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GLOBAL HEALTH LAW

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DRAFT Interim Fourth Report of the Committee
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I. Introduction

1. Since the end of the Second World War in 1945, few events have so profoundly affected the international community as the COVID-19 pandemic that began in late 2019. The toll in terms of death and disease has been great - 5.8 million deaths and more than 400 million cases of infection have been confirmed (so far), with the actual numbers bound to be higher. That toll is the direct global health impact of the devastating pandemic. Beyond that, economic losses are staggering, and these losses have disproportionately stricken the less affluent countries and populations. A long-term trend toward narrowing the disparity between rich and poor has been reversed. During the course of the pandemic international relations have frayed as countries turned inward and nationalism has reasserted itself.

2. As with other crises, the COVID-19 pandemic invigorated the scientific community and dramatically advanced progress on R&D with respect to new preventatives, diagnostics and therapeutics. The scientific community responded to the crisis in “emergency mode”. Governments stepped up subsidization and purchase commitments providing a boost to innovation.

3. The post-Second World War era was a period of intensive multilateral institution building. The United Nations, the International Monetary Fund, the International Bank for Reconstruction and Development (World Bank), the World Health Organization, the GATT (now-World Trade Organization) as well as the UN human rights mechanisms, all were “children” of war, born out of perceived necessity. In the same vein, as the international community begins to recover from the COVID-19 pandemic there are efforts pointing toward a new era of institution-building. It is too soon to tell what this might yield. The lessons of the COVID-19 pandemic may or may not be pointing toward enhanced multilateral engagement. While members of the Global Health Law Committee may prefer different approaches to addressing the challenges facing us, it is common ground that preserving and strengthening a cooperative approach to addressing global public health issues is a fundamental basis of the Committee’s work.

4. But even as we look to cope with the potential for future pandemics, the reality of climate change has become evident. Extreme weather events are becoming more commonplace. Sea levels are rising.

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5 William A. Haseltine, How COVID Changed Science, Scientific American, May 25, 2021, “What is unprecedented is not just the speed and focus with which the community responded to the pandemic but also the singular willingness of scientists all over the world to share new ideas and data immediately and transparently”, https://www.scientificamerican.com/article/how-covid-changed-science/.
Pollution is becoming trapped around metropolitan areas at alarming levels. All these developments or events have significant “public health consequences”.

5. The challenges posed by COVID-19 and climate change affirm the importance of international law and human rights in protecting global public health. There is, thus, a need to study the scope of existing standards, as well as to investigate the potential of new standards addressing contemporary public health threats.

6. During the period following the ILA 79th Biennial Conference (Kyoto) much of the work of the Committee and its members focused on legal mechanisms for improving response to the COVID-19 pandemic and to addressing perceived shortcomings of existing international institutional arrangements, including potential reforms at the WHO. This included participating in a research effort organized by the Chair of the American Branch of the ILA (ABILA) that resulted in the submission of proposals for reform to the WHO Independent Panel for Pandemic Preparedness and Response; sponsorship and organization by the Committee of a panel on “Global Governance and World Health Organization Reform in the wake of COVID-19” at the International Law Weekend hosted by the ABILA in October 2021, and; participation in a meeting sponsored by the German Branch of the ILA in September 2021 on “The Work Program of the Global Health Committee in an Era of Unprecedented Challenges: COVID-19 Pandemic and International Law”, In addition, individual members of the Committee were actively involved in various other projects addressing improvements in the way that the international community responds to public health emergencies. Members of the Committee responded to Russia’s invasion of the Ukraine by adopting on February 24, 2022 a “Statement condemning Russia's aggression against Ukraine by members of Global Health Law Committee of the International Law Association”.

7. In light of the changed and changing global landscape, the 2022 report of the Global Health Law Committee of the ILA pays attention to three important global health matters under international law: new instruments addressing pandemics, equity, pathogen and data sharing, and the public health dimensions of climate change. Principal drafting of contributions to this report were by Prof. Frederick Abbott (Parts I, II, IV (paras. 59-60) & VI), Prof. Brigit Toebes (Parts I & V), Prof. Pia Acconci (Part IV (paras. 49-58)), Prof Gian Luca Burci (Part II), Dr. Helene De Pooter (Part IV (paras. 49-58)), Prof. Stefania Negri (Parts II & V), Dr Ioanna Pervou (Part III), and Dr. Pedro A Villarreal (Part III).

II. A WHO “pandemic treaty”: what is it for and do we need it?

A. Introduction

8. The World Health Assembly (WHA), meeting at the end of November 2021 in its second special session, established an intergovernmental negotiating body (INB) open to all member states for the purpose of negotiating “a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response” with an ambitious but tentative deadline of May 2023. That decision is the outcome of a difficult and at times divisive discussion in multiple political forums on the need for new international rules on pandemic prevention and response as a consequence of the systemic shocks that the COVID-19 pandemic has inflicted in the last two years.

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9. Discussions have been dominated (and polarized) by a determined push in favour of the immediate negotiation of a new WHO “pandemic treaty”. The initiative came initially from the European Council of the European Union\(^7\) but gathered support from a number of states, think tanks and significantly from WHO’s Director-General who has become one of its most vocal advocates.\(^8\) The proposal has, however, also generated substantial confusion and uncertainties as well as negative reactions (notably from the USA, Russia and Brazil\(^9\)) as to its motives, the wisdom of engaging in a difficult negotiation while the COVID-19 pandemic is still raging, and the priority of strengthening the International Health Regulations (IHR) and other existing instruments.

**B. The search for better governance of pandemic preparedness and response**

10. The COVID-19 pandemic, although a health crisis in its essence, has revealed gaps and imbalances in most international policy and law regimes and continues to challenge their functioning and the equity of their outcomes and distributive effects. As in the case of other major outbreaks of the last 20 years, there has been a plethora of analyses, assessments and recommendations that have addressed crucial systemic problems such as the need for more coherent governance of global health, the search for a new financing model to deliver global public goods (i.e. mostly vaccines, treatments and personal protective equipment) and support national resilience, as well as how to overcome the flagrant lack of solidarity and equity in the allocation of vaccines and other resources.\(^10\) From a normative perspective, the IHR remain the centerpiece for the detection and international containment of infectious diseases, but their credibility has been affected by the perception of inherent weaknesses, low compliance, lack of accountability and enforcement mechanisms and their limited scope.\(^11\)

11. An important consideration is that the foregoing reviews and policy discussions have increasingly focused on “upstream” and “downstream” gaps beyond the scope of the IHR involving multiple international regimes besides global health law and policy, e.g. with regard to the environmental causes of diseases as well as the politically divisive question of equitable access to vaccines. They have also consistently focused on structural problems seen as a major weakness in the international regulation of health security, in particular how to ensure and maintain good faith and solidarity, incentivize compliance and secure accountability for international obligations of crucial global significance such as the reporting obligations grounded in the IHR.

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\(^{8}\) WHO, Director-General’s closing remarks at the World Health Assembly - 31 May 2021.


12. It is in this climate of mistrust and uncertainty, but also of realization of the existential importance of needed changes, that the proponents of the WHO pandemic treaty (calling themselves “friends of the treaty”), supported by all major review exercises mentioned above, actively promoted their initiative in multiple forums as an essential missing piece in global health architecture. There was strong pressure for an immediate launch of the negotiations at the May 2021 WHA since the treaty was presented as an emergency measure that would both strengthen and complement the IHR, fill existing legal gaps, shore up support for WHO and become the catalyst for much-needed coherence in global health security. As noted above, resistance and reluctance to enter into an immediate negotiating commitment led to a postponement of the final decision and to remaining uncertainties as to the legal nature of the instrument as shown by the mandate of the INB quoted above.

C. Why a pandemic treaty?

13. Political maneuvering and divisions on whether or not to immediately move towards a treaty vis-à-vis first strengthening the IHR, have led to the paradoxical result that so far there has been relatively little discussion - let alone agreement - within WHO’s governance on the main benefits of concluding a new treaty and what its structure and content should be. The “friends of the treaty”, in particular, have been unable to develop a unified and convincing narrative, possibly because of divisions within their ranks, with the most elaborate proposal coming from the European Commission in August 2021. At the same time, there has been a proliferation of supportive proposals from individual countries, think tanks and scholars that shows a veritable “Christmas tree” approach and reveals at times both a lack of understanding of what functions a pandemic treaty could usefully perform as well as of the international legal landscape in which the latter would be positioned.

14. To better understand the rationale for the new treaty, it is necessary to review the main proposals and justifications that, albeit in an oversimplified form, fall under the rubrics of substantive and structural proposals.

