GLOBAL HEALTH CENTRE | 2023

AVERTING A COLLISION COURSE? BEYOND THE PANDEMIC INSTRUMENT AND THE INTERNATIONAL HEALTH REGULATIONS

Pedro A. Villarreal, Hélène de Pooter, Elisa Morgera & Daniel Warner

Discussion papers prepared for the event held on 26 April 2023 at the Geneva Graduate Institute

GENEVA GRADUATE INSTITUTE
GLOBAL HEALTH CENTRE

Acknowledgements: We are grateful for inputs and comments received from Gian Luca Burci, Suerie Moon, Daniela Morich, Seyed-Moeen Hosseinalipour, Alessia Nicastro and Sara Lafontaine.

Global Health Centre

Geneva Graduate Institute
Chemin Eugène-Rigot 2 | Case Postale 1672
1211 Geneva 21 | Switzerland

Tel +41 22 908 4558
Fax +41 22 908 4594
Email globalhealth@graduateinstitute.ch

graduateinstitute.ch/globalhealth

TABLE OF CONTENTS

INTRODUCTION

COVID-19 exposed major gaps in global pandemic preparedness, prevention and response (PPR) and prompted profound debates on how to reform the global legal landscape to better respond to the next pandemic. As a result, two concurrent lawmaking processes are currently underway under the auspices of the World Health Organization (WHO). They could lead to the adoption of a new pandemic legal instrument and to amendments to the 2005 International Health Regulations (IHR), the existing WHO instrument governing the cross-border spread of infectious diseases.

This unprecedented parallel unfolding of two negotiating processes raises many questions. What are the political implications for negotiators? How will power dynamics affect the processes? Will it be possible to ensure complementarity between instruments? What are the possible outcomes on issues such as One Health and Pathogen- and Benefit-Sharing? Ultimately, is avoiding a collision course between these complex negotiations possible?

On 26 April 2023, the International Geneva Global Health Platform and Governing Pandemics Initiative of the Global Health Centre organised an event at the Geneva Graduate Institute to discuss these questions and negotiating processes. During the event, expert speakers shared their perspectives on the legal and political implications of pursuing parallel international law-making processes in the same fora, and discussed possible outcomes going beyond the confines of the two instruments (full event recording).

This publication compiles short papers written by the speakers on the following topics:

I. **Navigating the Overlapping Object and Scope of the IHR (2005) and the WHO CA+**
   by **Pedro A. Villarreal**, Senior Research Fellow at the German Institute for International and Security Affairs and at the Max Planck Institute for Comparative Public Law and International Law

II. **One Health in the pandemic negotiations**
   by **Hélène de Pooter**, Senior Lecturer in Law, University of Franche-Comté

III. **Critical considerations vis-à-vis the possible outcomes for fair and equitable sharing of pathogens, genetic sequences and benefits under a pandemic instrument**
   by **Elisa Morgera**, Professor of Global Environmental Law at Strathclyde University Law School (Glasgow, UK) and Director of the One Ocean Hub

IV. **U.S. WHO Policy: Thin Cooperation or Robust Collaboration?**
   by **Daniel Warner,** Political Scientist, former Deputy to the Director, Graduate Institute Geneva, Assistant Director for International Affairs at the Geneva Centre for the Democratic Control of Armed Forces (DCAF)

NAVIGATING THE OVERLAPPING OBJECT AND SCOPE OF THE IHR (2005) AND THE WHO CA+

PEDRO A. VILLARREAL

I. Introduction

Both the proposed WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response ("WHO CA+") and a number of amendments to the International Health Regulations (IHR) of 2005 are currently under negotiation in Geneva. The deadline for submitting both for adoption is the World Health Assembly of May, 2024. Both the Intergovernmental Negotiating Body (INB) and the Working Group on Amendments to the International Health Regulations (WGIHR) have a self-standing mandate to collect input from diverse stakeholders and draft the corresponding texts accordingly. But there is no pre-existing template for determining which of the textual proposals should be assigned or deferred to which negotiating body. This increases the risk of a duplication of efforts in separate political and legal tracks that need to be synergized, whilst avoiding unnecessary fragmentation.

Against this backdrop, the following lines provide, first, the different structures and guiding principles for each of the two negotiations; second, the discussion on the overlapping factual scope and obligations for each as per the current state of negotiations (May 2023); and third, practical and conceptual strategies for facing these challenges.

II. A Tale of Two Negotiations

Each of the two negotiation streams is taking place under different structures and principles. This is directly linked to their origins. The idea to initiate negotiations on a WHO CA+ was conceived by the President of the European Council in late 2020, and later suggested by the Independent Panel on Pandemic Preparedness and Response at the World Health Assembly of 2021.[1] Negotiations were officially launched in November 2021 at a Special Session of the World Health Assembly.[2] At the third meeting of the INB, a first conceptual zero draft of the WHO CA+ was presented, incorporating multiple ideas discussed in different rounds of public hearings and stakeholder consultations; in that same meeting, Member States decided that the WHO CA+ would be negotiated under the principle of "nothing is agreed until everything is agreed".[3] This means, in practice, that different items will not be negotiated and finalized individually and, therefore, negotiators may revisit text and subjects at any moment. [4] The current paper addresses the wording of the CA+ text as of June 2023 (see Figure 1).[5]

1 WHO, *Special session of the World Health Assembly to consider developing a WHO convention, agreement or other international instrument on pandemic preparedness and response*, World Health Assembly Decision WHA74(16) (31 May 2021).

2 WHO, *The World Together: Establishment of an intergovernmental negotiating body to strengthen pandemic prevention, preparedness and response,* World Health Assembly Decision SSA2(5), 1 December 2021.

3 INB, *Report of the Meeting: Third Meeting of the Intergovernmental Negotiating Body to Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response*, A/INB/3/6 (20 December 2022), para. 3.

4 The principle has guided, for example, post-Brexit negotiations between the United Kingdom and the European Union. See European Council, *Guidelines following the United Kingdom´s Notification under Article 50 TEU,* EUCO XT 20004/17 (29 April 2017).

5 WHO, *Bureau's text of the WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response*, A/INB/5/6 (2 June 2023).

In contrast, the current process for proposing amendments to the IHR (2005) has taken place under a stringent deadline agreed upon by states. Under Article 55 IHR (2005), amendments may be submitted at any moment, provided they are circulated to States Parties at least four months before the World Health Assembly in which they will be considered for approval. But, after the United States of America put forward a first package of proposals for amendments in January 2022,[6] WHO Member States partially approved one of them at the World Health Assembly of that year[7] and decided to initiate a process allowing for further submissions of proposals until 30 September 2022.[8] Crucially, the process was launched with the understanding that amendments would "not lead to reopening the entire instrument for renegotiation" (Figure 1).[9] A total of 300 individual amendment proposals were made by 16 States Parties including regional groupings.

Figure 1. Overview of negotiating streams

An IHR Review Committee was constituted for issuing technical recommendations related to the proposed amendments to the IHR (2005). The Review Committee's Report, which offers a stocktaking of the hundreds of individual amendments proposed, was submitted to the WGIHR in February 2023.[10] It ultimately rests upon the Member State-led WGIHR to decide whether and to what extent the Review Committee's recommendations will be reflected in the final draft submitted to the World Health Assembly of 2024. No such arrangement exists under the aegis of the INB. Since new proposals regarding the WHO CA+ may be submitted in subsequent meetings, it is unfeasible, within that stream, to undertake a definitive stocktaking similar the IHR Review Committee Report.

6 WHO, *Strengthening WHO preparedness for and response to health emergencies. Proposal for amendments to the International Health Regulations (2005),* A75/18 (12 April 2022).

7 Under the new Article 59 IHR (2005), the period for expressing rejections or reservations of amendments to the IHR (2005) has been reduced from 18 to 10 months after their notification; whereas the period for entry into force of said amendments was reduced from 24 to 12 months. World Health Assembly, *Amendments to the International Health Regulations (2005),* Resolution WHA75.12 (28 May 2022).

8 World Health Assembly, *Strengthening WHO preparedness for and response to health emergencies,* Decision WHA75(9)(2)(c) (27 May 2022).

9 World Health Assembly, *supra* note 7.

10 WHO, *Report of the Review Committee regarding amendments to the International Health Regulations (2005),* A/WGIHR/2/5 (6 February 2023) 13.

III. Facing Overlaps in the IHR (2005) and the WHO CA+

Not all overlapping obligations currently found in each draft would lead to fragmentation or to conflicts. Some are a restatement of common objectives. In other words, there are overlaps, and then there are overlaps. The following lines focus on those that could be problematic.

