum on the Recommendations on the Protection and Use of Health-Related Data, 5 October 2019.

[176] Systematic studies of the effectiveness of contact-tracing in the real world during the Covid-19 pandemic are unavailable as of yet. Most studies appear to rely on computer modelling. Their outcome is highly dependent on the assumptions of the models used. See e.g. Francisco Poso-Mati *et al*., 'Comparative Effectiveness of Contact Tracing Intervention in the Context of the Covid-19 Pandemic: A Systematic Review' (2023) 38(3) *European Journal of Epidemiology* 243.

rights law. Once more, if the amended IHR and/or the new WHO CA+ are adopted and implemented – especially amendments/new treaty provisions concerning the build-up of the global bio-medical surveillance system, genetic sequencing capacities and the running of the digital system of biomedical health certificates – the chances are high that violations of the right to privacy will remain and increase.

VII.3 Danger of undermining standards for medical product authorisations

Another considerable danger lurking in the proposed amendments to the IHR and the new WHO CA+ is that they, if adopted and applied, may contribute to further undermining long fought-for standards of medical law to ensure safety and efficacy of medical products.

As indicated above, proposed amendments and draft provisions in the WHO CA+ (Bureau's text) push for the rapid development of investigational medical products, in particular vaccines, and their rapid authorisation via domestic emergency authorisation procedures which states shall offer in their domestic law, and by entrenching WHO's EUL procedure further in international health law. A glance at the WHO's document setting out its EUL procedures shows that very little data from clinical trials showing effectiveness and safety is required from pharmaceutical companies to be granted an EUL for their investigational products.[177] EULs can be granted by the WHO once the WHO-DG has declared a PHEIC – a competence that may be extended significantly should the proposed wider definitions of what constitutes a PHEIC/intermediate public health alert/PHERC be adopted and implemented.[178]

The extensive harm that has been caused by the adverse effects of the globally rolled-out EUL-vaccines against Covid-19 is clear proof of this danger.[179]

VII.4 Unprecedented powers of the WHO-DG

Relatedly, the extensive power that the IHR already gives to the WHO-DG, and which will be increased further should the proposed amendments to the IHR (and, albeit to a lesser extent, the new WHO CA+) be adopted, are highly problematic. The WHO-DG will be able to almost unilaterally[180] declare a PHEIC potentially covering many types of situations – PHEICs, intermediate public health alerts and PHERCs under the amended IHR, and 'pandemics' under the WHO CA+.[181] In addition, broad discretion is left to the WHO-DG when exercising his powers.

Once the WHO-DG has made such a declaration, this may give him additional executive and legislative powers which can affect every human being on the planet, in particular if the proposed amendments are adopted that will convert the current temporary or standing non-binding recommendations for medical and non-medical countermeasures that the WHO-DG can issues once he has declared a PHEIC into legally binding instructions. As we observed during the Covid-19-PHEIC, the WHO-DG and the

[177] For details, see WHO, Emergency Use Listing Procedure (2022), *supra* n. 88.
[178] As described in section IV.1 above.
[179] See literature listed in *supra* n. 166.
[180] Note that the WHO-DG is not obliged to follow the advice of the Emergency Committee that he sets up under the IHR. For example, the WHO-DG declared an m-pox-PHEIC against the advice of the majority of the m-pox-PHEIC Emergency Committee that he had set up in July 2022. See WHO Monkeypox-EC, Statement on the Second Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Multi-Country Outbreak of Monkeypox, 23 July 2022.
[181] See section IV.1 above.

Covid-19-Emergency Committee issued recommendations ranging from recommendations to conduct mass testing (including of healthy people)[182] and domestic and international contact-tracing[183] (including through the use of digital technologies[184]), to recommendations to detect and share genomic sequences of SARS-CoV-2 virus variants[185] and to 'strengthen mechanisms to link individual-level clinical, vaccination and genomic data to facilitate assessment of the impact of and vaccine effectiveness against VOC [variants of concern]',[186] to recommendations to vaccinate an increasing percentage of a country's population with emergency-listed Covid-19 vaccines.[187]

In addition, the declaration of a PHEIC by the WHO-DG and his emergency committees triggers the EUL procedure, allowing the WHO-DG and a number of small expert committees appointed by the very same WHO-DG to issue EULs for investigational medical products which may then be distributed and administered around the world. According to the WHO's current document describing the EUL procedure, the WHO-DG also has the ultimate power to make decisions that are 'final and binding on the parties'[188] should disputes arise between an applicant manufacturer and the relevant WHO expert committees as to whether the applicant manufacturer's investigational medicinal product shall be granted an EUL.