D. Substantive proposals

15. Substantive proposals have been articulated by proponents directly or indirectly with reference to the IHR, i.e. whether or not they already fall under the current Regulations, and if they do why there is the need for an additional instrument. The rationale so far has been reactive and critical of the performance of the IHR during COVID-19 building also on the critical assessments during previous health crises such as the 2014-2016 Ebola outbreak in West Africa. In other words, on the one hand the IHR is criticized for its narrow scope and purpose that excludes many crucial aspects of pandemic preparedness and response; on the other hand, the perception of weakness and lack of enforceability of the Regulations is at the basis

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of proposals that overlap with its content for the purpose of strengthening or complementing them. Most of the recurrent proposals fall explicitly or implicitly under prevention, detection and preparedness and response as organizing and conceptual criteria; most of them have been formulated in general terms without much elaboration or detail. What follows is a simplified summary of some of the most frequent proposals:

16. **One Health:** Most proposals address the increasing risk of spillover of animal pathogens to humans (zoonotic spillover) and the “One Health” approach that seeks to coordinate human and animal health as well as food production and environmental protection. Mapping and reducing these risks at national level is indeed a blind spot in international law since the IHR only deal with detection and containment of occurring outbreaks and environmental treaties have a different focus. A pandemic treaty would instead pursue “deep prevention” trying to reduce the risk of zoonotic spillovers in the first place. One Health is an institutionally crowded topic given its many interfaces and the current joint work among WHO, FAO, OIE and UNEP. A future pandemic treaty will face the challenge of coordinating and rationalizing very diverse agendas and functional communities. If it is proposed to somehow subsume the inter-agency working group under a pandemic treaty, we can expect challenges and uncertainties related to the differences in memberships, role of the various governing bodies, and apportionment of resources and costs among the agencies;

17. **National capacities:** most proposals highlight the essential importance of national preparedness and resilience and the role played by public health systems in preventing disease spread. This issue is regulated under the IHR (so-called “core capacities”), but the level of compliance has been uneven at best, with reviews largely based on self-assessment, and WHO’s indicators have not been predictive of actual performance. The IHR Review Committee advocated for “all-of-government and whole-of-society coordinated national health emergency planning and preparedness” as a priority for the pandemic treaty, where performance would be linked to international assistance and funding. Regulating core capacities more strictly than the IHR will be a legal and political challenge, given the intrusive and unprecedented nature of international obligations on the organization of national public health systems;

18. **Pathogen and benefit sharing:** Even though not an acute problem during the COVID-19 pandemic, ensuring speedy and predictable multilateral sharing of human pathogens and related genetic sequences, as well as of the benefits deriving from their utilization, is a crucial component of global health security. Recent discussions have been dominated by the applicability of biodiversity law, which however is considered by many as unfit for public health purposes given its bilateral and transactional approach. A pandemic treaty would offer a unique opportunity to devise an international legal framework responsive to public health needs including the so far unregulated issue of genetic sequence data.

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16 See IHR Review Committee Report (n. 11), p. 50.
19 International Health Regulations, art. 5 and Annex 1.
21 IHR Review Committee Report (n. 11), p. 50.
23 IHR Review Committee Report (n. 11), p. 50.
this partial carve-out, subject to a number of conditions including consistency with the principles underpinning the whole biodiversity regime;

19. **Reporting obligations and WHO’s authority**: this is seen as one of the weakest aspects of the IHR and WHO’s role, thus requiring a new treaty as the tool to make it more credible and enforceable. The IPPPR gives a scathing indictment of the constraints imposed by the IHR on timely and reliable outbreak information sharing, on WHO’s excessive caution and deference towards member states and the lack of an inspection and verification system. Proposals range from creating a frame for automatic sharing of information to requiring WHO to use a precautionary approach for risk assessment and communication, enabling it to use and publish reliable but unverified information (e.g. from social media reports), and establishing a rebuttable presumption of states’ consent to WHO’s verification missions. The latter proposal is seen as politically motivated and directed against China, which has reportedly already objected to it in early discussions.

20. **Travel and trade restrictions**: COVID-19 response has been and continues to be characterized by a proliferation of uncoordinated, unilateral and at times unnecessary restrictions on international travel, as well as of export of commodities such as masks, ventilators and vaccines. Those restrictions have also been partly responsible for the current disruption of global supply chains for many commodities and consumer products. While the human rights and trade aspects of these measures are dealt with under their respective applicable regimes and institutions, proposals for the pandemic treaty have included the establishment of consultation mechanisms to facilitate coordination and harmonization between states, as well as obligations to allow essential travel and trade even during an acute health emergency. The discussion overlaps with states’ obligations under Article 43 IHR, on avoiding the restriction of international travel and trade to a greater extent than is necessary.

21. **Equitable access to vaccines and other medical countermeasures**: this is the proverbial elephant in the room and can easily become the major stumbling block in the negotiation of a pandemic treaty. From a political perspective, national COVID-19 response in most low and middle-income countries (LMIC) has been gravely affected by the hoarding of vaccines on the part of high-income countries (HIC) and the dominance of vaccine nationalism and corporate profit over solidarity and a truly multilateral approach. Many LMICs have made it clear that they expect credible guarantees of equitable access as a precondition to engage in negotiations, something that most HICs seem reluctant to commit to. From a legal, technical and practical point of view, the sheer complexity of the innovation, manufacturing and allocation chain is staggering and it is delusional to imagine that a single instrument can regulate such a fragmented and complex ecosystem. Proposals for a pandemic treaty therefore tend for the moment to remain general and rhetorical, expressing a political commitment to negotiate more

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25 See Mark Eccleston-Turner and Michelle Rourke, Arguments Against the Inequitable Distribution of Vaccines Using the Access and Benefit Sharing Transaction, 70 ICLQ (2021) 825.
26 Kerry Cullinan & Elaine Ruth Fletcher, China Nixes Proposal to Grant WHO Rapid Access to Outbreak Sites in Critical Talks About Pandemic Response, Health Policy Watch, 10 January 2022, available at https://healthpolicy-watch.news/china-nixes-who-access/.
equitable terms within the framework of a future treaty rather than raising concrete measures. This field is also subject to various forms of international and transnational regulation which are at times subject to active contestation from an equity perspective, thus increasing the overall complexity. Contestations and criticism range from the apparently endless discussion at the WTO on a waiver of intellectual property rights and the call for national enforcement of more balanced conditions on technology transfer and licensing from pharmaceutical companies, to disappointment at the performance of multi-stakeholder platforms such as ACT-A and COVAX. Several proposals address specific failures of the current market mechanism rather than suggesting a particular legal framework; this is the case for example of the IPPPR’s proposal to institutionalize ACT-A into an end-to-end platform for countermeasures, and the African Union’s call for increased regional manufacturing capacities to decrease dependence on the international market.

E. Structural proposals

22. A pandemic treaty would break the cycle of “panic and neglect” that has characterized pandemic preparedness and response, and ensure sustained political commitment at the highest level of national politics. Proponents point to other treaties that have become catalysts for political commitment and mobilization, e.g. the Framework Convention on Climate Change or WHO’s Framework Convention on Tobacco Control (FCTC). The IHR are seen as a technical instrument that mostly falls under the jurisdiction of health agencies and is not “political enough” to remain for long on the radar screen of heads of government and foreign ministers;

23. The pandemic treaty would be designed, prima facie, as a “framework convention”. It would establish an institutional framework ensuring both close involvement of parties in its governance and creating mechanisms for the progressive elaboration of the general obligations contained in the convention through protocols and other instruments. The framework convention approach has curiously become a veritable dogma in the public health community for any proposal of a new treaty since the adoption of the WHO FCTC. The mechanical transposition of a model that may have its rationale in the environmental field to a totally different legal and policy ecosystem, as well as the scarce success so far of the sole protocol adopted under the FCTC, calls for a more critical approach to the design of the treaty;

24. The treaty would provide a single unifying forum for a variety of measures that ultimately revolve around pandemic preparedness and response. It would provide a bridge towards other international agreements as well as a coordinating and collaborating framework for other international agencies, thus ensuring cross-sectoral coherence and mobilization;

25. Many proposals decry the lack of compliance assessment and accountability mechanisms in the IHR and more generally within WHO. This structural gap weakens further the already loose normative frame of the IHR, in particular with regard to core obligations of notification, disclosure, national core capacities and unilateral measures under Article 43 of the Regulations. Compounding this problem, critics also point to the absence of a functioning dispute settlement mechanism under the IHR as well as to the lack of enforcement mechanisms, including the imposition of sanctions for major breaches of core

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30 IPPPR Report (n. 12) 55.
32 IHR Review Committee Report (n. 11) 52.
obligations. Proposals on this issue range from a peer review process inspired by that of the Human Rights Council, to the establishment of a dedicated compliance committee.

F. Criticism and counterarguments

26. Besides comments on specific substantive aspects, the proposal of a new pandemic treaty as articulated above has raised a number of policy and systemic questions that challenge some of the assumptions on which that proposal is based. So far, there has not been to our knowledge an open discussion on these questions in an intergovernmental setting, but they may be raised at the beginning of the work of the INB and complicate its work.

27. A frequent set of questions concern the relationship between a future treaty and the IHR, which are in force for 196 states, given the overlap between some of the proposals listed above and the content of the Regulations. First of all, it seems counterintuitive to state that the weaknesses and limits of the IHR should be remedied through a different instrument rather than revising or strengthening the regulations themselves. Some of the arguments we are aware of point to the “technical” (as opposed to political) nature of the IHR as a weakness, or to the consideration that national leaders would find it difficult to invest considerable political capital in the revision of an existing instrument as opposed to adopting a new treaty. Underpinning these and other opinions there seems to be a belief that a WHO pandemic treaty will be “harder” and more enforceable than a WHO regulation - despite the lack of an in-built hierarchy between the two sources - and that strong and sustained political commitment at the highest level of government can be better expressed and implemented through a treaty. Critics also note that overlaps between two different instruments may lead to conflicts of obligations, confusion and fragmentation of the regulation of specific fact patterns. Further challenges would also be raised by the difference in participation in the two instruments for the foreseeable future, so that different sets of states would be bound by the treaty or the IHR and the resulting disconnect would have to be managed by WHO as the presumable secretariat of a future pandemic treaty.