The overlapping provisions between the proposed amendments to the IHR (2005) and the WHO CA+ draft include obligations to: share and distribute medical countermeasures equitably, with corresponding limitations of intellectual property rights; closely related thereto; data sharing, including genomic sequencing, as well as microbial and genetic material and samples with the WHO;[11] strengthen different capacities for health emergency and pandemic surveillance, preparedness and response, including those related to One Health; provide support for such capacity-building across countries, including the creation of international financial mechanisms for that purpose; and to refrain from unnecessary restrictions on international trade as a response to disease-related events and in ways affecting the production of pandemic-related products.

Similarly, so far there are proposals in both instruments to create parallel governance bodies and mechanisms, which could consist of WHO officials, subsidiary Member State-led bodies, or subsidiary meetings in the World Health Assembly. The creation of new governance bodies in each instrument may not be directly in direct tension with the other, and yet lead to a further proliferation of mechanisms for monitoring and fostering compliance. This could worsen already strained capacities across Member States.

The risk of disruptive fragmentation is enhanced by the different mechanisms of entry into force for the WHO CA+ and for amendments to the IHR (2005). Under Article 19 of the WHO Constitution, the WHO CA+ will only enter into force for Member States who accept it "in accordance with [their] constitutional processes", and initially only for a limited number of parties in accordance with the final clauses of the WHO CA+. After its adoption by the World Health Assembly, additional approval procedures by national bodies –usually the legislative branch– are needed. Conversely, according to Articles 21 and 22 of the Constitution, Regulations adopted by the Assembly will enter into force for all Member States at the same time, unless they reject them within a specified period of time ("opt-out"). Amendments to the IHR (2005) will therefore have a higher number of States Parties than the WHO CA+ unless and until the latter achieves practically universal participation. Moreover, the absence of a requirement for ratification in the case of Regulation means that politically sensitive subject matters, such as the role of intellectual property rights in access to medical countermeasures, might not go through domestic channels. This may weaken the effective implementation of such obligations at the national level, where additional reforms and political consensus are needed.

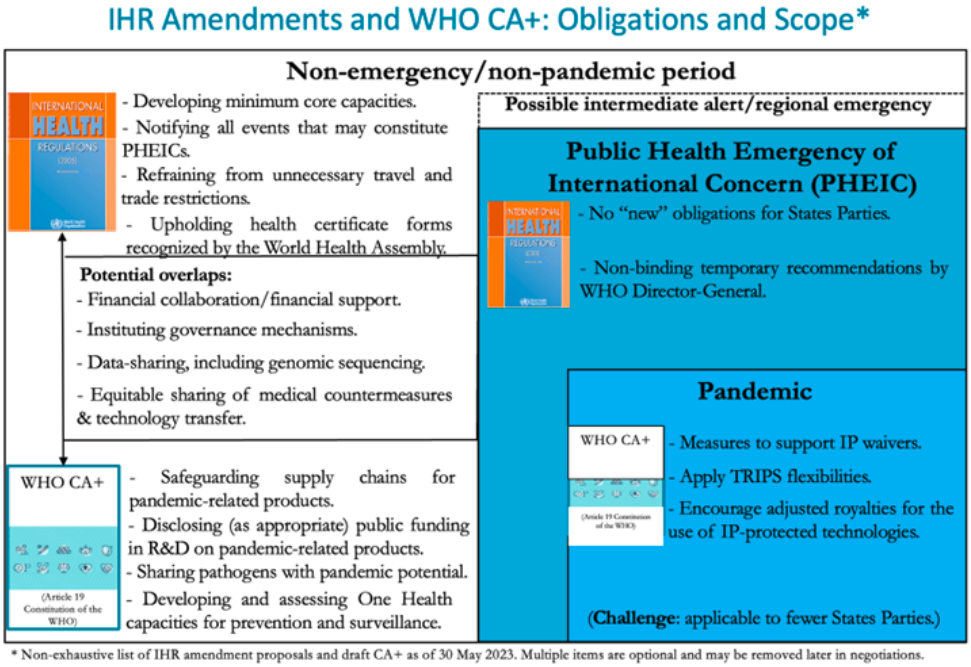
The diverging procedures for entry into force mentioned above complicate matters further for the effectiveness of future binding provisions. If the WHO CA+ has fewer States Parties than the IHR (2005), only some States would be bound by both, and others only by the IHR (2005) as amended. Specific obligations applicable during pandemics under the WHO CA+ might lack a sufficiently broad number of addressees to make them effective. Moreover, the possibility of some States Parties to the IHR (2005) rejecting some or all proposed amendments cannot be discarded yet. This entanglement of legal provisions could lead to a jigsaw puzzle of legal obligations. Such a scenario could undermine, for instance, the effectiveness of obligations to share genomic sequence data and pathogen samples, as well as equitable access to medical countermeasures. It raises the question of how meaningful an alert system where the declaration of a pandemic only applies to a limited number of states can be.

11 Proposed amendments to Article 7 IHR (2005) include the caveat that these two sets of obligations might instead be addressed in the WHO CA+.

The interaction between the two instruments in terms of their respective scope of application must be clarified. The IHR (2005), both currently and as may be amended, will seemingly have a broader factual scope of application than the WHO CA+.[12] The reason is, the IHR (2005) envisage a prevention, preparedness and response approach that aims to protect against diseases with a risk of cross-border spread and that may become public health emergencies of international concern (PHEIC). By contrast, the WHO CA+ is focused on "pandemics" proper, that is, events where a global spread is already taking place. Not all diseases falling within the scope of application of the IHR (2005) will end up being pandemics, but all pandemics would fall within the purview of the IHR (2005). It follows that, besides measures to be applied constantly as a strategy of prevention, the scope of the WHO CA+ will be narrower and more specific from a health security perspective, since PHEICs would be the genus and pandemics the species.

Both the IHR (2005) and one of the options for wording currently found in the draft WHO CA+ grant the WHO Director-General the power to issue two different declarations which, in turn, lead to different sets of consequences. Under Article 12 IHR (2005), the WHO Director-General may declare a PHEIC after consulting an Emergency Committee convened under Article 48 IHR (2005). So far, this act does not carry any legal consequences on its own. Once a PHEIC is declared, the WHO Director-General may issue temporary recommendations under Article 15 IHR (2005) addressed at States Parties, endorsing measures that can be effective at mitigating the cross-border spread of a disease, as well as those that are not. Conversely, Article 15(2) of the current text of the WHO CA+ would enable the WHO Director-General to declare a pandemic. There are, at the moment, no procedural requirements in place before such a declaration is made (see Figure 2).

Figure 2. Overlapping factual scope and obligations of WHO CA+ and IHR (2005)



12 As already identified by the Chairs of the INB in Roland Alexander Driece, Precious Matsoso, Tovar da Silva Nunes, Ahmed Soliman, Kazuho Taguchi and Viroj Tangcharoensathien, "A WHO pandemic instrument: substantive provisions required to address global shortcomings" (2023) *The Lancet* (online first) https://www.thelancet.com/action/showPdf?pii=S0140-6736%2823%2900687-6

IV. "Ironing Out" Problematic Overlaps: Practical and Conceptual Strategies

A number of **practical** and **conceptual** solutions to the problematic overlaps mentioned above come to the fore that could help avoid them altogether at the drafting stage. From a practical perspective, the **first** solution would be for the negotiating bodies of each instrument to meet and agree with the other on which provisions should go where. This, however, does not solve the pitfalls of delegates having to negotiate legal obligations separately and, to a certain extent, independently. Eventually, an agreement reached in one body could be on a collision course with a different one reached in the other. This is further complicated by the two different structures for negotiation, because the amendments proposed to the IHR (2005) were made during a specific timeframe, whereas the WHO CA+ is subjected to new revisions and proposals in each round. Therefore, a **second** practical solution —which might be both legally and politically challenging— would be to merge both negotiations into one. This could facilitate reaching a political agreement on obligations corresponding to different issue areas, while selecting where each obligation could be located could be decided afterwards. Such a strategy, however, would require a new decision by the Health Assembly merging the two processes. Elsewhere, negotiators have opined that it is unlikely the structure of negotiations will change at such an advanced stage.[13]

From a **conceptual** point of view, three strategies are immediately available. **First**, one instrument could explicitly affirm that obligations of the other would take precedence, which would leave a smaller room for interpretation. This is a well-known interpretive device in treaty negotiations. Cross-references may be included where necessary, and new wording could affirm that provisions of one instrument are "understood as being in conformity" with, or "without prejudice" to the other one, which means the latter one prevails. **Second**, should legal conflicts emerge in the future as a result of novel factual circumstances, the international law doctrine of lex specialis could help solve questions of interpretation. As explained above, the WHO CA+ currently has a more specialized factual remit than the IHR (2005), hence the former's obligations might prevail in case of conflict. **Third** and last, the different procedures for entry into force hint at the type of obligations that can be included in one legal instrument or the other. Being "Regulations", the IHR (2005) could keep its focus on technical aspects of inter-state coordination and WHO' managerial role in public health emergency prevention, preparedness and response. Conversely, the WHO CA+ could tackle issues with a higher degree of governance complexity, such as the regulation of the different phases in medical research and development, decisions on intellectual property rights, as well as a mandatory percentage of national health budgets devoted to international capacity-building. While the conceptual separation between technical and political aspects is not always crystal clear, it could nevertheless help distribute activities in the upcoming drafting processes.

