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INTERNATIONAL LAW ASSOCIATION

GLOBAL HEALTH LAW

Athens Biennial 2024

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I. Introduction

1. The Kyoto Biennial Conference of the International Law Association was convened remotely as in December 2020 the COVID-19 pandemic precluded in-person gatherings. The Lisbon Biennial in July 2022 was among the first in-person events attended by many of its participants as the shadow of the pandemic dissipated. As the ILA prepares for its Athens Biennial in June 2024 the international community has largely returned to "normalcy" from a public health standpoint. Yet unfinished business from the COVID-19 pandemic remains as we seek to lay the groundwork for preventing and mitigating future pandemics. In a

paradoxical sense, the COVID-19 pandemic opened a window of opportunity for governments and civil society to put in place institutional mechanisms to accomplish these objectives. Yet that window may not remain open for long. Planning and spending time to address low probability, high risk events – paradigmatically pandemics -- does not occupy a high government priority because returns on investment are uncertain, and political leaders are not likely to be credited by their constituencies for spending ? to address uncertainties. It may be that pandemics are today more likely to recur because boundaries between the natural environment and heavily populated cities have broken down, and transport has been facilitated. But budgets everywhere remain constrained, and before long the window of attention to pandemic preparedness may close. It is with that background that this report of the Global Health Law Committee largely focuses on the policies and legal instruments being debated and negotiated to prepare for and address future public health emergencies. In addition, the Committee recognizes that the wake of the Covid-19 pandemic may potentially create a window of opportunity for norm development and potential standard setting in the health field, beyond health emergencies.

2. The Committee decided to focus this Report on One Health, the Pandemic Agreement negotiations, and the IHR negotiations because each of these subjects is intricately linked to preventing, preparing for, mitigating, and treating potential future pandemics and similar public health emergencies. Also, a major feature of the COVID-19 pandemic was its immediate and longer-term impacts on the mental health of individuals and communities around the world. The effects are felt in the day-to-day life of individuals, and more generally they have influenced social attitudes and political conditions in ways that have not been favorable to public order, or to international peace and security. For this reason, Committee members decided to address the promotion and protection of mental health, focusing on the protection of mental health under international (human rights) law. This Report finally discusses the potential for new investments to address the social environments in which mental health disorders arise.

3. This Report falls into two principal parts. The first part (Sections II-IV) is devoted to policies and international instruments debated and negotiated at the World Health Organization (WHO) that are intended to prepare for and address future pandemics. This includes the One Health approach, negotiation of a WHO Pandemic Agreement (focusing on medical countermeasures), and negotiations regarding potential amendments to the International Health Regulations (2005). Moving beyond pandemics, the second principal part of the Report (sections V-VI) addresses social and environmental determinants of mental health in the context of international human rights, with a concluding section addressing the relationship between international investment law and mental health. Finally, the Report briefly addresses the future work program of the Global Health Law Committee (Section VII).

4. WHO member States have collectively recognized that the response to the COVID-19 pandemic was inadequate.[1] This is not to discount the substantial successes particularly reflected in the scientific advances that resulted in the rapid development of efficacious vaccines based on new technologies. However, vaccines were deployed in a way that favored the countries making the most substantial investments in the development of technology and expenditures on procurement. There was a significant

[1] See, e.g., Report of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies to the special session of the World Health Assembly, Report by the Director-General, SSA2/ Nov. 23, 2021; The Independent Panel for Pandemic Preparedness & Response, COVID-19: Make it the Last Pandemic, report to the Seventy-fourth World Health Assembly, May 2021.

gap between the initial development of efficacious vaccines and their deployment based on clinical review and regulatory requirements.[2] There was and remains concern about China's willingness to make available information concerning the source of SARS-CoV-2 outbreak and the timing at which the risks of the virus were made public. The COVID-19 pandemic placed an enormous strain on national economies and the global economy that impacted countries at all levels of economic development. On a relative basis the economic impact has fallen most harshly on low- and middle-income countries (LMICs).[3] The COVID-19 pandemic was accompanied by substantial societal pressures in countries at all levels of development. These pressures were occasioned in part by periods of social isolation, curtailment of educational activities, and concomitant impacts on mental health. Inaccurate and misleading information regarding the pandemic outbreak and efforts to address it spread prolifically. The fundamental problem of addressing the low probability-high risk public health event re-emerges.