28. A second set of comments reacts to the claim about the unifying effects of the pandemic treaty and expresses the concern that it would actually increase the fragmentation of the overall international legal landscape devoted directly or indirectly to the prevention and control of a pandemic or the management of its effects. Besides the interactions with the IHR, the proposals reviewed above also overlap or interact with several international treaties or the mandates of international organizations, e.g. environmental and trade law as well as the mandate of the various international organizations with jurisdiction over One Health. For this reason, critics of the treaty proposal advocate a more conservative approach, focusing first on strengthening the IHR and other existing instruments both within and outside WHO, and only later embark on a treaty negotiation if normative gaps have not been addressed through other measures and interventions.

29. A related question is whether WHO is the right forum to negotiate a pandemic treaty. It is evident from the short overview above that several proposals probably exceed WHO’s constitutional mandate and overlap with that of other international organizations. Constitutional questions can be

34 IHR Review Committee Report (n. 11) 53, para. 123.
addressed flexibly and creatively given the required political consensus; moreover, the successful framing of an issue by norm entrepreneurs can create a normative momentum and path dependency that shifts its perception and treatment, as confirmed by the successful framing of tobacco as a health problem rather than trade or agricultural concern. However, focusing only on WHO as the institutional basis of the treaty may raise not only constitutional questions, but also complex aspects of coordination, involvement and possible resistance of other international organizations as well as the lack of resources and expertise within the WHO secretariat to deal with non-health questions. A plausible alternative from a constitutional perspective, raised by some scholars, consists in moving negotiations under the aegis of the UN and having the UN General Assembly as the responsible body for launching and monitoring them and eventually adopt the treaty. However, the health frame has clearly prevailed and the WHA has launched the negotiation process without any opposition from a constitutional and functional perspective. The UN political organs have actually played a weak and marginal role in the response to COVID-19 so far.

G. A middle ground

30. As just noted, already there is significant momentum toward addressing gaps in preparedness, surveillance and response to pandemics through a new instrument negotiated under the auspices of the WHO (and/or by amending the IHR). However, effectively addressing future pandemics will require very substantial commitments of financial resources both for supporting more resilient health systems and for responding to pandemic outbreaks in real time by financing global public goods such as vaccines and other essential countermeasures. Besides funding, pandemic preparedness and response also requires an overarching framework to provide some coherence to pandemic governance as well as coordination among international institutions and regimes beyond health. The WHO does not have the financial resources, nor the expertise in managing large-scale expenditures of funds, that is going to be required. It also arguably does not have the political weight to play the role of central coordinator. (There are other areas, such as for addressing supply chain bottlenecks, regarding which other organizations (e.g., WTO) are better suited.)

31. There are middle-ground solutions for establishing a holistic global framework for pandemic preparedness and response between a limited focus on WHO, on one side, or negotiating a comprehensive agreement under the auspices of the UN, on the other. This would entail establishing a system of coordination and cooperation among relevant institutions, each of which would take on a role and responsibility consistent with its mandate and expertise. Systems for coordination and cooperation already have been proposed, including by the G20 Independent High Level Panel in proposing the establishment of a Global Health Threats Board for systemic financial oversight to ensure enhanced and predictable global financing over a range of activities, with a minimum $15 billion per year in new international financing ($75 billion over 5 years). This system would operate in tandem with a Health Security Assessment Program that would be coordinated by the WHO and World Bank, as well as reporting to and by the IMF. The WHO Independent Panel for Pandemic Preparedness and Response recognized the importance of addressing financial considerations. It proposed at least as an intermediate measure to integrate pandemic preparedness into existing instruments used by the IMF and World Bank, and ultimately an International Pandemic Financing Facility that would be able to distribute $50-200 billion at

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short notice. It suggested establishing a Global Health Threats Council at the Head of State and Government level on a recommendation by, but independent from, the UN General Assembly to allocate funding from the Facility, to monitor progress and further coordination and collective action.\(^{40}\)

32. A more comprehensive institutional approach to addressing pandemic preparedness and response than can realistically be incorporated in a WHO instrument is almost certainly required. The fact that negotiations have been initiated at WHO, and that solutions may be reached there, does not preclude contemporaneous negotiation alongside the WHO that focus on other institutions, such as the IMF, World Bank, other multilateral development banks, WTO, political networks such as the G7 and G20, and others.

**H. Committee Perspectives**

33. The Committee has not endeavored to formulate a consensus position regarding a preferred way forward for improving international institutional arrangements for addressing global public health emergencies. The foregoing discussion, as well as the following discussion of potential reform of the IHR, presents options and arguments favoring or disfavoring one or another approach. The current state of negotiations and the potential for reaching consensus on preferred approaches will be discussed at the Lisbon Biennial. The Committee does not currently contemplate proposing a Resolution(s) for adoption by the ILA at the Lisbon Biennial on the subjects addressed in this Report.

**III. Strengthening the International Health Regulations: Are Amendments the Way Forward?**

**A. Introduction**

34. Being the core international law instrument in the field of cross-border spread of disease, the International Health Regulations (IHR) of 2005 have been at the spotlight in the wake of the COVID-19 pandemic. Questions of whether the IHR (2005) is fit for purpose for facing devastating all-of-society pandemics abound.\(^{41}\) The WHO, on the basis of requests by its Member States, has commissioned a series of independent and external inquiries on the handling of the pandemic by both the organization and the international community at large. Among the multiple recommendations by these independent bodies,\(^{42}\) strengthening the IHR (2005) either by creating more robust implementation and compliance monitoring mechanisms,\(^{43}\) or by launching an amendment process,\(^{44}\) have been posited. In light of these

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\(^{40}\)See, supra … The Global Preparedness Monitoring Board also recognized the importance of UN participation at the Heads of State level in addressing pandemic preparedness and response, and the need for creating more resilient and targeted financial mechanisms. See From Worlds Apart to a World Prepared, GPMB Report, 2021.


\(^{42}\) Notably, the IPPPR Report (n. 12), the IHR Review Committee Report (n. 11), and the Report by the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme (5 May 2021) A74/16, para. 7.

\(^{43}\) IPPPR Report (n. 12) 16; IHR Review Committee Report (n. 11) 10.

developments, the atypical nature of the procedures to both issue and reform Regulations by the WHO merits a closer look.

B. Legal Background

35. In terms of the subject matter they may cover, regulations may be issued only with respect to a specific list of themes envisaged by Article 21 of the Constitution of the WHO. Notably, this does not include matters concerning equitable access to medical countermeasures at the global level, a matter which has been at the forefront of current controversies. During the COVID-19 pandemic, constant calls by high-level officials such as the United Nations Secretary-General, the WHO Director-General and the High Commissioner for Human Rights have highlighted the urgency of that question. Nevertheless, considering the limitative list of Article 21 of the Constitution of the WHO, it is unlikely such a matter can be addressed through amendments to the IHR.

36. As for procedural issues, while they are legally binding instruments of international law, regulations adopted under the Constitution of the WHO are atypical in terms of how they enter into force or are amended. Regulations are adopted and amended through resolutions adopted by the World Health Assembly, requiring a simple majority. Once approved, a period of time will be set for states to express their desire to “opt out” of being bound by regulations. In fact, in past iterations of the IHR (2005), namely in the International Sanitary Regulations of 1951 and in the IHR of 1969, some WHO Member States opted out of them. Unlike Conventions under Article 19 of the Constitution of the WHO, no procedure of subsequent ratification is required for regulations to enter into force, even though a few Member States have deposited their instruments of ratification with the Secretary-General of the United Nations.

37. As for a determined period of notice before their entry into force, no stipulated timeline is established in the Constitution of the WHO. Every Regulation may stipulate different periods for that purpose. Thus, for example, while the IHR (2005) envisage a period of eighteen months for States to express the rejection of the Regulations, or formulating reservations, the Nomenclature Regulations currently in force foresaw only eight months for the same notice.

38. The procedure for amending regulations is foreseen in each of them as well. The IHR (2005) requires an even more compact procedure than its entry into force. Under Article 55, the salient requirement is for the proposed amendments to be circulated across all Member States at least four times, unless a Member State opposes, and without a roll call to tally each vote.

46 Article 21, Constitution of the WHO.
47 Article 60 of the Constitution of the WHO. Nevertheless, under the Rules of Procedure and as a matter of practice, adoption may take place through consensus, ie unless a Member State opposes, and without a roll call to tally each vote.
48 See the list of countries opting out of the IHR 1969 as late as 1997 in WHO, ‘International Health Regulations: Position of WHO Member States, Associate Members and Other States bound by the International Health Regulations’, 45 Weekly Epidemiological Record (7 November 1997) 338
49 https://treaties.un.org/Pages/showDetails.aspx?objid=08000002801d31cc&clang=en
50 Article 59(1) IHR (2005).
months before a meeting of the World Health Assembly takes place. No subsequent formality is established. Moreover, no distinction is made in terms of which parts of the IHR (2005) may be amended. Consequently, major overhauls may be undertaken through the same procedure as minor ones.