V. Conclusions

The overview of the parallel streams of negotiation for both amendments to the IHR (2005) and a new WHO CA+ presented above underscores the diverging guiding principles and structures. These factors help understand the current status quo in each process, and the pitfalls in forthcoming negotiations. Multiple legal overlaps have emerged so far, some more problematic than others. Duplication of legal obligations and an initially asymmetric number of States Parties would risk undermining the eventual implementation of the amended IHR (2005) and the new WHO CA+. Facing these prospects, the analysis above posits **two practical solutions** addressing the structure of negotiations, and **three conceptual ones** focused on drafting strategies. Considering the deadline of May 2024 is fast approaching, these suggestions would allow for streamlining ongoing efforts to create new international law rules for a more effective and equitable coordination against future health threats.

13 Kerry Cullinan, 'Focus on Influencing Substance of Pandemic Accord as Process Unlikely to Change, EU Official Advises Civil Society', *Health Policy Watch* (18 May 2023) https://healthpolicy-watch.news/focus-on-influencing-substance-of-pandemic-accord-as-process-unlikely-to-change-eu-official-advises-civil-society/.

ONE HEALTH IN THE PANDEMIC NEGOTIATIONS

HÉLÈNE DE POOTER

I. Key considerations for deciding on the allocation of One Health between the IHR and the pandemic instrument

One Health is among the key topics being discussed by the Intergovernmental Negotiating Body (INB) established by the World Health Assembly (WHA) to adopt an instrument for pandemic prevention, preparedness and response (PPR)[1]. In parallel, some Member States submitted amendments to the International Health Regulations (IHR) that tend to align the Regulations with the One Health approach. Thus, the allocation of subject matters between the IHR and the pandemic instrument (probably a treaty) is a preliminary question to think about, as the two instruments do not have the same features[2].

The IHR (2005) were adopted on the basis of Art. 21 (a) of the WHO Constitution, which refers to 'sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease'. Going back to the intention of the drafters of the WHO Constitution, Art. 21 Regulations were not conceived as transactional political commitments, of the type found in traditional treaties. Rather, they were conceived as technical and procedural instruments designed for the sake of efficient international coordination, beneficial for all States regardless of their political cleavages and specific interests. Thus, the prime vocation of Regulations is to be universal. This is the rationale for the unusual procedure governing their entry into force: to facilitate their universality, Regulations are not subjected to the traditional ratification process. They enter into force automatically for all Member States of the WHO, except for those opting-out or formulating reservations[3].

Thus, from a methodological point of view, States should first consider whether a subject matter could be discussed as an IHR amendment, before considering its allocation to the pandemic instrument. This applies to One Health as to any other topic. As far as they reflect the spirit of Art. 21 Regulations and do not exceed the limited scope of Art. 21 (a), proposals on One Health can be discussed as IHR amendments.

Thinking about allocation is not a minor or mere technical question. As "the multilateral system is under greater strain than at any time since the United Nations were created"[4], the success of the WHO negotiations cannot be taken for granted. Against this background, a proper allocation can contribute to keeping health discussions safe from global tensions and disturbances. To safeguard the universality of the IHR, it is fundamental that IHR amendments rely on a broad consensus as to their relevance and necessity. Ignoring the rationale of Art. 21 by turning the IHR into a political and potentially divisive instrument will expose international health law to even more fragmentation, as States will be encouraged to opt-out from the revised version or to formulate reservations. The result would be a complex web of differing commitments across States, at odds with the purpose of the Regulations which is to enable an efficient and orderly international coordination. Ultimately, it would work against the collective effort to improve the current IHR and it would undermine the achievement of its goals.

---

1 DRAFT Bureau's text of the WHO CA+ (A/INB/X/X, 22 May 2023, advanced copy unedited), Art. 1, Art. 3.8 option 8.A, Art. 5, and Art. 23.

2 ILA Committee on Global Health Law, *Note on the Negotiation of a Pandemic Accord and Amendments to the International Health Regulations*, March 30, 2023, https://frederickabbott.com/ila_global_health.

3 Art. 22 of the WHO Constitution.

4 UN Secretary General, 9308th meeting of the Security Council, 24 April 2023.

II. One Health in the IHR

Embedding the One Health approach in the IHR will not constitute a radical paradigm shift, as the Joint External Evaluation Tool of the IHR already contains many references to One Health and its components such as antimicrobial resistance (AMR) and zoonoses[5]. The IHR are thus already interpreted and implemented with a One Health lens. This should facilitate a codification in the text itself.

Among the major provisions of the current IHR are those on 'core capacities' for surveillance, detection, reporting, assessment and response (Art. 5 and Annex 1), notification (Art. 6.1 and Annex 2) and information-sharing (Art. 6.2, 8, 9, and 10). Such provisions could be adapted to the One Health approach without disrupting the whole IHR. Firstly, the amendment process could be an opportunity to expand the human-health-centered core capacities towards 'One Health core capacities' including the integrated surveillance of diseases and drivers, zoonotic spillovers and AMR, their early detection and prompt reporting for on-time response. As a matter of fact, proposed amendment to IHR Annex 1A – on the development of collaborative surveillance networks to quickly detect public health events at the human-animal-environmental interface, including zoonotic spillovers and AMR[6] – is an illustration of what such 'One Health core capacities' could be. Some WHO Member States expressed the view that this kind of provisions should be included in the pandemic instrument[7]. Indeed, the Bureau's text of the pandemic instrument does include a reference to 'One Health capacities'[8]. While this draft does not contain any clear list of these capacities so far, specific proposals scattered throughout the text could actually be labelled 'One Health capacities' (e.g., One Health surveillance mechanisms[9], laboratory capacities in line with the One Health approach[10]). As long as they fit Art. 21 (a) of the WHO Constitution, and provided there is a broad consensus on their necessity, it would be more appropriate to have these capacities discussed as IHR amendments rather than at the INB level, as these amendments would merely adapt an existing list of core capacities to the One Health approach. As some States might consider 'One Health core capacities' useful but burdensome and costly, there could be a progressive calendar for their implementation[11], and States could benefit from the assistance of the WHO[12] and from financial support[13].

Secondly, current IHR provisions on notification and information-sharing could be adapted to the One Health approach. However, to some extent, this might face some political resistance. On the one hand, developing interinstitutional information-sharing should be rather consensual. As a matter of fact, proposed amendments to Art. 6.1 do support information-sharing by the WHO with other institutions involved in One Health (FAO, UNEP, WOAH/OIE)[14]. These are interesting amendments, although they could be more specific on the purpose of such sharing (such as encouraging joint risk assessments and issuing risk management recommendations). On the other hand, some States might be reluctant to the

5 WHO, *Joint external evaluation tool: International Health Regulations (2005)*, 3rd ed., 2022.

6 WHO, *Proposed Amendments to the International Health Regulations (2005) submitted in accordance with decision WHA75(9) (2022)*, p. 70.

7 Sixth meeting of OHHLEP (6 May 2022), *Note for the Record*, p. 4.

8 DRAFT Bureau's text of the WHO CA+ (A/INB/X/X, 22 May 2023, advanced copy unedited), Art. 5, option 5.A.4.

9 *Id*., Art. 4 option 4.B.6, Art. 5 options 5.A.6, 5.A.7.d, and 5.A.8.

10 *Id*., Art. 5 options 5.A.6 and 5.A.8.

11 Art. 5 and 13 of the IHR stipulate a five-year timeframe, with possible extensions, for the implementation of core capacities.

12 As already provided by IHR Art. 5.2, 5.3 and 44.

13 *E.g.*, from the Pandemic Fund or the partnership contribution of the Pandemic Influenza Preparedness (PIP) Framework, which is already supporting IHR implementation.

14 WHO, *Proposed Amendments to the International Health Regulations (2005) submitted in accordance with decision WHA75(9) (2022)*, p. 60, p. 106.

expansion of the amount and nature of information to be notified and shared with the WHO. Therefore, keeping the current wording of Art. 6, 8, 9, 10, and Annex 2, could be an option, as these provisions are broad enough to be interpreted consistently with the One Health approach.