Another problem is the fact that the WHO-DG also has the power to end a PHEIC, and that, once more, broad discretion is left to him in exercising this power. The reason for this is *inter alia* that there is currently no clear 'severe' or 'life-threating' disease benchmark defining a PHEIC to ensure that PHEIC declarations are only issued if the world is indeed facing a severe health hazard deserving the highest level of alert justifying the far-reaching legal and practical consequences such a declaration can have on a global scale, nor are there any proposed amendments to the IHR to introduce such benchmarks. This means that there are also no severity benchmarks to effect the timely termination of PHEICs once a PHEIC-causing disease falls below the severity threshold and become equivalent in their pathology

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[182] See among many, WHO-Covid-19-EC, Statement on the Third Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Coronavirus Disease (COVID-19), 1 May 2020, rec. to WHO Secretariat and States parties on surveillance; Statement on the Eighth Meeting, *supra* n. 108, rec. 2 to State parties; Statement on the Tenth Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Coronavirus Disease (COVID-19) Pandemic, 19 January 2022, recs. 1 and 2 to State parties.

[183] See among many, WHO-Covid-19-EC, Statement on the Second Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Novel Coronavirus (2019-nCoV), 30 January 2020, rec. to WHO and State parties; Statement on the Fourth Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Coronavirus Disease (COVID-19), 20 August 2020, rec. 4 to WHO Secretariat and recs. 4 and 8 to State parties; and Statement on the Ninth Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Coronavirus Disease (COVID-19) Pandemic, 26 October 2021, recs.1 and 2 to State parties.

[184] See among many, WHO-Covid-19-EC, Statement on Third Meeting, *supra* n. 182, rec. to State Parties; and Statement on Seventh Meeting, *supra* n. 108, rec. 16 to WHO Secretariat.

[185] See among many, WHO-Covid-19-EC, Statement on Sixth Meeting, *supra* n. 108 recs. 1–3 to WHO Secretariat and recs. 1, 2 and 11 to State parties; Statement on Eighth Meeting, *supra* n. 108, rec. 4 to WHO Secretariat and rec. 4 to State parties; Statement on the Ninth Meeting, *supra* n. 183, rec.4 to State parties.

[186] WHO-Covid-19-EC, Statement on the Tenth Meeting, *supra* n. 182, rec. 4 to State parties; Statement on Eleventh Meeting of the International Health Regulations (2005) Emergency Committee regarding the Coronavirus Disease (COVID-19) Pandemic, 13 April 2022, rec. 5 to State parties.

[187] See e.g. WHO Covid-19-EC, Statement on the Eighth Meeting, *supra* n. 108, rec.3 to State parties (10%); Statement on the Ninth Meeting, *supra* n. 183, rec. 3 to State parties (40%); Statement on the Tenth Meeting, *supra* n. 182, rec. 3 to state parties (70%); Statement on Twelfths Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Coronavirus Disease (COVID-19) Pandemic, 12 July 2022, rec. 3 to states parties ('achieve the highest possible vaccination coverage among persons at highest risk of severe disease outcomes and among persons at highest risk of exposure, health workers, the elderly and other priority groups' including a 'booster dose'); Statement on the Fourteenth Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Coronavirus Disease (COVID-19) Pandemic, 30 January 2023, rec. 1 ('achieve 100% [vaccination] coverage of high-priority groups').

[188] WHO, Emergency Use Listing Procedure (2022), *supra* n. 88, p. 17.

and prevalence to other endemic diseases. As has been the case concerning the Covid-19-PHEIC and m-pox-PHEIC, the WHO-DG can thus uphold the PHEIC as long as he deems it necessary without there being any (objective) criteria for him to take account of. The Covid-19-PHEIC was upheld for more than three years despite the fact that it was clear very soon in spring 2020 that Covid-19 has a low infection fatality rate.[189]

VII.5 Questions of accountability

This brings us directly to the next problematic aspect in the WHO architecture for global health emergency prevention, preparedness and response: the lack of accountability mechanisms to hold the WHO, its powerful DG and members of staff accountable for any of the potentially negative consequences of either their decisions to declare a PHEIC or the recommendations for medical or non-medical countermeasures they issue. Currently, neither the WHA, nor the International Court of Justice nor domestic courts can review or adjudicate such decisions. Among other, the reason for this are the immunities granted to international organisations and their members of staff,[190] and increasingly also to the WHO's PPPs like GAVI.[191] The WHO's reliance on a growing number of influential PPPs in developing and carrying out their work in the area of PHEIC/pandemic prevention, preparedness and response further diffuses accountability for damages caused by this work.

There are no indications in the proposed amendments to the IHR or the WHO CA+ (Bureau's text) to address these serious shortcomings.