39. From a normative perspective, procedures to approve and amend regulations present tradeoffs. On the one hand, the potential to guarantee a successful outcome is higher than with regular procedures to ratify treaties. There are numerous historical examples of international law instruments being approved and signed by plenipotentiaries, which did not see the light of day due to a lack of follow-up procedures by other national bodies.52 Such was the fate of several international health conferences in the XIX Century, where consensus was achieved on several new legal instruments, which never entered into force due to a lack of follow-up by other national organs of the states participating in such conferences.53

40. On the other hand, by removing the ratification procedure, WHO regulations reduce the participation of important stakeholders. In the past, there has been little to no input beyond that provided by delegates to the World Health Assembly or, in the respective case, by working groups tasked with presenting reforms. This is a tradeoff in terms of inclusiveness. Despite the high number of IHR States Parties – all 194 WHO Member States plus the Holy See and Liechtenstein – voices beyond those of governmental delegates were mostly absent in their approval, and fully absent in their amendment. Usually, most of the input by non-state actors, including those from civil society, is provided by those being in “official relations” with the WHO.54 It is a common standard among international organizations, as even with the gradually increasing participation by non-state actors in their decision-making, delegates of different countries continue to be in a dominant position.55 Additionally, NGOs do not necessarily represent any particularly constituency from a country let alone the public at large,56 but may rather further the goals of their own stakeholders. Moreover, the fact that non-state actors are in official relations is no guarantee they will remain active, as it is dependent upon their capacities in terms of resources, and upon their interest in a specific subject matter. Thus, when the IHR (2005) were first approved, only a few NGOs participated in their drafting process57 whereas basically none did so in the only amendment process, as explained below.

41. If approved, new amendments of the IHR (2005) in the wake of the COVID-19 pandemic would mark the second such occasion. The first amendment took place in 2014, and consisted of updating Annex 7 of the IHR, namely on the subject certificates for yellow fever vaccinations as a condition of entry for travelers. Due to this amendment, certificates demonstrating immunization against the disease may now be lifelong instead of only for 10 years as originally established when the IHR (2005) entered into force in 2007. Considering the highly specific and relatively minor implications of the issue, the amendment

52 See, for example, the failure by the United States to ratify the Treaty of Versailles of 1919, creating the League of Nations; as well as the Havana Charter of 1948, effectively preventing the creation of the International Trade Organization. See also Pedro A Villarreal, ‘Beware of Procedural Perils. Towards a Treaty on Pandemic Preparedness and Response’, Völkerrechtsblog (14 April 2021) https://voelkerrechtsblog.org/beware-of-procedural-perils/
54 See the current list at https://www.who.int/publications/m/item/non-state-actors-in-official-relations-with-who
procedure was low-profile and was not the subject of protracted debates at the World Health Assembly. Moreover, the matter received basically no attention by commentators or media outlets.

C. The political path towards amending the IHR (2005) after COVID-19

42. A series of decisions and resolutions approved by the World Health Assembly have focused on potential means to strengthen the International Health Regulations (IHR) of 2005. Since the resolution of 2020 entitled “COVID-19 response”, and more recently in the decision adopted at the World Health Assembly Special Session in November 2021, the possibility to amend the IHR (2005) has been suggested as a potential way forward.

43. Nevertheless, the political momentum for amendments has not been linear. A report issued by an IHR Review Committee, an expert WHO body composed of independent members, considered that there was no visible advantage in opening the amendment process. Such a plea evokes similar recommendations by past IHR Review Committee Reports, namely one commissioned in the context of the West African Ebola crisis of 2014-2016 where amending the IHR (2005) was deemed to be “cumbersome”. Nevertheless, Reports by IHR Review Committees are recommendatory in nature, and do not bind either the WHO Director-General – with the authority to summon such Committees nor the Member States. Thus, the World Health Assembly may choose to take a different path than the one recommended. Considering the contents of recent decisions and resolutions, the political momentum to amend the IHR is alive. Thus, recently, a number of WHO Member States have expressed their willingness to open the amendment process.

44. Gathering the necessary consensus at the World Health Assembly for in-depth amendments to the IHR will likely require lengthy negotiations to accommodate potentially diverging interests. Whereas multiple states from the “Global North” have emphasized the need to enhance security and data-sharing, a large number of states from the “Global South” underscore tackling the absent equity and solidarity during the COVID-19 pandemic response as a contentious point for debate and a bargaining chip with regard to the parallel work on a future pandemic treaty.

D. Substantive Questions of IHR (2005) Amendments

45. Among the topics subjected for debate, the following can be highlighted:

46. Clarifying notification obligations. The contentious issue of whether the Chinese government promptly notified the WHO when the SARS-CoV-2 virus was first detected has led to debates amongst Member States on whether and how to revise the current wording of Article 6 IHR. The provision affirms that states “shall assess events” occurring in their territory that may constitute a PHEIC and notify the WHO within 24 hours of making such an assessment. In terms of how quickly national authorities should “assess” an event that may constitute a PHEIC, currently no mandatory period is foreseen. A proposal by

58 World Health Assembly, Resolution WHA73.1, 19 May 2020.
61 Article 48 IHR (2005).
the United States of America seeks to clarify this by specifying the obligation to assess ongoing events within 48 hours upon the reception of information by the National Focal Points designated under Article 4 IHR. Thus, the obligation would entail that authorities designated as NFPS should be responsible for assessing an event and determine whether it must notify it to the WHO on the basis of Annex 2 IHR. The remaining piece of such a puzzle lies on the timeframe for notification by first-responding health authorities, i.e. those that first identify the event, to said NFPS. This depends on whether domestic laws on disease surveillance envisage a mandatory timeframe for notification to designated authorities.

47. Creating an intermediate level of alert. The possibility to create a different category of emergency declarations by the WHO Director-General has been put forward. The existing definition of a public health emergency of international concern reflects a binary nature: either there is an emergency, or there isn’t. Past expert panels and IHR Review Committee reports have criticized this as reductionist. Moreover, emergency declarations by the WHO Director-General have been seen as having reputational consequences for Member States affected by the corresponding event. An intermediate level of alert is considered by some to be an alternative for addressing the potentially negative connotations of being affected by an emergency, including the fear of disproportionate responses by other states in terms of travel and trade restrictions. The intermediate alert would, theoretically, signal the need for a progressive preparation in case a situation evolves into a full-blown emergency. It would thus be more than taking note of the urgency of a health, as it occurred after the first meeting of the Emergency Committee due to the then-emerging coronavirus on 23 January 2020. Nevertheless, some commentators are critical of a multi-tiered approach towards emergency declarations, as among other things it multiplies categories potentially leading to a confusion, leaving the thresholds for, and the consequences of each level even less clear.

48. Strengthening compliance monitoring and promotion. The haphazard implementation of the IHR (2005)’s obligations before and during the COVID-19 pandemic has led to contesting its overall effectiveness in fulfilling its twin goals of preventing, protecting against and responding to the cross-border spread of disease, on the one hand, while avoiding unnecessary restrictions on international travel and trade, on the other hand. Non-compliance has been reported ever since the first public health emergency of international concern, the H1N1 influenza pandemic in 2009, was declared. States fail to both promptly notify events to the WHO under Article 6 IHR, as well as to refrain from imposing

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66 For instance, when issuing the declaration of a PHEIC due to the spread of SARS-CoV-2, the WHO Director-General clarified that it “should be seen in the spirit of support and appreciation for China, its people, and the actions China has taken on the front lines of this outbreak, with transparency, and, it is to be hoped, with success”, while not recommending any travel or trade restrictions against the country. See WHO, Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus Declaration of 30 January 2020, https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)
67 On the fear of disproportionate responses by states to emergency declarations, see Benjamin Mason Meier et al, ‘Travel restrictions amid COVID-19; revising global health law to reflect public health evidence’, Bulletin of the WHO (forthcoming, February 2022).
68 IHR Review Committee Report (n 11) 38.
Tackling the disincentives of disproportionate travel and trade restrictions. Under Article 43 IHR (2005), States must refrain from imposing restrictions on international travel and trade which are “more restrictive than necessary” to provide the “adequate” level of protection to health. When deciding whether to impose these restrictions or not, states should pay heed to the WHO’s recommendations on the matter. In case they do not follow such recommendations, states must notify the fact and offer a public health rationale for doing so. Nevertheless, events during the COVID-19 pandemic have displayed how states’ fear of being subjected to travel and trade restrictions is not ill-founded. In November 2021, the government of South Africa notified the WHO of the presence of a new “variant of concern” of the SARS-CoV-2 virus. This was in conformity with the second paragraph of Article 6 IHR (2005), which requires states to remain in constant communication with the WHO on new developments related to public health emergencies of international concern. Yet a number of states reacted to South Africa’s reporting of the Omicron variant by immediately subjecting it, as well as other neighbouring countries, to blanket travel bans. These reactions undermine, in the short and longer term, states’ willingness to come forward with notifications of either new events that may constitute public health emergencies of international concern, or evolving circumstances related thereto. In terms of travel and trade restrictions as provided for in Article 43 IHR (2005), the current wording is quite open. Although the provision mandates Member States to take into consideration the WHO’s temporary recommendations issued when declaring a PHEIC, states may choose to impose more restrictive measures they deem to offer a higher level of health protection, provided they notify the WHO and justify their decision under scientific principles. Reforming Article 43 will depend on to what extent there is a political will by WHO Member States to yield the sovereign right to impose those restrictions when individual states consider it to be necessary.