III. One Health in the pandemic instrument

The pandemic instrument appears better suited for more general or more politically oriented provisions on One Health. At the same time, given the recent shift of the international community towards the 'One Health mindset' – fueled by the work of the One Health High-Level Expert Panel (OHHLEP) which is bearing fruit but is still in its inception phase[15] – it may be too early to set specific principles and norms in a pandemic instrument that is due to apply for an indefinite future. Moreover, the very relevance of embedding One Health provisions in the pandemic instrument is disputed, as evidenced by the Bureau's text which sees Art. 5 on One Health as a mere option, the alternative being to delete this article. More generally, the entry into force and universality of the pandemic instrument should not be taken for granted. Thus, it may be risky to develop sophisticated One Health mechanisms such as the WHO Pathogen Access and Benefit-Sharing System (envisioned by Art. 12.B of the Bureau's text) while there is no guarantee as to the participation in this instrument[16].

For the time being, WHO Member States should address One Health in an open manner and not close the door to future scientific, methodological, and institutional evolutions. The priority should be to acknowledge One Health as a guiding principle for pandemic prevention at source, as this is the only long-term and mutually beneficial solution[17]. States could commit to adopt One Health national plans and to define One Health national contributions to pandemic prevention at source, by tackling the drivers (AMR, deforestation, intensive farming, trade in wild species…)[18]. Such contributions could be diversified and reinforced with time, in a similar fashion as the Nationally Determined Contributions of the Paris Agreement. The pandemic instrument could also encourage States to develop the 'One Health argument' in all sectoral policies (climate change mitigation, animal welfare, environmental protection…) as this argument will give more incentives for ambitious policies in all sectors.

Whatever is adopted in the pandemic instrument and the revised IHR, these instruments will remain a small portion of a wide ecosystem of international norms, institutions, and mechanisms already contributing to the One Health objectives. Thus, beyond the IHR and pandemic instrument negotiating processes, the challenge is also to embrace the possibility of 'regime complexity' and 'regime integration'.

IV. Thinking beyond the IHR and the pandemic instrument: foster 'regime complexity' and envision the possibility of 'regime integration'

The global One Health agenda is broader than pandemic prevention and relies on a considerable amount of normative, technical and policy work, scattered throughout various international bodies (e.g., Codex Alimentarius standards, soft instruments by the Quadripartite,

15 For example, OHHLEP is currently conducting a systematic review of the drivers of pathogen spillover. See 9th Meeting of OHHLEP (2-3 March 2023), *Note for the record*, p. 4.

16 Informed by the history of the Pandemic Influenza Preparedness (PIP) Framework – which is the 2011 legal outcome of 60 years of strong and well-tried scientific cooperation through the Global Influenza Surveillance and Response System (GISRS, previously known as GISN) – States should attempt to protect scientific collaboration from legal and political contingences. Thus, a new mechanism for pathogen sharing should build on empirical scientific cooperation and could be discussed separately.

17 The importance of One Health for prevention purpose is implicit to Art. 4 option 4.B and Art. 6.4.e of the DRAFT Bureau's text of the WHO CA+ (A/INB/X/X, 22 May 2023, advanced copy unedited).

18 *Id*., Art. 5, option 5.A.3.

WHO guidelines, FAO or OIE/WOAH instruments, Commission on Phytosanitary Measures recommendations, COP decisions on biodiversity, climate change, or endangered species of wild fauna and flora…). From a One Health perspective, this diversity of rules and fora can seem confusing, lead to challenges in coordinating and monitoring compliance, and give the overall impression that global governance efforts are fragmented and not optimized. However, as these norms, institutions, and mechanisms are mutually supportive of the One Health approach, integration in a single new agreement is not an immediate legal necessity besides being legally and institutionally difficult. Rather, States should start with ensuring their application, reinforcing them, filling the gaps, and focusing on managing the challenges of this diversity, through what some scholars call 'regime complexity'[19]. WHO, FAO, and WOAH/OIE (recently joined by UNEP) have been engaged in cooperation and coordination for One Health purposes for more than a decade, and their collaboration increased after the COVID-19 pandemic[20]. However, these dynamics and interactions should expand towards other bodies, sectors and activities.

As 'the directing and coordinating authority on international health work'[21], the WHO must play a major role in managing regime complexity on One Health. WHO Member States could adopt a WHA Resolution calling for the Director General to encourage further multi-stakeholder discussions and joint initiatives relevant for One Health. For instance, instead of developing a Universal Health and Preparedness Review following the classical siloed approach, WHO Member States could initiate the shift towards a One Health Universal Review, by mandating the Director General to engage discussions on such a project at the Quadripartite level. That initiative would probably require parallel decisions by the governing bodies of the other organizations. The Quadripartite Universal One Health Review would be based on One Health capacities, best practices and norms defined jointly. This Review would both serve as a One Health compliance monitoring tool and as an opportunity to define One Health priorities, helping States to manage their efforts. To that end, the WHO could draw the attention of the international community on the possibility of establishing a One Health science-policy interface mechanism that would inform policymaking through commissioning and curating science, providing scientific advice, identifying gaps, and highlighting priorities, as this would contribute to streamlining One Health initiatives[22].

Regime complexity and interaction should not be confined to the Quadripartite Alliance between WHO, FAO, WOAH/OIE, and UNEP. In particular, WHO Member States could mandate the Director General to invite the WTO and the other members of the Quadripartite Alliance to discuss the possibilities of mainstreaming One Health into trade law, through the interpretation of the health and environmental provisions of the WTO Agreements in line with the One Health approach. Ultimately, a One Health standard-setting mechanism could be recognized in Annex A of the SPS Agreement. States adopting trade measures in conformity with these One Health standards would be presumed to act in conformity with the SPS Agreement and the GATT. This would be a strong incentive for a widespread One Health mindset.

Once the One Health mindset is more mature and widespread, States could attempt to switch from 'regime complexity' to 'regime integration', by dedicating an entire instrument to One Health, for codification and development of One Health principles, norms, and practices. Due to the very nature of One Health, such a comprehensive instrument may have to be negotiated

19 Regime complexity can be defined as 'systemic dynamics and interaction among functionally overlapping elemental institutions with potentially rival authority claims on international governance of an issue-area' (L. Gómez-Mera, "International Regime Complexity", SSRN, 23 Feb. 2021, p. 10).

20 The four institutions recently adopted the One Health Joint Plan of Action 2022-2026.

21 Art. 2 (a) of the WHO Constitution.

22 8th Meeting of OHHLEP (11 & 12 November 2022, Singapore), *Note for the record*, p. 8.

outside the WHO, at a more general scale. The upcoming UN high-level meeting on pandemic prevention, preparedness, and response (20 September 2023) is an opportunity to mobilize political momentum for such purpose.

V. Conclusion

The WHO negotiations are an opportunity to make concrete steps towards a comprehensive approach of health through the recognition of the interconnection between humans, animals, plants and their shared environment. One Health provisions can be embedded in the IHR and in the pandemic instrument, with different purposes. The pandemic instrument could contribute to preventing pandemics at source through a One Health approach tackling the drivers of the pandemics (AMR, land use change, intensive farming…). For its part, the IHR could enhance the capacity of States to contain and respond to the spread of infectious diseases through adaptation of core capacities (surveillance, detection and assessment, notification, information-sharing) to the One Health approach. Beyond the current negotiations, States should look for possible dynamics and interactions among the fragmented activities and institutions relevant for One Health. Ultimately, once the One Health mindset is more mature and widespread, States could attempt to address One Health through an integrated regime.

CRITICAL CONSIDERATIONS VIS-À-VIS THE POSSIBLE OUTCOMES FOR FAIR AND EQUITABLE SHARING OF PATHOGENS, GENETIC SEQUENCES AND BENEFITS UNDER A PANDEMIC INSTRUMENT

ELISA MORGERA

I. Premises

The premise of this paper is the tension between the alluring rhetoric of "fair and equitable benefit-sharing" as a solution to complex questions in international (and transnational) law, on the one hand, and the limited success and continued re-development of benefit-sharing mechanisms under existing international regimes.[23]

A preliminary word of caution is, therefore, necessary about avoiding the temptation to 'borrow' specific benefit-sharing approaches from other international regimes and rather focus on inter-regime learning – the underlying and evolving understanding of the questions in international law that are being addressed through benefit-sharing under different international regimes. It is also important to focus on the value and limitations of fair and equitable benefit-sharing as a principle, as well as an obligation and mechanism to respond to these questions.[24]

Perhaps the most important lessons learnt across all international benefit-sharing regimes is the need to enhance international scientific collaboration through fair research partnerships, as this is ultimately essential for the realisation of the treaty objectives in different sectors in which benefit-sharing is applied.[25]

In that connection, it may be useful for the negotiators of the pandemic treaty to reflect on the relevance of the human right to science (in addition to the human right to health), which is also understood as implying a benefit-sharing dimension:[26]

- right to share in the benefits of science by everyone without discrimination
- opportunity for all to contribute to scientific research
- obligation to protect all persons against negative consequences of scientific research or its applications on food, health, security & environment
- obligation to ensure access to applications of scientific progress that are critical to the enjoyment of the right to health and other economic, social and cultural rights
- obligation to ensure that priorities for scientific research focus on key issues for the most vulnerable

23 Morgera, 'The Need for an International Legal Concept of Fair and Equitable Benefit-sharing' (2016) 27 *European Journal of International Law* 353.