5. Estimates regarding the number of "excess deaths" from the COVID-19 pandemic range from roughly 6.5 million to 15 million individuals.[4] Almost certainly the low-end figure is undercounted because it is well known that certain countries substantially underreported deaths. The number of excess deaths during the COVID-19 pandemic is significantly less than the comparable figure for the Spanish Flu pandemic (1918-20), for which estimates run from 25 to 100 million excess deaths.[5]

6. WHO member States agreed to initiate negotiations on a Pandemic Agreement to address the shortcomings of the response to the COVID-19 pandemic.[6] The negotiations have proven to be contentious with respect to a number of elements. This is not surprising given the overall international political environment and the fact that countries at different levels of economic development and with different capacities are making claims arguably at cross purposes. As 2023 came to a close, significant progress had been made in refining an initially unwieldy text that attempted to reflect a multiplicity of perspectives into a text that has substantially narrowed the "points of difference".[7] Some of that narrowing reflected a

[2] Frederick M. Abbott, Intellectual Property and Technology Transfer for COVID-19 Vaccines: Assessment of the Record, World Intellectual Property Organization (Geneva), Nov. 2023, https://www.wipo.int/publications/en/details.jsp?id=4684&plang=EN.

[3] See, e.g., A Global Deal for Our Pandemic Age, Report of the G20 High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response, www.pandemic-financing.org. June 2021.

[4] Msemburi, W., Karlinsky, A., Knutson, V. et al. The WHO estimates of excess mortality associated with the COVID-19 pandemic. Nature 613, 130–137 (2023). https://doi.org/10.1038/s41586-022-05522-2. Excess deaths as calculated by WHO include deaths from other conditions that could not be treated because health systems were overburdened by the pandemic. See 14.9 million excess deaths associated with the COVID-19 pandemic in 2020 and 2021, WHO Press Release, May 5, 2022, https://www.who.int/news/item/05-05-2022-14.9-million-excess-deaths-were-associated-with-the-covid-19-pandemic-in-2020-and-2021.

[5] See, e.g. Wikipedia, Spanish flu, Mortality, https://en.wikipedia.org/wiki/Spanish_flu, visited Feb. 8, 2024; Jonathan D. Quick, *What We Can Learn From the 20th Century's Deadliest Pandemic*, WALL ST. J. (Saturday Essay), Mar. 6, 2020, https://www.wsj.com/articles/what-we-can-learn-from-the-20th-centurys-deadliest-pandemic-11583510468.

[6] See Zero draft report of the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies to the Seventy-fifth World Health Assembly, Ninth Meeting of the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies, May 3, 2022.

[7] Proposal for negotiating text of the WHO Pandemic Agreement, Seventh Meeting of the Intergovernmental Negotiating Body to Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response A/INB/7/3, Provisional agenda item 2, Oct. 30, 2023.

tempering of ambitions in terms of the scale of potential reforms. Nonetheless, even with that refined delineation of differences in perspective, there remained significant outstanding questions.

7. [**COMMITTEE EDITORIAL NOTE**: the preparation of this draft Report was completed as of February 20, 2024. However, as the INB and IHR negotiating processes are ongoing and scheduled to be completed prior to the Athens Biennial, the Committee will provide an updated version of this Report prior to the Biennial. The draft text of the Pandemic Agreement as of March 13, 2024, can be found here: https://apps.who.int/gb/inb/pdf_files/inb9/A_inb9_3-en.pdf.] As this Report is being prepared, negotiations within the Intergovernmental Negotiating Body (INB) established by the World Health Assembly (WHA) to draft and negotiate a Pandemic Agreement are continuing, and each revision of the draft text presents new elements for discussion and analysis. The INB will conduct negotiating sessions February 19-March 1, March 18-29, and April 29 to May 10, 2024, with a view toward presenting a final text for adoption by the Seventy-Seventh World Health Assembly planned for May 27-June 1, 2024.[8] Because the text is continuously evolving,[9] the discussion in this Report of its provisions -- which is primarily related to those regarding "medical countermeasures", does not concentrate on specific language, but rather the general intent of the draft provisions. Negotiations regarding amendment of the International Health Regulations (2005) are proceeding in parallel with the Pandemic Agreement negotiations. The IHR amendment process is discussed in the following section of this Report.

8. Perhaps the main obstacle confronting successful conclusion and adoption of the Pandemic Agreement is the political landscape within certain countries whose approval will be central to carrying out potentially more ambitious purposes based on economic capacity and R&D infrastructure. In the United States, by way of illustration, there is considerable uncertainty regarding the political party that will control the levers of power following the November 2024 elections. Donald Trump, as prospective leader of the Republican Party, has been pointedly skeptical of the WHO as an institution making it difficult to foresee approval of a major WHO-negotiated agreement should the Republican Party control the government, absent some significant change in perspective.[10] Even if the Republicans do not control the executive branch of government following the 2024 election cycle, approval of a Pandemic Agreement will nevertheless require a majority of Congress or a supermajority of the Senate, matters which again are in doubt. Similar observations could be made regarding the EU and prospects for approval given the perspective of the German pharmaceutical industry, among others.[11] Although member States of WHO are equal from the standpoint of voting and sovereign rights, as a practical matter the economic and scientific capacity of members are significantly different. A Pandemic Agreement that is concluded without

[8] See Proposal by the Bureau on an updated timeline and deliverables, development of the zero draft of the WHO CA+, and establishment of drafting group modalities, Third Meeting of the Intergovernmental Negotiating Body to Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness And Response, A/INB/3/4, Provisional agenda item 3, November 25, 2022.