E. Fostering inclusiveness in the IHR amendment process

From a substantive perspective, the sensitive nature of the issues addressed in the current debates on IHR amendment are not comparable to the previous one on Annex 7. The range of potential reforms likely requires a more inclusive process of discussion, taking into account input from multiple Member States and from other international organizations and bodies, like the World Trade Organization, the International Civil Aviation Organization, the International Organization for Migration, the United Nations Office of the High Commissioner for Human Rights, the World Bank, to name but a few. Furthermore, a more thorough amendment process of the IHR (2005) would be joined by gathering input from other stakeholders besides the ones previously listed. For instance, the scientific community could offer substantive insights on what the most accurate way to frame scientific principles for the purposes of Article 43 IHR (2005) could be. Civil society organizations, in turn, may put forward ideas on how to properly ensure rights of travelers in the IHR (2005), as enshrined in its Article 3(1). Considering the short duration of the required anticipation between submitting an amendment proposal and discussing it at

70 IHR Review Committee Report (n 11) 53.
the World Health Assembly, a more robust discussion and collection of different views would ideally be undertaken before the entire procedure is formally launched.

IV. Pathogens and data sharing, and equitable access to benefits

A. Translating equity into reality

51. The attainment of the highest attainable standard of physical and mental health, as a human right, a collective public interest, and a requirement for ensuring better living conditions, requires that investments in preparedness and prevention are made “for all” under the perspective of the UN agenda for “universal health coverage” (UHC). This means all people should have effective access to the healthcare services, essential drugs, and vaccines they need, without financial hardship. Yet, States have failed to reach this goal.

52. In the specific context of the COVID-19 pandemic, while several countries are advocating for the recognition of vaccines as “global public goods”, so far these vaccines have remained private goods whose distribution and access are mostly driven by market forces. The COVID-19 Technology Access Pool (C-TAP) launched from the WHO in May 2020 to “facilitate timely, equitable and affordable access of COVID-19 health products by boosting their supply [through the] sharing [of] intellectual property and know-how” encountered low voluntary adherence by companies and developers. The COVAX initiative has also been unable to be a real game changer. Despite the WHO Director General calling for a “moratorium” regarding booster doses of vaccines until the end of 2021 and warning against blanket boosters, some States are rolling out blanket booster programs covering people who are not at risk of serious symptoms, while in other countries some people willing to be vaccinated because they are at risk have no access to such vaccines. This situation confirms an overall lack of equity in access to pharmaceutical products.

53. Yet, the need for equity, as a principle that connects with the right to health, has been largely acknowledged by States and international actors lately. One year before the COVID-19 pandemic, the Council of the European Union recalled that it endorses “the principles and overarching values of universality, access to quality care, equity and solidarity, which are of paramount importance to ensure equity of access to vaccination services regardless of age, social status, or geographical location”. On January 2021, the Parliamentary Assembly of the Council of Europe urged Member States and the European Union to “ensure respect for the principle of equitable access to healthcare, as laid down in

71 Paragraphs 49-58 were contributed by Pia Acconi and Helene de Pooter.
74 https://www.who.int/initiatives/covid-19-technology-access-pool
75 WHO Director-General’s opening remarks at the media briefing on COVID-19, 8 September 2021.
76 WHO Director-General’s opening remarks at the media briefing on COVID-19, 22 December 2021.
Article 3 of the Oviedo Convention, in national vaccine allocation plans, guaranteeing that Covid-19 vaccines are available to the population regardless of gender, race, religion, legal or socio-economic status, ability to pay, location and other factors that often contribute to inequities within the population”.

During the World Health Summit in October 2021, the president of the European Council declared that a new international pandemic treaty “would guarantee equity”. Equity is also mentioned not less than ten times in the “Zero Draft” released on 28 October 2021 by the Intergovernmental Working Group in charge of assessing the benefits of developing a new international instrument regarding pandemics. Members of the Working Group have agreed that equity is “a priority area” which is “at the core of the breakdown of the current system and is ideally suited for negotiation under the umbrella of a potential new instrument”. Overall, observers have witnessed equitable access to medical countermeasures rising like “a deal-breaker” in the current process to draft and negotiate a new instrument to strengthen pandemic prevention, preparedness and response. Thus, although equity is a concept yet to be fully recognized as a principle in International Health Law, it is being largely called for as a core requirement, especially by States, at the point where we might witness the outset of an emerging principle.

Therefore, it seems timely to think about “equity” as a concept different from equality and charity, that could irrigate International or Global Health Law through concrete legal norms and contribute to the emergence of a core principle of this body of law. The current circumstances are likely to foster such an objective, which can also benefit from a precedent: the Pandemic Influenza Preparedness (PIP) Framework for the sharing of influenza viruses and access to vaccines and other benefits. This little-known legal instrument was adopted in 2011 by the World Health Assembly as WHO Constitution Article 23 recommendation. It offers a concrete example of equity being translated into concrete norms. As indicated by its name, the PIP Framework relies on two pillars. The first pillar is the global sharing of influenza viruses with human pandemic potential, among the laboratories belonging to the Global Influenza Surveillance and Response System (GISRS). These laboratories collect and share samples to analyze them and ultimately identify which influenza virus will be responsible for the next human influenza pandemic. This virus will serve as the virus of reference to develop and manufacture test kits, diagnostic reagents, medical devices, vaccines, adjuvants, antivirals and other medical countermeasures (the “benefits”) necessary to protect people from this pandemic. Laboratories belonging to the GISRS are

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80 WHO doc. A/WPR/43.
81 WHO doc. A/WGPR/43, § 18 (c) and § 22 (b).
82 This expression was used by Gian Luca Burci during the International Law Weekend, “Reinvesting in International Law”, 99th Annual Meeting of the American Branch of the International Law Association (ILA), via Zoom, 29 October 2021 (https://www.youtube.com/watch?v=HV6c8UHBktw).
83 Some authors consider that equity has already been recognized as a general principle in other fields of international. See Nico Schrijver, The Evolution of Sustainable Development in International Law: Inception, Meaning and Status, Pocketbooks of The Hague Academy of International Law, 2008, p. 232: “the principle of equity is a ‘general principle of international law’ in the field of international law relating to sustainable development”.
85 PIP Framework, Section 2.
bound by agreed WHO terms of reference and their activities are regulated through “material transfer agreements” limiting their capacity to obtain intellectual property rights.

55. The second pillar of the PIP Framework is the access to vaccines and the sharing of other “benefits”. The goal of the PIP Framework is to make sure that these benefits are shared in an equitable manner. In principles 8 and 9 introducing the PIP Framework, States “recognize that the benefits […] should be shared with all Member States based on public health risk and need” as well as “the need for a fair, transparent, equitable and efficient framework […] for the sharing of benefits, including access to and distribution of affordable diagnostics and treatments, including vaccines, to those in need, especially in developing countries, in a timely manner”.

Further on, the PIP Framework provides that:

“[t]he PIP Benefit Sharing System will operate to […] prioritize important benefits, such as and including antiviral medicines and vaccines against H5N1 and other influenza viruses with human pandemic potential as high priorities, to developing countries, particularly affected countries, according to public health risk and needs and particularly where those countries do not have their own capacity to produce or access influenza vaccines, diagnostics and pharmaceuticals. Prioritization will be based on assessment of public health risk and need, by experts with transparent guidelines”.

56. Thus the PIP Framework is rich of provisions translating equity into concrete legal guidance and criteria such as “public health risk and need”, “those in need”, “affordability”, “developing countries”, “particularly affected countries”, “countries that do not have their own capacity to produce or access”, “transparent guidelines”, principles that are also recognized under the right to health. While the PIP Framework only applies to influenza viruses with human pandemic potential, these criteria seem particularly relevant from a public health perspective generally, whatever the virus responsible for the pandemic is. Yet these criteria have been largely put aside during the COVID-19 pandemic, at the national and international levels. This appears to be one of the major misguided ways of the global strategy to fight this pandemic. One of the priorities of the future WHO instrument should be to recognize the importance of equity as a principle of International Health Law, to operationalize this principle through guidance and criteria which are relevant from a global public health perspective and to make sure these criteria are respected in times of pandemic.

57. In addition to translating equity into concrete legal criteria, one of the great achievements of the PIP Framework is to involve private businesses in the realization of equity, in two major ways. First, if an entity outside the Global Influenza Surveillance and Response System (GISRS) – especially the pharmaceutical industries – wants to have access to the “PIP biological material” shared inside the GISRS to launch the manufacturing of “benefits”, this access will be possible provided this entity has previously concluded a legally binding contract with WHO whereby the former agrees to contribute to the fair and equitable access to these benefits. This contribution can take various forms like a donation of vaccines or antivirals to WHO or voluntary licenses to developing country manufacturers.

Secondly, the PIP Framework imposes on external entities benefiting from the GISRS to pay the “annual partnership

87 PIP Framework, Section 1 (8) and (9).
88 PIP Framework, Section 6.0.2 (iii).
89 E.g. General Comment 14 to Article 12 ICESCR, para 12.
90 PIP Framework, Section 5.4.2 and Annex 2.
contribution” which is partly used to help countries improving their national capacities as required by the International Health Regulations (IHR) (2005).