24 Morgera, 'Fair and Equitable Benefit-sharing' in E Orlando and L Krämer (eds), *Encyclopedia of Environmental Law: Principles of Environmental Law* (EE, 2018) 323.

25 Morgera, 'Fair and equitable benefit-sharing in a new international instrument on marine biodiversity: A principled approach towards partnership building?' (2018-19) 5 *Maritime Safety and Security Law Journal* 48.

26 Morgera, "Fair and Equitable Benefit-sharing at the Crossroads of the Human Right to Science and International Biodiversity Law" (2015) 4 *Laws* 803, https://www.mdpi.com/2075-471X/4/4/803; Morgera, 'The Relevance of the Human Right to Science for the Conservation and Sustainable Use of Marine Biodiversity of Areas Beyond National Jurisdiction: A New Legally Binding Instrument to Support Co-Production of Ocean Knowledge across Scales' in Vito De Lucia, Lan Nguyen and Alex G. Oude Elferink (eds), *International Law and Marine Areas beyond National Jurisdiction: Reflections on Justice, Space, Knowledge and Power* (Brill, 2022) 242, https://ssrn.com/abstract=3870399.

- obligation to prioritize allocation of public resources to research in areas where there is the greatest need for scientific progress in health, food and other basic needs related to economic, social and cultural rights, especially with regard to vulnerable and marginalized groups.[1]

The human right to science is particularly important from the perspective of **One Health,** which is referred to in the current draft of the WHO pandemic instrument. Due to the multiple interactions between different dimensions of human health and biodiversity,[2] and the relevance of biodiversity science (from fundamental biodiversity research to bio-discovery) and global biodiversity governance for achieving global health security within the purview of the WHO, it will be crucial to reflect on the needs to support synergies across different areas of biodiversity-related research and governance, and to reflect on possible impacts of the WHO Pandemic instrument on biodiversity research and governance. For instance, the draft text pays limited attention to environmental drivers of pandemic risk [3] and to the contributions of marine biodiversity and marine biodiversity research to pandemic responses[4] (e.g. thermostable enzymes produced by hydrothermal vent bacteria were used in virus test kits for COVID-19), to mention a couple of examples.

Fundamentally, the design of a new instrument should be informed by the need to enhance **international collaboration through fair research partnerships** for the realisation of international objectives, keeping in mind the need for coherence and new synergies across the full spectrum of scientific cooperation and international governance at the **biodiversity-health nexus**.

II. Fair and equitable benefit-sharing as a principle and objective of public international law

It is also helpful to reflect on the role of fair and equitable benefit-sharing as a general principle of equity in international law, which is inter-linked with good faith and effectiveness.[5] The common feature of benefit-sharing as a principle across different areas of international law can be summarised as iterative and dialogic partnership-building in the context of power asymmetries. Accordingly, rather than one-way, one-off flow of benefits to passive recipients, benefit-sharing is about the agency of beneficiaries in the co-identification of benefits & sharing modalities.[6]

---

1 Report of the Special Rapporteur in the field of cultural rights Shaheed: the right to enjoy the benefits of scientific progress and its applications (UN Doc A/HRC/20/26, 14 May 2012); Committee on Economic, Social and Cultural Rights, General Comment No 25 (2020) on science and economic, social and cultural rights (arts 15(1)(b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights (2020) UN Doc E/C.12/GC/25.

2 CBD/WHO, *Biodiversity and Human Health: A State of Knowledge Review* (2015), https://www.who.int/publications/i/item/9789241508537.

3 One Ocean Hub blog post "What do the 2022 UN Biodiversity Conference Outcomes Mean for the Ocean and Ocean Research? A Focus on Marine Biodiversity and Human Health (Part 3)", April 2023, https://oneoceanhub.org/what-do-the-2022-un-biodiversity-conference-outcomes-mean-for-the-ocean-and-ocean-research-a-focus-on-marine-biodiversity-and-human-health-part-3/.

4 One Ocean Hub blog posts: G Hamley, "Marine Biodiversity: An Underappreciated Foundation for Human Rights" (2020) https://oneoceanhub.org/marine-biodiversity-an-underappreciated-foundation-for-human-rights/; and R Wynberg et al, 'Biodiscovery: Exploring The Science-Policy Interface In The One Ocean Hub' (2020), https://oneoceanhub.org/biodiscovery-exploring-the-science-policy-interface-in-the-one-ocean-hub/.

5 Morgera, Switzer & Tsioumani, Study into Criteria to Identify a Specialized International Access and Benefit-sharing Instrument, and a Possible Process for Its Recognition, UN Doc CBD/SBI/2/INF/17 (2018). https://www.cbd.int/doc/c/9376/a644/1bed20a1837af8e3d1edc5f9/sbi-02-inf-17-en.pdf

6 Morgera (n 1).

To that end, it is essential to take stock of current unfair distribution of resources and capacities for pandemic prevention, preparedness, response and recovery, as well as past experiences of unfair practices in collaborating in scientific research and activities related to pandemic prevention, preparedness, response and recovery. In addition, it is necessary to build upon the latest understanding of the systemic conditions for inequitable relations among States in this context, as well as among actors involved in the biodiversity-health nexus. A common message in this connection emerging from across all international benefit-sharing regimes is that scientific research priorities and modalities tend to be determined by Global North donors and researchers, with the result of overlooking the needs and priorities in the Global South, lessons learnt in terms of fairness in previous collaborations, and generally may not provide the necessary focus to enhance research and response capacities in the Global South in contextual ways. On that basis, there has been a call across relevant regimes to move away from assumptions of unidirectional provision of research, capacity building and technology development opportunities from the Global North to the Global South, towards research collaborations co-development, mutual capacity building between Global North and Global South governments and actors (to ensure effective and appropriate benefits to local contexts) and co-development of technologies.[7]

Practically, this understanding of benefit-sharing requires recognizing and responding to multiple dimensions of equity to build trust (which in turn, requires understanding "what went wrong" in past attempts at collaboration in a particular sector). It implies moving beyond a transactional approach and a focus solely on distributive justice (of specific benefits), towards a system that also supports flows of global benefits and contextual justice related to capabilities.[8] Contextual justice has been proposed in the ecosystem services literature to capture a combination of pre-existing social, economic and political conditions that influence an actor's ability to enjoy all other (substantive and procedural) dimensions of justice. On the one hand, it points to embedded power asymmetries,[9] and on the other hand, it draws on theories of capabilities that see justice as the distribution of opportunities for individuals and groups to freely pursue their chosen way of life and wellbeing.[10]

Participatory governance (as discussed below) by different actors can shed light on different dimensions of fairness and equity as experienced by them - which in turns contributes to understand the complexity to be addressed in the development and implementation of benefit-sharing mechanisms, with a view to:

- develop a common understanding of fair **partnerships to enhance capabilities for pandemic prevention, preparedness, response and recovery**;
- balance competing rights & interests to the **benefit of all**; and
- maximize international cooperation on **global benefits**.

III. Fair and equitable benefit-sharing as a mechanism – the need for iterative co-development (based on systematic learning)

a. Accruing benefits

Access does not need to be necessarily linked to fair and equitable benefit-sharing: in fact,

7 One Ocean Hub policy brief: https://oneoceanhub.org/publications/policy-brief-mutual-learning-through-capacity-building-on-marine-biological-diversity-of-areas-beyond-national-jurisdiction/.

8 Morgera, 'Justice, Equity and Benefit-Sharing Under the Nagoya Protocol to the Convention on Biological Diversity' (2015) *Italian Yearbook of International Law* 113.

9 McDermott, Mahanty and Schreckenber, 'Examining Equity: A Multidimensional Framework for Assessing Equity in Payments for Ecosystem Services' (2013) 33 *Environmental Science and Policy* 416.