VII.6 Incentivisation of gain-of-function research instead of strict prohibition

Last but not least, the proposed amendments to the IHR and provisions in the new WHO CA+ fail to address the highly likely root cause of the Covid-19-PHEIC: so-called GoF-research that, in all likelihood, bioengineered SARS-CoV-2 in the Wuhan Institute of Virology, funded by the USA.[192] GoF-research implies that scientists use a variety of techniques to make viruses and other microorganisms more transmissible or more pathogenic (i.e. increase the severeness of the illness they cause). The common justification for such research is that scientist must 'get ahead of nature' to predict what might be future pandemic threats.[193] However, this very GoF-research can also turn ordinary or pathogenic viruses or bacteria into biological weapons, and in the USA for instance, funding for natural pandemics

[189] The IFR indicates the risk of death if infected. Overall, in 2021, Covid-19 had an average IFR of 0.15% (reduced to an average of 0.05% for people under the age of 70). See the evolving work of John Ioannidis: John Ioannidis, 'Infection Fatality Rate of Covid-19 Inferred from Seroprevalence Data' (2021) 99 *Bulletin of the World Health Organization* 19; John Ioannidis, 'Reconciling Estimates of Global Spread and Infection Fatality Rates of COVID-19: An Overview of Systematic Evaluations' (2021) 51(5) *European Journal of Clinical Investigation* 1; and Angelo Maria Pezzullo *et al.*, 'Age-stratified Infection Fatality Rate of COVID-19 in the Non-elderly Population' (2022) 216 *Environmental Research* 114655, concluding that the median IFR was 0.0003% at 0-19 years, 0.002% at 20-29 years, 0.011% at 30–39 years, 0.035% at 40-49 years, 0.123% at 50-59 years, and 0.506% at 60-69 years. To compare: Seasonal influenza has an average IFR of 0,16%, Ebola of 50%.

[190] Convention on the Privileges and Immunities of the United Nations (1946); and Convention on the Privileges and Immunities of the Specialized Agencies (1947).

[191] GAVI, 'Gavi Recognised an International Institution', 23 June 2009.

[192] See mounting evidence that SARS-CoV-2 originates from GoF-research, e.g. Sharon Lerner *et al.,* 'NIH Documents Provide New Evidence U.S. Funded Gain-of-Function Research in Wuhan', *The Intercept*, 10 September 2021; Katherine Eban, '"This Shouldn't Happen": Inside the Virus-Hunting Non-profit at the Center of the Lab-Leak Controversy', *Vanity Fair*, 31 March 2022; 'Why the Chair of the *Lancet's* Covid-19 Commission Thinks the US Government is Preventing a Real Investigation into the Pandemic', interview with Prof. Jeffrey Sachs, *Current Affairs*, 2 August 2022; and Roland Wiesendanger, Studie zum Ursprung der Coronavirus-Pandemie, *Preprint*, February 2021.

[193] Sharon Begley, 'U.S. Lifts Moratorium on Funding Controversial, High-Risk Virus Research', *Scientific American*, 19 December 2017.

and biological defence funding has long been lumped together.[194] GoF-research has been described as an extraordinary dangerous endeavour, and there have been numerous reports over the years of bioengineered viruses escaping or otherwise originating from labs,[195] with SARS-CoV-2 only being the most recent one. On the other hand, there are no indications that many decades of US GoF-research have ever resulted in the development of beneficial drugs or vaccines.[196]

Given this background, to address this root cause of the Covid-19-PHEIC, neither the IHR would need to be amended nor would there be a need for a new WHO CA+. Rather, what is called for is the reform of the 1972 UN Bioweapons Convention (BWC).[197] Whilst the BWC clearly prohibits any GoF-research for the development of any *defensive* or *offensive* bioweapons,[198] it does not prohibit research with 'microbial or other biological agents' that is for 'prophylactic, protective or other peaceful purposes'.[199] Therefore, a full prohibition of any type of GoF-research, no matter for what purpose, should be included into a reformed BWC. Even more importantly, a truly independent international institution would need to be established to effectively supervise and control the implementation of such a strict prohibition.[200]

However, given the proposed amendments to the IHR and draft provisions in the WHO CA+ (Bureau's text) on building a global bio-surveillance system and genetic sequencing capacities, it is highly likely that both the amended IHR and the new WHO CA+ will *incentivise more highly dangerous GoF-research* in biolabs around the world. As indicated above,[201] many of the proposals aim at building and expanding biolab networks around the world that must have genomic sequencing capacities,[202] i.e. implying biolabs in every country that would sequence the numerous viruses that they detect through the pathogen surveillance activities they will be obligated to carry out. More concretely, draft Article 9(5) WHO CA+ (Bureau's text) directly refers to (GoF-)research facilities that 'carry out research to better understand the pathogenicity and transmissibility of pathogens with pandemic potential' and states prospective duties to 'prevent the unintended consequences of such research, while minimising unnecessary administrative hurdles for research'.[203] Other proposals mentioned above to globally conduct more research on pathogens with pandemic/PHIEC-potential,[204] to speed up clinical trials and to quickly authorise investigational medical products through introducing regulations in all national legal orders that permit emergency use authorisations[205] will contribute to producing such incentives.