58. Therefore, equity as conceived by the PIP Framework is not only translated into inter-States commitments. It directly involves the private pharmaceutical businesses themselves, whose considerable profits increase during the COVID-19 pandemic, partly based on public funding, should drive them to contribute to the global financial effort bear by States and citizens. While “corporate social responsibility” has mostly been formulated as a negative obligation so far (business enterprises should not violate (‘respect’) human rights), Principle 1 of the UN Global Compact also provides that “businesses should support […] the protection of internationally proclaimed human rights”, which calls for a positive contribution to the respect of human rights, especially the right to health. This positive contribution from the private sector could be an essential remedy to the global shortage of health professionals, health facilities, medicines, personal protective equipment, ventilators, and other essential medical devices for intensive care units, that was confirmed during the first wave of the pandemic in Spring 2020. States should encourage this “positive dimension” of corporate social responsibility and make sure that pharmaceutical companies and other manufacturing enterprises activities are based on a mutual satisfactory balance between “universal health coverage” – in terms of equal access to healthcare, as an essential component of the right to health – and revenue-expectations. By supporting the positive dimension of corporate social responsibility, States will enhance their own credibility, in terms of reliability and commitment to universal health coverage for health protection. States that would make such a political effort would also contribute to setting international standards and benchmarks for corporate conduct worldwide.

59. In many ways could the PIP Framework serve as a model for a global mechanism on pathogen sharing and equitable access to medical countermeasures. This global mechanism should escape the logic of the Nagoya Protocol, which relies on the prior consent rule and on bilateral agreements for the access to benefits. Public health considerations require that access to pathogen samples be rapid and systematic (which is not compatible with the negotiation of ad hoc bilateral agreements on a case-by-case basis, as provided by the Nagoya Protocol) and that equitable sharing of benefits be based on risk and public health needs. Applying the Nagoya Protocol to pathogens threatening the human life appears contrary to the ultimate objective of this treaty, which is the conservation of biological diversity. As the deliberate eradication of the smallpox virus has shown, public health considerations sometimes prevail over the conservation of biological diversity and require measures that fall outside the scope of the Nagoya Protocol.

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91 PIP Framework, Section 6.14.3.
92 This recalls the French theory of “enrichissement sans cause” (unjust enrichment), which relies on the principle of equity “which prohibits enrichment to the detriment of others” (Cass. req., judgment of 15 June 1892, Boudier).
93 See the 2011 OECD Guidelines for Multinational Enterprises (especially Guideline IV) and the 2011 UN Guiding Principles on Business and Human Rights implementing the UN ‘Protect, Respect and Remedy’ Framework (especially Principles 2-3, 5 and 8-24).
94 Nagoya Protocol, art. 5, § 1, and art. 6, § 1.
96 Nagoya Protocol, art. 1: “The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components” (emphasis added).
Protocol. The Nagoya Protocol itself recognizes “the importance of ensuring access to human pathogens for public health preparedness and response purposes”\(^{97}\). Further on, Article 8 (b) obliges parties to:

“Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including to affordable treatments by those in need, especially in developing countries”.

60. Thus there is no legal impediment to the establishment a global mechanism on pathogen sharing and equitable access to medical countermeasures parallel to the Nagoya Protocol. To be up to date with current challenges and practices, such a global mechanism should not be limited to influenza viruses and should take into consideration the development of viral synthesis from genetic sequences data. This latter practice should lead to the regulation of the use of databases such as GISAID or Genbank. Currently, while GISRS laboratories must “submit genetic sequences data to GISAID and Genbank or similar databases in a timely manner […]”\(^{98}\), access to these platforms by entities outside the GISRS is not regulated by the legally binding contracts concluded with WHO. This increasingly appears as a ‘legal vacuum’ threatening the objective of an instrument such as the PIP Framework. As such, this vacuum should be addressed by a future international legal instrument.

B. Confronting the reality of achieving equity – reflecting on the PIP Framework negotiations\(^{99}\)

61. Assuming the concept of equity is agreed as a baseline for negotiating a new arrangement for the sharing of pathogens with pandemic potential, and related genetic sequence data, WHO members must still address the financial and technical realities of achieving that objective. It is well to recall that the negotiations leading to the PIP Framework were initiated following a decision by the government of Indonesia in 2007 to withhold sharing of biological samples (including H5N1 virus) precisely because of what it regarded as inequitable treatment under the then-existing global health framework.\(^{100}\) Indonesia observed that the samples it provided would be used by originator pharmaceutical companies to create and patent new therapeutics and vaccines, and to sell these at prices that the government of Indonesia would be unable to afford. In its view, this was an inequitable result. At the time of Indonesia’s announcement, WHO officials first asserted that biological samples are part of the public domain and Indonesia should make them freely available.\(^{101}\) However, WHO officials were confronted with the international legal framework establishing sovereign rights over natural resources, including biological materials, within the territory of a country. This framework was in part codified by the Convention on Biological Diversity (subsequently followed by the Nagoya Protocol). Debate ensued regarding whether the CBD was intended to cover pathogenic viruses, how its terms might be interpreted or reinterpreted, and so on.\(^{102}\) Moreover, it is not only the CBD and Nagoya upon which sovereign jurisdiction over genetic resources is based, but also under general principles of international law. Of course, there may be

\(^{97}\) Nagoya Protocol, preamble.


\(^{99}\) Paragraphs 59-60 were contributed by Frederick Abbott.


\(^{101}\) Id., pg. 5 (& note 22).

\(^{102}\) See generally, F. Abbott, supra note 90.
good policy arguments in favor of treating pathogenic materials and genetic information as “global public goods”, but it is also worth pointing out that despite initial proclamations by some governments that technology relevant to producing COVID-19 vaccines would be treated by them as global public goods, these proclamations largely failed to manifest themselves in practice.

62. Addressing the broadened sharing of biological materials with pathogenic potential and related data will need to address the legitimate demands of more than one group. The problem that underlay Indonesia’s refusal to provide biological samples in 2007 was that it foresaw an inequitable consequence of sharing, i.e., providing benefits to pharmaceutical companies that in turn prioritized and supplied higher income countries in return. One of the principal demands of LMICs in the PIP negotiations was for mandatory transfer of technology to establish capacity in those LMICs to manufacture and distribute therapeutics and vaccines. The pharmaceutical industry pushed back, and the result was a compromise that allowed the industry to provide some vaccines to a stockpile administered by WHO, or to voluntarily transfer technology. There has been no reported voluntary private sector transfer of technology under the PIP Framework. One could argue that LMICs during the COVID-19 pandemic have been subject to the very type of access inequity that Indonesia objected to in a previous go-around leading to the PIP Framework. As WHO experience with C-TAP has illustrated, reliance on voluntary contributions from industry to create equitable access to “medical countermeasures” is not a robust approach. This is one challenge of any forthcoming negotiations regarding pathogen-sharing.

V. Public health, climate change and international law: the right to health argument

A. Introduction

63. Climate change is considered potentially the greatest threat to global health in the 21st century due to its direct and indirect adverse impacts on human health and its environmental determinants.\(^\text{103}\)

64. The public health community has rapidly increased its engagement on climate change and health in recent years, providing better understanding of the links between the two, raising awareness of the significant health threats, offering solutions to avoid the worst impacts and assessing the health benefits of climate actions, including the degree to which these will offset the costs of mitigation. This work now involves a large community of organizations, including United Nations agencies, academia, all levels of government and nongovernmental organizations, which are working together to meet the commitments made by governments under the United Nations Framework Convention on Climate Change (UNFCCC)\(^\text{104}\) and the 2015 Paris Agreement.\(^\text{105}\)

65. Synergies between international regimes regulating climate change and human rights protection can provide the appropriate legal tools to hold States responsible for their contribution to climate change, notably in terms of failure to adopt effective and ambitious measures of mitigation and adaptation capable of preventing climate-induced health risks. In this respect, recent trends in international practice suggest that the right to health argument has the potential to play a pivotal role in climate litigation before

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\(^\text{105}\) Paris Agreement, Paris, 12 December 2015.
international courts and human rights bodies, who are increasingly called to adjudge complaints filed by youth and elder petitioners fighting for global climate change action. [Relying heavily on the work by Negri,] this section will discuss the nexus between public health, climate change, international law and human rights.

**B. Climate change and public health: the facts**

66. The World Health Organization (WHO) reports that preventable environmental risk factors are responsible for over 13 million premature deaths every year, amounting to about one quarter of the global burden of disease. Some of these risks, especially air pollution and stratospheric ozone depletion, also contribute to climate change.  

67. Both the Intergovernmental Panel on Climate Change (IPCC) and the WHO have warned that mounting evidence shows that climate change is exacerbating existing health threats while creating new public health challenges. In fact, on the one hand, climate change and global warming are affecting the environmental determinants of health (notably clean air, safe drinking water, sufficient and safe food and secure shelter), while, on the other hand, extreme heat, increased occurrence of infectious diseases and climate-induced natural disasters are contributing to multiply deaths from cardiovascular and respiratory diseases, communicable diseases, drowning and other serious physical injuries. In practice, climate change increases morbidity and mortality by multiplying a broad range of risks that are going to affect human society worldwide in an unprecedented and unpredictable manner, with long-term devastating implications for health and well-being, livelihoods, security and the enjoyment of fundamental human rights.