10 Nussbaum and Sen, *The Quality of Life* (Oxford, 1993).

many scholars from the legal and socio-ecological studies perspectives see a need to move away from a merely transactional approach with access to pathogen samples provided by countries in exchange for medical countermeasures or other benefits. To that end, it is essential for the pandemic instrument to differentiate international public law obligations of States from the contractual obligations of private actors, as part of the benefit-sharing mechanism.

On the side of State obligations, these should focus on:

- creating necessary **preconditions** for fair and equitable benefit-sharing, such as obligations to regulate publicly funded research so as to include equity conditions, such as: requiring project co-development with partners in the Global South, prioritising mutual capacity building, technology co-development and joint ventures; and integrating Monitoring, Evaluation and Learning (MEL) in scientific collaborations;[11]
- providing **support**, such as including funding and reliance on the flexibilities in the intellectual property rights system;
- supporting **integrated implementation** of other relevant international obligations and goals; and
- allowing for the iterative co-identification of benefits.

On the side of contractual obligations of companies/private actors, it is recommended:

- including a **mix of benefits**, that can be adapted to the particular needs prioritized at a particular point in time (and in light of lessons learnt in the implementation of the instrument);
- specifically articulating benefits that contribute to **fair scientific collaborations**, mutual capacity building and technology co-development in pandemic prevention, preparedness, response and recovery; and
- specifically requiring regularly updated data management plans.

In that connection, Art. 9(2) and Option 6(c).X of Option 12.B in the May 2023 draft instrument text (A/INB/X/X) provides a marked improvement compared to the February 2023 zero draft, on which I commented upon in the oral version of this paper delivered in April 2023.

b. Distribution of benefits

Essential to the generation of global benefits is taking a combined approach to strategic implementation of obligations on information-sharing, capacity-building, technology co-development, and scientific cooperation. In addition, it is crucial to keep in mind that these activities do not arise "naturally" but need support, particularly with a view to addressing equity issues and fair distribution across countries and regions, through institutional support to broker opportunities and match them with expressed needs. This is a development across existing international benefit-sharing regimes.[12] To that end, in light of evolving scientific practices and understanding of fair practices, it is recommended that the instrument provides for an ongoing identification of gaps and equity issues that prevent the enhancing of knowledge & capacities for pandemic prevention, preparedness, response and recovery in different countries and regions. Such an iterative approach should be inspired by a comprehensive understanding of the **biodiversity-health nexus** (which could support the One Health approach, the human right to a healthy environment and other human rights, and the realization of multiple SDGs).

11 One Ocean Hub policy brief, "How to enable transformative science during the International Decade of Ocean Science for Sustainable Development "Transforming ourselves before we transform how we make decisions" (2021): https://oneoceanhub.org/publications/policy-brief/.

12 Morgera (n 3).

With regard to **digital information**, it is essential to reflect on the limited capacity of users in different countries to access and make use of the information contained in databases. These are often-ignored equity issues as countries that do not have funds and capacity to maintain databases reap the majority of the benefits from digital sequence information as they inherently design databases to the benefit of their users.[13]

State obligations should include:

- **prohibition to** impose regulations that unduly interfere with protection of human health and environmental protection, as well as trade;
- **duty to cooperate to co-identify in an iterative manner** integrated responses to capacity & operational needs (including responses to previous equity issues - "what went wrong"), as well as evolving scientific practices, as part of the institutional structure supporting the implementation of the treaty;
- **duty to cooperate to co-develop** sharing modalities, including funding, taking into account the range of needs of relevant actors (independent experts, stakeholders & users from different communities of practices in Global North & South (natural & social scientists) across the biodiversity-health research, innovation and governance spectrum, database managers, and representatives of other international benefit-sharing regimes.
- obligation to **cooperate across different fora**.

With regard to the last three points, I suggest taking inspiration from the innovative provisions of the Agreement on Biodiversity of Areas beyond National Jurisdiction under the Convention on the Law of the Sea ("BBNJ Agreement"),[14] which provides the latest example of an international benefit-sharing instrument:

- art 44(3-4) "Capacity-building and the transfer of marine technology should be a country-driven, transparent, effective and iterative process that is participatory, cross-cutting and gender-responsive";
- art 6(2) reads: "Parties shall endeavour to promote, as appropriate, the objectives of this Agreement when participating in decision-making under other relevant legal instruments, frameworks, or global, regional, subregional or sectoral bodies";
- 43(1) "Parties shall cooperate, directly or through relevant legal instruments and frameworks and relevant global, regional, subregional and sectoral bodies, to assist Parties, in particular developing States Parties, in achieving the objectives of this Agreement through capacity-building and the development and transfer of marine science and marine technology.

In that connection, Art. 11 (Option 11.B of the May 2023 draft instrument text (A/INB/X/X), provides a marked improvement compared to the February 2023 zero draft, and appears to build on the language of the BBNJ Agreement art 44(3-4).

c. Institutional structure to support iterative co-design and learning

Participatory governance and iterative co-design of fair and equitable benefit-sharing mechanisms and approaches, based on systematic learning from experience, has also emerged as a key feature across different benefit-sharing regimes. Because of the complexity

13 CBD Secretariat, Synthesis of views and information on the potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention and the objective of the Nagoya Protocol, (2018) UN Doc CBD/DSI/AHTEG/2018/1/2, at 13.

14 Agreement on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction (BBNJ Agreement). At the time of writing, the Agreement has not yet been formally adopted. All references to BBNJ Agreement provisions in the present work refer to the advanced unedited draft published in early March 2023 and available at https://www.un.org/bbnj/sites/www.un.org.bbnj/files/draft_agreement_advanced_unedited_for_posting_v1.pdf.

of the subject-matter and the need to understand different experiences of equity, as well as potential impacts across the biodiversity-health research, innovation and governance landscape, it is recommended to establish at the international level an independent body of experts, stakeholders and users from different communities of practices in the Global North and the Global South (scientists from different geographies and disciplines, database managers, experts from different sectors, representatives of other international benefit-sharing regimes), with a view to adapting the benefit-sharing system in the light of changing scientific practices and evolving understanding of equity in the sector. This body could be mandated under a periodic review clause under the treaty to, iteratively:

- Co-identify benefits (as contractual terms) and pre-conditions (as support from States) as integrated responses to capacity and operational needs (including previous equity issues - "what went wrong"), as well as evolving scientific practices;
- co-develop sharing modalities and funding mechanisms, taking into account the range of needs of relevant actors and providing brokering services;
- support the brokering and match-making of opportunities;
- provide oversight of the distribution of benefits across different regions, identify good practices and lessons learnt in ensuring fairness and equity, as well as any as well unintended consequences on fairness and equity, including in the use of funding and IPRs;
- contribute to the periodic review of implementation (looking at questions of efficacy together with questions of equity) and suggest adjustments to the regime for consideration by the Conference of the Parties.

Once again, I suggest taking inspiration from the following provisions of the BBNJ Agreement:

-
- art. 52(11): "The Conference of the Parties shall, in addition, undertake a periodic review of the financial mechanism to assess the adequacy, effectiveness and accessibility of financial resources, including for the delivery of capacity-building and the transfer of marine technology, in particular for developing States Parties";
- art. 47(2)(d): "Capacity-building and the transfer of marine technology undertaken in accordance with the provisions of this Part shall be monitored and reviewed periodically…output, outcomes, progress, effectiveness, successes, challenges."

The proposed Global Pandemic Supply Chain & Logistics Network and/or the Benefit-sharing Expert Committee could serve as a multi-actor learning platform, to support the co-identification of equity issues and the co-development of solutions. It would be essential to ensure fair representation of different interests, experiences and expertise from the Global North and South.

While currently the May 2023 draft text (A/INB/X/X) foresees an individual responsibility for Parties to timely matching of supply to demand and mapping manufacturing capacities and demand (Art. 11A(4)(b)), it is recommended to support multilateral match-making as occurring under other international benefit-sharing mechanisms. In this connection, I suggest taking inspiration from art 51(3)(b) of the BBNJ Agreement, which reads: "The clearinghouse mechanism shall…Facilitate the matching of capacity-building needs with the support available and with providers for the transfer of marine technology".

On the question of developing a specialised ABS instrument in accordance with Art 4 of the Nagoya Protocol, it is recommended maximising opportunities for regime interaction and cross-regime learning,[15] with explicit provisions and clear entry points across the international institutional structure for the implementation of the new instrument.