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[194] Meryl Nass, 'The WHO's Proposed Amendments will Increase Man-made Pandemics', *The Brownstone Institute*, 17 August 2023.

[195] See *ibid*., citing *inter alia* the joint CDC-USDA Federal Select Agent Program (FSAP) which keeps track of research on potential pandemic pathogens and has collected reports of about 200 accidents or escapes yearly from labs situated in the US.

[196] See *ibid*., citing former CDC Director Robert Redfield's statements to the US Congress in March 2023.

[197] 1972 UN Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (BWC), 1015 UNTS 163.

[198] Art. 1(1) BWC read in conjunction with the preamble of the BWC indicating that the BWC's object and purpose is to 'exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons' (neither offensively nor defensively). See e.g. Jozef Goldblat, 'The Biological Weapons Convention' (1997) 318 *International Review of the Red Cross* 251, p. 254. This would mean that the US' Bioweapons Programme which allegedly 'produced' SARS-CoV-2 is in violation of the BWC. For full details of the argument, see Francis Boyle, *Biowarfare and Terrorism* (Clarity Press, 2005), pp. 16-18, 69 and 71-74.

[199] Art. 1(1) BWC.

[200] This could be a reformed Implementation Support Unit of the BWC, currently operating under the UN Office for Disarmament Affairs.

[201] See section IV.2 above.

[202] See e.g. Arts. 6(3) and 6(4)(d) and (h) WHO CA+ (Bureau's text).

[203] Art. 9(5) WHO CA+ (Bureau's text).

[204] See section IV.3 above.

[205] See section IV.4 above.

VIII. Conclusions and Call for Open Debate

The ongoing negotiations at the WHO to overhaul the international legal framework on PHIEC/pandemic preparedness, prevention and response are of great concern. If the proposals summarised in this document will be adopted in May 2024, all eight building blocks of the already existing WHO architecture for PHEIC/pandemic prevention, preparedness and response will be expanded considerably.

First, the WHO-DG's special powers to declare a PHEIC/pandemic and to issue GHS-informed medical and non-medical countermeasures will increase significantly, and with this the situations to which these countermeasures apply. Second, the planned global bio-surveillance system will collect and share vast amounts of biological material and genomic sequence data, increasing not only the likelihood for the detection of new, emerging or re-emerging pathogens (allegedly) with PHEIC/pandemic potential but also incentivising highly dangerous GoF-research. Third, preventive R&D on pathogens with PHEIC/pandemic potential will be significantly expanded, especially R&D of modRNA-based vaccines. Fourth, rapid emergency authorisation of investigational PHEIC/pandemic products shall be enabled in international and regional law, as well as in the domestic legal orders of all WHO member states. Fifth, the WHO is likely to be converted into an agency that commands the global production, procurement and distribution of PHEIC/pandemic products during PHEICs/pandemics, with WHO member states being obliged to build up their domestic production and distribution networks for such products. Sixth, a biomedical system for the control of cross-border movements, utilising digital health passports on globally interoperable platforms is likely to become reality. Seventh, states must invest in their health infrastructure that enables them to administer WHO-recommended medical and non-medical countermeasures, including mass vaccination campaigns, likely diverging large chunks of their health budgets to PHEIC/pandemic prevention, preparedness and response activities. And eighth, global pre-bunking and de-bunking – including direct censorship – of WHO-defined mis- or disinformation about a PHEIC/pandemic causing pathogens and illnesses will increase significantly.

The adoption and implementation of these GHS-informed reform proposals currently under negotiation will thus likely have far-reaching negative consequences for the health and enjoyment of human rights of every human being on the planet. They will undermine states' rights and duties to determine and implement domestic health laws and policies that are in line with the priority health needs of the population, and that respect and ensure respect for the human rights of all individuals to health, privacy, freedom of expression, bodily integrity, life and to be free from torture or inhuman or degrading treatment. They will further the public-private hybridisation of formally public international health institutions like the WHO by giving ever-increasing influence and power to philanthropic foundations, multinational corporations and PPPs. This does not only riddle the WHO with additional conflicts of interests and increases the opportunities for PHEIC/pandemic profiteering by these private actors. But it also further diffuses international responsibilities and prevents the establishment of effective accountability mechanisms for harms caused by global pandemic/PHEIC prevention, preparedness and response programmes. The reforms are also incentivising highly dangerous GoF-research. Last but not least, the implementation of these reforms will require immense (public) resources.

Against this background, this document ends with an urgent call for an open and inclusive debate about the planned amendments to the IHR and the planned WHO CA+ and their far-reaching implications in all WHO member states. This will be a first step towards stopping the negotiations of international concern and their potentially monstrous consequences for health and human rights worldwide.