68. In consideration of possible direct and indirect repercussions on health, the WHO has estimated that climate change is expected to cause approximately 250,000 additional premature deaths per year between 2030 and 2050, with a disproportionate burden on vulnerable and disadvantaged populations and groups, including women, children, ethnic minorities, poor communities, migrants or displaced persons, older populations, and those with underlying health conditions. In addition, the Report *Lancet Countdown*...
(2021) shows that the health impact of the climate crisis is accelerating across 43 composite indicators, affecting people’s livelihood in all regions of the world. According to the United Nations Special Rapporteur on the right to health, “[t]he failure of the international community to take the health impact of global warming seriously will endanger the lives of millions of people across the world”.

C. Climate change and the interaction between international standards

69. The link between climate change, human rights and health is not apparent in climate change treaties. The UNFCCC does not mention the right to health as such, but it does consider public health as a priority. In this respect, it is worth noting that articles 1, 3 and 4 weigh the public health impacts of climate change while delineating the relevant State obligations. Article 1 defines the “adverse effects of climate change” as the “changes in the physical environment or biota resulting from climate change which have significant deleterious effects … on human health”; article 3, para. 3 requires the Parties to “take precautionary measures to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects” (including on human health); article 4 calls upon the Parties to “take precautionary measures to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects” (including on human health); article 4 calls upon the Parties to minimize the public health impact of the mitigation and adaptation projects or measures they undertake. This notwithstanding, the Paris Agreement is seen by many as the real breakthrough in international law and the WHO COP24 Special Report on climate change and health refers to this treaty as “potentially the strongest health agreement of this century”. The reason for this lies primarily in the wording of the Preamble to the Agreement – urging the Parties “when taking action to address climate change, [to] respect, promote and consider their respective obligations on human rights, the right to health […]” – which was largely considered by those participating in its negotiations as a major step towards the legal recognition of a link between climate change and the enjoyment of human rights, first and foremost the right to health.

70. The relationship between climate variations, global warming and individual rights is a widely debated subject in legal scholarship and the object of special attention within international institutions like the UN Programme on the Environment.

71. This relationship has also been discussed for more than a decade at the United Nations Office of the High Commissioner for Human Rights (OHCHR) and the fundamentals of the topic have been condensed in a 2021 Fact Sheet on Human Rights and Climate Change.

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72. In 2009, the OHCHR drafted the first ever report on the relationship between climate change and human rights.\textsuperscript{117} Building on the views of States, international organisations, NGOs and other stakeholders, the report outlined the main aspects of this relationship and set the scene for a human rights-based approach to climate change. It highlighted the potential direct and indirect implications of global warming for the effective enjoyment of a wide range of internationally recognised human rights – including the right to life, health, adequate food, adequate housing, safe drinking water and sanitation – while exploring the way climate change was projected to impinge on each of these rights. With specific regard to the right to health, the report noted that increased malnutrition, infectious diseases and extreme weather events were going to affect the health status of millions of people and to pose a severe additional stress to health systems worldwide. It stated that “protecting the right to health in the face of climate change [calls for] comprehensive measures, including mitigating the adverse impacts of global warming on underlying determinants of health and giving priority to protecting vulnerable individuals and communities”.\textsuperscript{118}

73. In more general terms, the report reached the following major conclusions: first, climate change adversely affects several human rights but its impact does not necessarily constitute a violation thereto; second, human rights law places duties on states concerning climate change, including an obligation of international cooperation; third, these legal obligations extend extraterritorially.\textsuperscript{119} Most notably, the report clarified that it is practically impossible to frame in precise legal terms the effects of climate change as human rights violations, attributable to a particular country on the basis of a clear causal link between its greenhouse gas emissions and climate-related harm. This notwithstanding, the report stressed that international human rights law imposes obligations aimed at providing legal protection to the individuals whose rights are affected by measures taken by States to respond to climate change.

74. UN Human Rights Treaty Bodies have further expanded on the intrinsic relationship between climate change and the right to health. In September 2019, ahead of the UN Climate Action Summit, five human rights treaty bodies (the Committee on the Elimination of Discrimination against Women, the Committee on Economic, Social and Cultural Rights, the Committee on the Protection of the Rights of All Migrant Workers and Members of Their Families, the Committee on the Rights of the Child and the Committee on the Rights of Persons with Disabilities) issued a Joint statement on human rights and climate change, calling on states to comply with their human rights obligations, including the ones on the right to health, when fulfilling their climate commitments.\textsuperscript{120} The position taken by these Committees was significant inasmuch as – as emphasized by the Committee on Economic, Social and Cultural Rights (CESCR) in its 2018 statement on climate change and the International Covenant on Economic, Social and Cultural Rights – human rights mechanisms have an essential role to play in ensuring that States avoid taking measures that could accelerate climate change, and that they dedicate the maximum


\textsuperscript{118} OHCHR Report, para. 34.

\textsuperscript{119} See discussion by Knox (n. 13), pp. 484 et seq.

available resources to the adoption of measures aimed at mitigating climate change. These five UN Committees have stressed that under the Conventions they monitor States Parties have obligations, including extraterritorial obligations, to respect, protect and fulfil all human rights of all peoples. They have clarified that “[f]ailure to take measures to prevent foreseeable harm to human rights caused by climate change, or to regulate activities contributing to such harm, could constitute a violation of States’ human rights obligations. In order for States to comply with their human rights obligations and to realize the objectives of the Paris Agreement, they must adopt and implement policies aimed at reducing emissions. These policies must reflect the highest possible ambition, foster climate resilience and ensure that public and private investments are consistent with a pathway towards low carbon emissions and climate resilient development.”

1. Substantive Obligations

75. As articulated by UN Committees, substantive human rights obligations build on the well-known tripartite typology of obligations to “respect, protect and fulfil” human rights.

76. These obligations apply extraterritorially inasmuch as States have to both refrain themselves and prevent third parties under their control from interfering with the enjoyment of human rights in other countries. Moreover, States have to take steps through international cooperation and assistance to facilitate fulfilment of human rights, including the right to health. In this respect, the OHCHR report emphasised that “international cooperation is not merely a matter of the obligations of a State towards other States, but also of the obligations towards individuals”.

77. In endorsing the OHCHR report, the HRC stated that “human rights obligations and commitments have the potential to inform and strengthen international and national policymaking in the area of climate change, promoting policy coherence, legitimacy and sustainable outcomes”. Since then, the HRC has repeatedly stressed the importance of a rights-based approach to tackle the global climate emergency and its severe consequences on human rights.

78. With specific regard to the right to health, in 2016 the OHCHR delivered an analytical study discussing the relevant obligations and responsibilities of States and other actors, as well as the elements and benefits of a rights-based approach to addressing the effects of climate change on human health. This study reaffirmed that “human rights obligations, standards and principles have the power to shape policies for climate change mitigation and adaptation and hold countries accountable for implementation

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122 Joint Statement on “Human Rights and Climate Change” (n. 19), paras. 10-11.


124 OHCHR Report, para. 87.


of climate commitments”. Along these lines, it delineated the obligations of States to limit emissions of greenhouse gases in order to mitigate the negative human rights impacts of climate change and, subsidiarily, to ensure appropriate adaptation measures to protect and fulfil the rights of all persons, particularly the most endangered ones. The study also added that human rights norms and principles, including the rights to participation and information, transparency, accountability, equity and non-discrimination, should guide and inform global efforts against climate change impacts on human health. It concluded that protecting the right to health from climate change requires mitigation and adaptation measures that are rights-based, effective and participatory across the whole law- and policy-making, monitoring and implementation cycle. The study finally recommended targeted measures to prioritise health protection and capitalise on climate and health co-benefits in investments, resource mobilization, cooperation and development.

79. In addressing the impact of climate change from a human rights perspective, both OHCHR reports emphasised how human rights principles and standards complement climate change law through synergic integration of legal obligations. They considered that States that have ratified international legal instruments relating to climate change and human rights treaties are bound to implement them at national level by measures aimed at preventing and remediying the adverse effects climate change on the right to health, including with regard to the environmental and social determinants of health. These findings have been largely confirmed by Human Rights Treaty Bodies in their General Comments and by the above-mentioned Joint Statement of 2019.

80. In conclusion, despite the above-noted impossibility to frame the overall effects of climate change as human rights violations attributable to individual States, human rights bodies have established a strong normative and political basis for integrating human rights, including the right to health, in climate action. In this sense, human rights standards require action to prevent to the greatest extent possible the foreseeable negative impacts of climate change on human health and to ensure transparency, accountability, equity and non-discrimination in the context of climate actions. Failure to take urgent action to protect the most vulnerable from the negative health impacts of climate change breaches State (negative and positive) human rights obligations and threatens the enjoyment of the right to health for all.

2. Procedural Obligations

81. Procedural obligations in the context of climate change action are epitomised by the duty of State authorities to guarantee the rights to information, participation in decision-making and access to justice. The enjoyment of the corresponding procedural rights can play a key role in affording protection and remedies to the victims of climate change, especially through climate justice and the possibility to advance rights-based claims founded on the right to health. This means that those individuals whose health is adversely affected by climate change and global warming should have access to appropriate

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128 Ibid., para. 31.
129 See e.g., CRC, General Comment No. 15 on the right of the child to the enjoyment of the highest attainable standard of health (art. 24), U.N. Doc. CRC/C/GC/15, 17 April 2013, para. 50; HRC, General Comment No. 36 on article 6 of the International Covenant on Civil and Political Rights, on the right to life, U.N. Doc. CCPR/C/GC/36, 30 October 2018, para. 62.
130 Article 7 of the Paris Agreement emphasises that adaptation “should be country-driven, gender-responsive, participatory and full transparent, taking into consideration vulnerable groups and communities with a view to integrating into relevant socio-economic and environmental policies”.
remedies – including judicial and other redress mechanisms – to hold States accountable for climate-related harm stemming from inadequate or absent national measures of mitigation and adaptation, including failure to adequately regulate the emissions of businesses under their jurisdiction.