15 Morgera, Switzer & Tsioumani (n 9).

In this connection too, I suggest taking inspiration from the following provisions of the BBNJ Agreement:

- art 12(4bis): “The access and benefit-sharing committee may consult and facilitate exchanges of information with relevant legal instruments and frameworks and relevant global, regional, sub-regional and sectoral bodies on activities under its mandate including benefit-sharing, the use of digital sequence information on marine genetic resources, best practices, tools and methodologies, data governance and lessons learned”;
- art 20(a): “[Emergency] Measures adopted under this article shall be considered necessary only if, following consultation with relevant legal instruments or frameworks or global, regional, subregional or sectoral bodies, the serious or irreversible harm cannot be managed in a timely manner through the application of the other articles of this Agreement or by a relevant legal instrument or framework or global, regional, subregional or sectoral body”.

Finally, all review mechanisms (including the proposed peer-review mechanism/universal health and preparedness review – art. 8A of the May 2023 draft instrument text (A/INB/X/X)) should be clearly linked to multilateral learning across relevant regimes, and to the multi-actor learning platforms, before leading to recommendations for consideration by the COP.

U.S. WHO POLICY: THIN COOPERATION OR ROBUST COLLABORATION?

DANIEL WARNER

In his first major foreign policy address as the new president, Joe Biden spoke to American diplomats at the State Department on February 4, 2021. He said: "America is back. America is back. Diplomacy is back at the center of our foreign policy." He went on to say: "We must meet the new moment, accelerating global challenges. From the pandemic to the climate crisis, to nuclear proliferation…will only be solved by nations working together and in common, we can't do it alone."

It is important to remember that in 2020 the Trump administration announced the U.S. withdrawal from the World Health Organization (WHO) just when the organization was facing the biggest health emergency in its history, the Covid-19 pandemic. Biden's words were warmly welcomed throughout the multilateral system. "America is back," he said it twice, meaning America was back engaged in diplomacy.

But what did his statement mean in terms of multilateral diplomacy? Specifically, what did it mean in terms of global health security?

Parallel negotiations recently took place in Geneva towards amending the 2005 International Health Regulations (IHR) and adopting a new pandemic treaty. Amending the IHR was the preferred US option, while the EU and other countries backed a pandemic treaty. The dual pursuit of both instruments at the same time reflects a political compromise. With the U.S. unlikely to ratify a treaty, what is the rationale for the US to engage actively and in good faith also in the pandemic treaty negotiations?

BACKGROUND

To set the context: There is no question that global health security is an important issue for the United States. According to Global Health Policy bulletin May 21, 2021, "President Biden's initial Fiscal Year 2022 budget request included "nearly $1 billion for global health security, and the administration has also taken steps to bolster U.S. global health security efforts including:

- reinstating the National Security Council's Global Health Security and Biodefense Directorate,
- creating a Coordinator for Global COVID Response and Health Security at the Department of State,
- reversing the prior administration's decision to withdraw the U.S. from membership in the World Health Organization (WHO), and
- affirming that the current administration "will treat epidemic and pandemic preparedness, health security, and global health as top national security priorities," per a January 2021 national security memorandum on advancing global health security."

Whereas Biden and his team have been presented as globalists as opposed to Trump's team of nationalists and America Firsters, the difference between the two merits examination in view of a U.S. Joint Statement by the Department of State and the Department of Health and Human Services on Negotiations of a Pandemic Accord issued by the Office of a Spokesperson Department of State on March 8, 2023: "While the United States is deeply committed to a

process that should result in shared commitments and shared responsibilities among nations, we are also aware of concerns by some that these negotiations could result in diminished U.S. sovereignty."

Is the United States willing to back global health security in terms of voluntary limitations to its sovereignty for the purpose of finding multilateral solutions to global problems?

The question is what Biden's statement that "America is back" means in Geneva in the context of the WHO and the two currently ongoing processes within the organization, the Intergovernmental Negotiating Body for the pandemic treaty (INB) and the Working Group on Amendments to the IHR. The conclusion of both processes is scheduled for the 77th World Health Assembly in May 2024.

The U.S. positions on the future pandemic instrument and the IHR are both within the larger position of the United States that global health is a top national security priority, as indicated above. The United States has consistently seen disease outbreaks as security threats, equating natural disease outbreaks with bioterrorism. Securitizing health has consequences on U.S. priorities and its negotiating position in the WHO processes, including its preference for the IHR.

But like all national security priorities, specific positions on specific issues can change depending on circumstances. The operationalization of the abovementioned State Department statement through the two processes reflects shifting sands in the security ecosystem rather than absolute principles carved in stone.

It is important to note that while the pandemic instrument and the IHR are separate processes and separate instruments, many country representatives sit on both processes that are meant to be "complementary." But as Prof. Suerie Moon has written: "Two international pandemic rulemaking negotiations taking place in parallel can only be the result of a political compromise. Indeed, it was the implicit agreement between countries that favored a pandemic treaty and those that preferred the IHR. An implication of this compromise, however, is an exacerbation of power disparities between countries: simply put, it is exceedingly difficult for smaller countries to engage meaningfully in both processes."[1]

The difference between the legal nature of the instruments emerging from these processes is important for the United States' position since any treaty would have to be subject to the advice and consent of the United States Senate. The same requirement allegedly does not apply to amendments to the IHR. The United States Senate is reluctant to ratify multilateral treaties; this is well known by other countries. As such, one wonders whether developing countries are adding numerous proposals as their priority issues in the IHR in expectation that the United States will be more prepared to make a deal there since they realize the problems in having the Senate ratify a treaty. The consequences for the negotiations in this case would be an increasing overlap between the two texts, changing the nature of the IHR from a technical and operational instrument into one of increasing regulatory and transactional nature.

INB

The INB is set out to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness, and response. During its second meeting in Geneva from 18-21 July 2022, it concluded by consensus that the new instrument should be legally binding.

In response to the notion of a legally binding international instrument, following the fourth

1 Suerie Moon, "How to mitigate disputes in global pandemic rulemaking?" The Collective Blog. University of Oslo. November 8, 2022.

meeting of the INB which ended on March 3, 2023, the Joint Statement of March 8, 2023, by the Department of State and the Department of Health and Human Services stated: "The United States will not support any measure at the World Health Organization, including in these negotiations, that in any way undermines our sovereignty or security. Any accord resulting from these negotiations would be designed to increase the transparency and effectiveness of cooperation among nations during global pandemics and would in no way empower the World Health Organization or any other international body to impose, direct, or oversee national actions. It will not compromise the ability of American citizens to make their own health care decisions."

Whereas some countries are uncertain about the possibility of the United States Senate allowing the ratification of a treaty, critics in the United States argue that the WHO could become a kind of superpower above the country's control. This type of argument has been used in the past about the United Nations becoming a restrictive world government or some other international organization taking over the world. The role of social media and disinformation should not be ignored in terms of how internal American politics affects the United States's negotiating position. Much has been made about how fears of fraud in the 2020 American presidential election led to the January 6 Capitol invasion. Social media and conspiracy theories can exercise strong political influence, and not only in the United States but also in the INB negotiations beyond the United States.

As an example of American fear, a damning article from the conservative Heritage Foundation that also follows much U.S. policy in criticizing China reported: "Although the draft WHO CA+ makes transparency and cooperation mandatory (using the term "shall" when referencing facilitating access and sharing of research and genomic data), it provides no consequences for non-compliance. Thus, there is little reason to believe that China would live up to its obligations any better than it did under the voluntary IHRs."[2] The draft treaty is drawing criticism from some U.S. senators. They have drafted a resolution demanding that the treaty be submitted to the Senate for advice and consent pursuant to the U.S. Constitution.

In concluding their Heritage article and its main argument about preserving U.S. sovereignty, Brett Schaefer and Steven Groves wrote: "Only a treaty that would preserve American sovereignty, address the mistakes of the COVID-19 pandemic, and protect the intellectual property of U.S. companies should be considered for approval by the United States."

In order to assuage worries about the U.S. losing sovereignty, the Director-General of the WHO tweeted: "No country will cede any sovereignty to WHO. Countries will decide what the Pandemic Accord says, and countries will implement the Accord in line with their own national laws."

On 22 May 2023, the Bureau of the INB (i.e. the six officers elected by the INB to lead and facilitate the process) released a so-called "Bureau's text" of the pandemic treaty for member states' consideration at the subsequent meetings of the INB. The draft, inter alia, contains several provisions that seek to operationalise equity within the context of pandemic prevention, preparedness, and response, including redistributing resources.

In the past month or so, noteworthy state-level initiatives have emerged as potential points of interest for this paper, aimed at countering the WHO treaty.

In addition to U.S. hesitancy to a treaty, China has also been opposed to provisions in the Zero Draft that would allow the WHO to conduct inspections on its soil. In addition, China and the United States together moved to exclude sharing the draft treaty with non-state actors in what the Geneva Observer referred to as "strange bedfellows."

2 Brett Schaefer and Steven Groves. "Why the U.S. Should Oppose the New Draft WHO Pandemic Treaty." The Heritage Foundation. February 27, 2023.