[9] This includes a draft of Feb. 8-15, 2024 "leaked" in advance of the February 19-March 1 meeting. See Kerry Cullinan, *Read Latest Pandemic Agreement Draft Ahead of Monday's Negotiations*, HEALTH POLICY WATCH, February 15, 2024.

[10] See, e.g. Frederick M. Abbott, *Child-Proofing Global Public Health in Anticipation of Emergency*, Washington Univ. Global Studies L. Rev., Vol. 20, No. 3, pp. 583-92 (2021).

[11] See, e.g. Stefan Anderson, No Pandemic Agreement Without Intellectual Property Protection, says German Health Minister, Health Policy Watch, Oct. 16, 2023, https://healthpolicy-watch.news/no-pandemic-Agreement-without-intellectual-property-protection-says-german-health-minister/.

the participation of the members with the greatest capacity for developing and producing (or transferring technology for) products to address pandemics may face substantially greater obstacles in implementation -- including financial obstacles -- than one including that participation.

9. Outside of the WHO centered negotiations, there are a wide range of other efforts directed toward addressing one or more aspects of the shortcomings of the global response to the COVID 19 pandemic. These include efforts at multilateral organizations, such as the World Bank[12] and WTO,[13] efforts among collaborating governments in various configurations (including, e.g., among the G20),[14] through foundations,[15] and among regional groupings.[16] This Report focuses on negotiating efforts at the WHO because of the intention to craft a new international instrument that envisages broad participation and is legal subject matter aligned with the interests of this Committee.

10. The major subject matter issues that are proposed to be addressed in the Pandemic Agreement are reflected in the title of the draft articles. The first chapter of the draft Agreement outlines the scope of the agreement in terms of preventing, preparing for and responding to pandemics (Article 2). It goes on to frame general principles and approaches (Article 3). These general principles are: respect for human rights, sovereignty, equity, responsibility, recognition of different levels of capacity, common but differentiated responsibilities and respective capabilities in pandemic prevention, preparedness, response and recovery of health systems, solidarity, transparency, accountability, inclusiveness, science and evidence, proportionality, and privacy, data protection and confidentiality. From an international legal standpoint certain of these principles are aspirational as compared with a reflection of customary international legal norms.

11. This section of the Report was initially drafted based on the October 30, 2023, negotiating text, but references are now primarily made to the "leaked" text of mid-February 2024.[17] [See Editorial Note above, para. 7, including link to March 13, 2024, text]

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[12] World Bank Group, Preventing, Preparing for, and Responding to Disease Outbreaks and Pandemics, Jan. 11, 2023, https://openknowledge.worldbank.org/server/api/core/bitstreams/2189d4e8-7d41-599f-8196-55dc1fc353b2/content; The Pandemic Fund Announces Second Round of Funding with Half-a-Billion-Dollar Envelope, World Bank Press Release, Dec. 22, 2023, https://www.worldbank.org/en/news/press-release/2023/12/22/the-pandemic-fund-announces-second-round-of-funding-with-half-a-billion-dollar-envelope.

[13] See WTO portal on COVID-19 and world trade, https://www.wto.org/english/tratop_e/covid19_e/covid19_e.htm, visited Feb. 8, 2024.

[14] See, e.g. note 3, supra.

[15] See, e.g., *Bill & Melinda Gates Foundation and Wellcome pledge $300 million to CEPI to fight COVID-19 and combat threat of future pandemics*, CEPI Press Release, Jan. 19, 2022, https://cepi.net/news_cepi/bill-melinda-gates-foundation-and-wellcome-pledge-300-million-to-cepi-to-fight-covid-19-and-combat-threat-of-future-pandemics/.

[16] See, e.g., Africa CDC, Emergency Preparedness and Response, https://africacdc.org/programme/emergency-preparedness-response/, visited Feb. 8, 2024; European Commission, Preparedness and response planning, https://health.ec.europa.eu/health-security-and-infectious-diseases/preparedness-and-response-planning_en, visited Feb. 8, 2024.

[17] See note [9] supra.