82. In this respect, the first OHCHR report affirmed that “[t]he human rights framework also stresses the importance of accountability mechanisms in the implementation of measures and policies in the area of climate change and requires access to administrative and judicial remedies in cases of human rights violations”. It thus concluded that legal protection is crucial “as a safeguard against climate change-related risks and infringements of human rights resulting from policies and measures taken at the national level to address climate change”. According to the report, access to justice remains a critical human rights concern and obligation under international law.

83. The approach adopted by the OHCHR has thrown additional light on the relevance of procedural rights – as enshrined in key human rights treaties as well as in the Aarhus Convention and the Escazú Agreement – and their potential for a more effective protection of human rights from environmental harm, including harm related to climate change. Indeed, as recent national and international case law testifies, access to climate justice can represent a powerful tool to enhance the protection of the right to health against the adverse impacts of climate change.

D. Climate litigation and the right to health

84. Recent trends in climate litigation show that the right to health is one of the major legal arguments – along with the rights to life and to a healthy environment, and intergenerational equity – advanced by victims of climate change to support rights-based claims brought against States for lack of effective or appropriate measures of prevention and precaution. At the global level, the number of judicial cases on climate change issues has more than doubled since 2015. Courts around the world are increasingly filling the gap left by politicians who are failing to address climate change related health issues and to protect human rights of present and future generations. In the above-mentioned 2018 statement on climate change and human rights, the CESCR welcomed the fact that national judiciary and human rights institutions are increasingly engaged in ensuring that States comply with their duties under existing human rights instruments to combat climate change.

85. Notably, the right to health argument has largely been used before domestic courts to sue governments for their inadequate consideration and lack of sufficient action to address climate change-related risks. One of the most emblematic examples is offered by the landmark case of Urgenda.

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132 OHCHR Report, paras. 83, 96, respectively.
133 Ibid., paras. 71, 96.
137 For a detailed survey of relevant climate cases brought before United States courts on the basis of domestic regulations, see Sabrina McCormick et al., “The Role of Health in Climate Litigation”, 108(S2) American Journal of Public Health (2018) pp. S104–S108. More specific information on both U.S. and non-U.S. climate cases brought against States and corporations and involving health-related issues can be retrieved from the Climate Change Litigation Databases provided by the Sabin Center for Climate Change Law at Columbia Law School and Arnold & Porter, at http://climatecasechart.com/.
Foundation v. The Netherlands, where the duty to take meaningful action to protect present and future generations, the environment, public health and well-being was placed squarely upon the Dutch government on the basis of international obligations stemming from both climate change law and international human rights law. Other major cases decided by or submitted to national courts, among others in France and Italy, have also represented significant steps forward in the direction of holding States responsible for their climate policies and imposing on them immediate and concrete actions to comply with their commitments. Overall, in Europe, human rights-based climate lawsuits have been brought before domestic courts in the Netherlands, Austria, Belgium, France, Germany, Ireland, Norway, Sweden, Switzerland, and the United Kingdom.

86. The same trend is reported with regard to international climate litigation. For example, relevant obligations to protect the right to health stemming from both climate change and international human rights regimes have been at the core of the plaintiffs’ legal arguments in the well-known – but unfortunately unsuccessful so far – People’s Climate Case submitted to the Court of Justice of the European Union.

87. Similarly, the violation of the right to health represents one of the major legal arguments in the application concerning the Youth for Climate Justice v. Austria et al. case, submitted to the European Court of Human Rights on 2 September 2020. This is the first-ever climate case brought before the Strasbourg Court against 33 European governments (all European Union Members, Norway, Russia, Switzerland, Turkey, Ukraine and the United Kingdom). The applicants, four Portuguese children, have complained that the respondent States are breaching the European Convention on Human Rights (ECHR) because of their respective contributions to climate change, notably through the release of emissions from their territory and the lack of adequate legislative and administrative measures regulating the activity of private actors. In particular, in alleging the violation of articles 2 (right to life) and 8 (right to private life) ECHR, the applicants have stressed their special vulnerability to exposure to life and health risks related to increased heat and associated consequences, while recalling that States have positive obligations to adopt targeted measures of protection of individuals under their jurisdiction against serious and substantial threats to their health and well-being which may derive from environmental hazards and noxious emissions. As noted in the application, such obligations equally apply to risks that may

138 Relevant documents can be retrieved at https://www.urgenda.nl/en/themas/climate-case/.
143 For more information, see at https://youth4climatejustice.org/. On 30 November 2020 the European Court of Human Rights announced the fast-tracking of the case and its communication to the defendant countries, which will have to respond by the end of February 2021.
144 Application, paras. 14-23.
materialise in the long term or in the future and should be complied with in accordance with fundamental principles such as precaution, intergenerational equity and “the best interests of the child”.  

88. These legal arguments are in large part coincident with those articulated in the communication to the Committee on the Rights of the Child in the case of Chiara Sacchi et al. v. Argentina, Brazil, France, Germany, and Turkey, another first-ever complaint presented by sixteen children petitioners including Greta Thunberg to protest lack of government action on the climate crisis, which is legally based on articles 3 (best interest of the child), 6 (right to life), 24 (right to health) and 30 (indigenous’ right to culture) of the CRC. In this case, too, the petitioners have laid stress on the respondent States’ responsibility for “exacerbating the deadly and foreseeable consequences of climate change” and their failure to take necessary preventive and precautionary measures to guarantee their right to health. However, in its decision of 22 September 2021, the Committee declared the Communication inadmissible. This decision is indicative of some of the procedural challenges that climate cases will face in the future. Whereas the Committee recognized that the authors of the Communication had victim status, and established that it had jurisdiction over the case, it found the case inadmissible for failure to exhaust domestic remedies.

89. Along the same lines, the right to health argument is at the basis of the case Union of Swiss Senior Women for Climate Protection v. Swiss Federal Council, a second relevant application filed with the European Court of Human Rights on 26 November 2020. The applicants, a group of older women aged above 75, complained that they are direct and potential victims of climate change-induced heatwaves and suffer from heat-related illnesses due to their special vulnerability linked to age and gender. They alleged that Switzerland has violated articles 2 and 8 ECHR for failure to set climate reduction targets in line with international climate law and the best available science. On 26 March 2021, the Court accepted the case and gave it priority status.

90. All these cases testify that the right to health is gaining increasing momentum in international climate litigation and has the potential to play a significant role in the scrutiny of State reduction and adaptation strategies.

E. The prospective role of the right to health argument in climate action

91. As generally recognised, climate change is amplifying existing health and survival risks that vulnerable groups face routinely, while also undermining public health globally.

92. Although the OHCHR aptly stressed that it is extremely challenging to legally construe the adverse effects of climate change as human rights violations, synergies and interaction between international legal regimes can nonetheless provide effective tools to hold States accountable for their failure to adopt prevention, reduction and adaptation policies that are necessary to protect individuals from climate-related damage to health. On the one hand, substantive obligations stemming from both

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145 Ibid., paras. 27-27; Annex, para. 8.
climate change and human rights treaties require that States integrate policies on health and human rights in their national action plans for climate mitigation and adaptation, in the intended nationally determined contributions submitted in compliance with the Paris Agreement and in other climate policies and actions at all levels, improving cross-sectoral cooperation and designing specialised frameworks to tackle threats to health relating to climate change. On the other hand, procedural obligations require that States guarantee that individuals are duly informed of climate-related health risks, are allowed to take part in decision-making processes and have access to climate justice at both national and international levels.

93. Within this framework, invoking the right to health argument adds remarkable strength to the legal complaints advanced by current and projected victims of climate change and allows them to have access to appropriate remedies. Indeed, as the most recent international practice seems to suggests, the right to health has the potential, yet to be fully exploited, to become one of the core legal argument in climate litigation before international courts and human rights treaty bodies.

VI. Future Work Program

94. The subject matter areas discussed in this Report each represent ongoing concerns of the international community, including what may be extended negotiating efforts. The Committee intends to continue its attention to these subjects, that is, new instruments or other mechanisms to address pandemic preparedness and response (including potential amendment of the IHR); sharing of pathogens with pandemic potential and related genetic sequence data, and; public health aspects of climate change. In addition, as reflected in its 2020 (Kyoto) Report, the Committee will continue to follow developments in the field of artificial intelligence (AI) and machine learning (ML) as they may affect health, as well as continuing to address the promotion of equitable access to health technologies for the benefit of all. Assuming the continuing relaxation of travel restrictions, the Committee anticipates resuming its practice of convening at least one meeting of its members and external participants in the year between ILA Biennials to address one or more of the subjects in its work program. These meetings allow for sharing of ongoing research, and the exchange of ideas for the development of Committee reports and proposals. The Committee anticipates that its reports from its work program will form the basis of proposals for adoption by the ILA of Resolutions at future Biennial Conferences. As the field of Global Health Law continues to draw in important new subject matter — as challenges and potential solutions evolve — the Committee seeks an extension of its mandate to continue its work.

150 OHCHR Analytical study, para. 56.