In conclusion, although time is tight for concluding a treaty before May 2024, the United States declared on Feb. 23, 2023: "The United States is committed to the Pandemic Accord, to form a major component of the global health architecture for generations to come. Shared commitment, shared aspirations and shared responsibilities will vastly improve our system for preventing, preparing for, and responding to future pandemic emergencies." U.S. Negotiator for the Pandemic Accord Ambassador Pamela Hamamoto released in a statement. "We seek a Pandemic Accord that builds capacities; reduces pandemic threats posed by zoonotic diseases; enables rapid and more equitable responses; and establishes sustainable financing, governance, and accountability to ultimately break the cycle of panic and neglect."

IHR

196 countries are parties to the IHR, a binding international legal instrument that entered into force in its current form on 15 June 2007. The stated purpose and scope of the IHR are "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."

Notably, 13 out of the more than 300 amendments proposed for the IHR have been initiated by the United States. Some of those amendments would lead to extending executive power to the WHO Director-General to declare global emergency-like situations and pressure states into increasing transparency and accepting verification of their epidemiological situation by WHO.

Whereas the U.S. was adamantly in favor of defending its sovereignty in the INB, its proposed amendments to the IHR would increase WHO's power towards the state on whose territory an event occurs, an obvious reference to China and the failure of the WHO to have access during the Covid-19 pandemic. Other amendments deal with compliance and the establishment of a universal peer review mechanism as well as compliance assessment by a smaller technical body.

But questions remain about why the United States, and possibly other countries as well are ready to accept more restrictions and obligations under the IHR than a putative pandemic treaty. In an analysis of conservative claims that U.S. amendments "would take health policy decision-making powers away from U.S. officials and grant unilateral authority to the WHO's director-general," an Associated Press article quoted several experts to counter these arguments as well as the director-general who said" "WHO is an expression of Member States' own sovereignty and WHO is entirely what the sovereign 194 Member States want WHO to be,"[3] an obvious attempt to assuage fears in the U.S. and other states about threats to their sovereignty in the IHR as he had done about the INB.

Professor Lawrence Gostin, director of the O'Neill Institute for National and Global Health Law at Georgetown University also gave a counter argument about sovereignty concerning IHR, [Even if the U.S. signs an agreement, it] "would not interfere with the sovereign right of the U.S. government to make decisions about pandemic measures in the United States."[4]

As far as the U.S. position on the relationship between the INB and the IHR, in a major public article, Secretary of State Antony Blinken and Secretary of Health and Human Resources Xavier Becerra wrote in 2021: "Some major strides to advance global health security may take years to accomplish, for example, the creation of a new international instrument on preparedness and response, which the WHO and a number of other countries have endorsed. But it is not necessary to choose between a new instrument and a revised standing legal framework; immediate steps can make a meaningful difference. One is strengthening the

3 See Sophia Tulip. "WHO health regulations don't infringe on U.S. decision-making." Associated Press. May 18, 2022.

4 Quoted in Sophia Tulip. Op.cit.

WHO's International Health Regulations (IHR)…it that can be fixed, particularly around early warning systems, coordinating the response, and information sharing. Through targeted amendments following established practice at the WHO, the IHR can be revised to improve risk assessments, advance equity, help create an environment in which the WHO can fulfil its mission."[5]

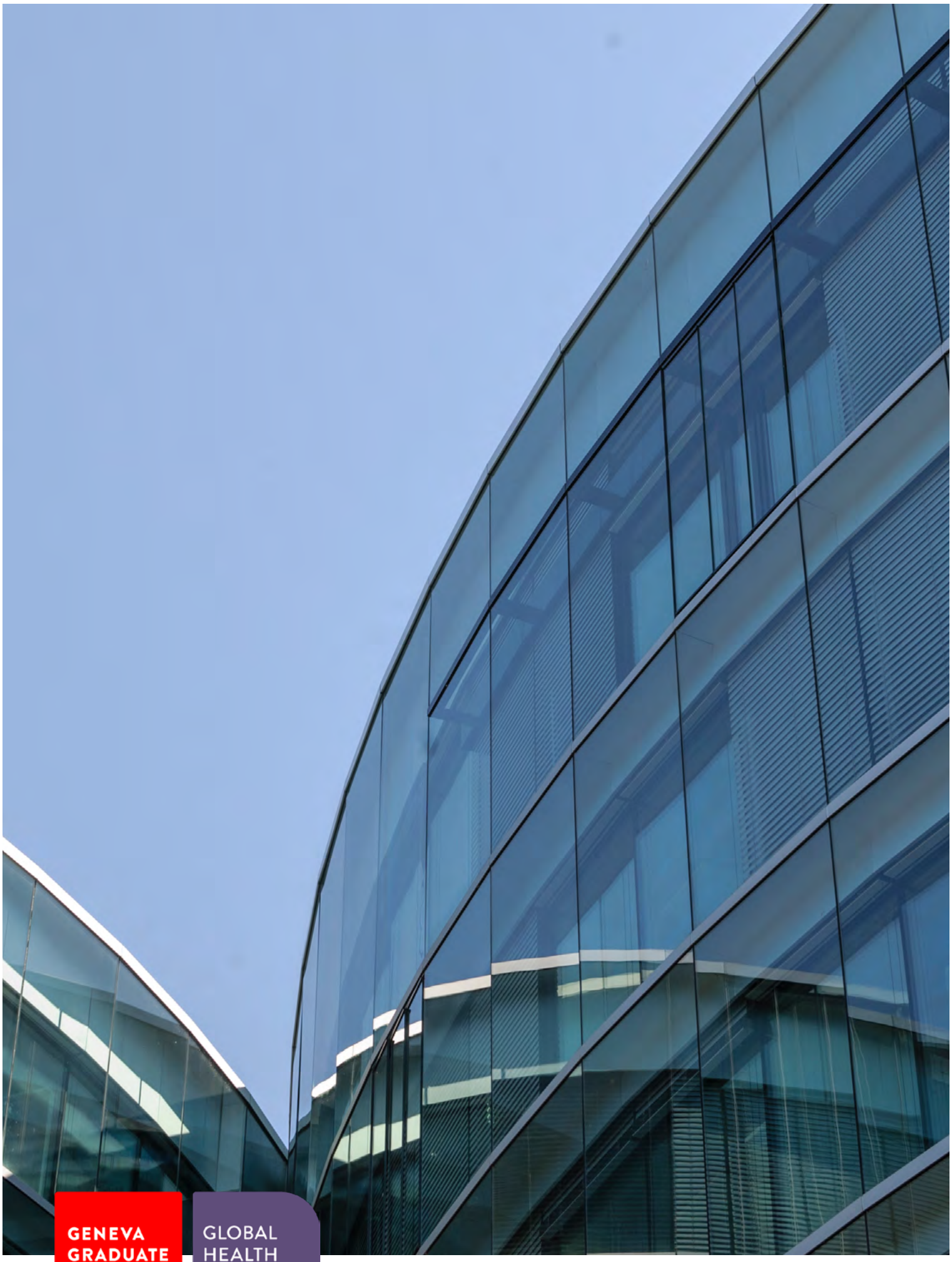
CONCLUSION

This article has raised several questions. The first concerns whether the United States will go along with a pandemic treaty. It probably will not. The political fallout from such a position so close to the 2024 election seems highly unlikely. However, the United States has an interest in shaping the rules that other countries adopt, and those rules may exert the force of soft norms later in the United States. Some of these soft norms could be adopted via Executive Order or another channel if the president wishes. But with very small margins in the Senate for Democrats - very far from a 2/3 majority - and Republicans already using the Pandemic Accord as a political talking point regarding loss of sovereignty, there doesn't seem any political likelihood of ratification in the medium to long term.

The second question, and the title of this article, questions whether the American position in the two WHO processes is thin cooperation or robust collaboration. The answer is probably both. Depending on the U.S.' national interest, its positions waver between the two. The fact that an eminent ambassador, Pamela Hamamoto, has been named to negotiate the INB despite the unlikely signing by the U.S. shows a degree of engagement that testifies to the importance of global health security for the United States.

In a larger context, while the United States leadership is preoccupied by the war in Ukraine and tensions with China, it still prioritizes a leading role in the multilateral system. "America is back" should not be ignored. Global multilateral leadership is still high on the U.S. agenda. And the role of the WHO and its two current processes represent important issues in global and American security.

5 Antony Blinken and Xavier Becerra. "Strengthening Global Health Security and Reforming the International Health Regulations." JAMA. 2021;326 (13): 1255-1256.



GENEVA GRADUATE INSTITUTE

GLOBAL HEALTH CENTRE