12. Human rights experts have stressed the importance of explicit human rights protection under the Pandemic Agreement.[18] The envisaged treaty should make explicit reference to the right to health, framing efforts to maintain core public health capacities, and ensuring the availability, accessibility and quality of diagnostics, medications, vaccinations and other health services and basic needs. Equally, human rights principles should provide a framework for rights-based public health practices.[19] The Committee endorses the aim of including clear and explicit human rights language in the Pandemic Agreement, and notes with regret that the most recent version of the draft Agreement substantially curtails references to human rights, limiting that to a general reference in Article 3, but dropping language in the more directly operative provisions.

II. One Health Approach

The One Health Approach in International Law[20]

13. Draft Article 5 of the Pandemic Agreement commits parties to "promote and implement a One Health approach for pandemic prevention, preparedness and response". Specific mechanisms for implementation are proposed to be developed by subsequent meetings of the Conference of the Parties (COP) established by the Agreement. The following discussion provides context regarding the One Health approach.

13. The COVID-19 pandemic and other major public health emergencies that have occurred in the last twenty years (SARS, MERS, Ebola, Zika virus disease, avian and swine influenza) evidence the close interconnections between human, animal and environmental health, and at the same time highlight the relevance of zoonoses [21] in the overall framework of infectious diseases. In this latter respect, it is reported that an estimated 60% of existing human pathogens originate in domestic or wild animals and nearly 75% of newly discovered or emerging infectious diseases (EID) are transmitted through animal-to-human spill-over. EID are also in large part driven by environmental factors, such as pollution, climate change, food systems, deforestation, land use change, urbanization, encroachment into wild areas and wildlife trade. In order to achieve a timely and effective prevention and response, such complex health risks need to be addressed in a holistic and collaborative manner, building on a multisectoral, interdisciplinary and interinstitutional cooperation, coordination and communication, as advocated by the One Health approach.

14. In facing complex global health challenges, "One Health" is essential to enable a holistic vision of health and to overcome silos approaches. It is key to strengthening prevention, preparedness and

[18] E.g. Timothy Fish Hodgson et al, 'Human Rights Must Guide a Pandemic Treaty' (editorial), *Health and Human Rights*, 20 November 2021, available at https://www.hhrjournal.org/2021/11/human-rights-must-guide-a-pandemic-treaty/.
[19] Fish Hodgson et al, 2021.
[20] This section on The One Health Approach in International Law was principally drafted by Stefania Negri.
[21] "A zoonosis is an infectious disease that has jumped from a non-human animal to humans. Zoonotic pathogens may be bacterial, viral or parasitic, or may involve unconventional agents and can spread to humans through direct contact or through food, water or the environment." WHO, "Zoonoses" available at https://www.who.int/news-room/fact-sheets/detail/zoonoses.

response to public health emergencies, including pandemics.[22] In fact, in the aftermath of the COVID-19 pandemic, One Health gained huge momentum and was raised to the top of the international political agenda. Indeed, in May 2021 the World Health Organization (WHO) announced the establishment of a One Health High-Level Expert Panel (OHHLEP),[23] the World Health Assembly (WHA) adopted resolution WHA74.7 putting One Health at the centre of strengthening WHO's preparedness and response to health emergencies,[24] and the Rome Declaration from the G20 Global Health Summit expressed the world leaders' commitment to work towards and support enhanced implementation of this multisectoral and evidence-based approach.[25]

15. Based on the 2004 Manhattan Principles on "One World, One Health",[26] the One Health concept embodies a holistic approach to public health threats emerging at the human-animal-environmental interface. Notably, it promotes multisectoral responses to food safety hazards, risks from zoonoses, antimicrobial resistance (AMR), environmental contamination and other major risks connecting public health, animal health and welfare, plant health and environmental protection. According to the comprehensive consensus definition developed by OHHLEP, "*One Health is an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and interdependent. The approach mobilizes multiple sectors, disciplines and communities at varying levels of society to work together to foster well-being and tackle threats to health and ecosystems, while addressing the collective need for clean water, energy and air, safe and nutritious food, taking action on climate change, and contributing to sustainable development.*"[27]

16. From an operational viewpoint, One Health provides a platform to work on the synergies among those fields and to combine the strengths and efforts of various institutions and organisations towards common objectives, including the prevention of disease outbreaks and the mitigation of their impact. In this respect, as said before, the One Health concept has great potential for strengthening preparedness and response to newly-discovered and emerging infectious diseases, especially by contributing to ensure early detection through the integration of control systems across animal, food and human sectors.

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[22] See, among others, Stefania Negri & Mark Eccleston-Turner (2022), *One Health and Pathogen Sharing: Filling the Gap in the International Health Regulations to Strengthen Global Pandemic Preparedness and Response*, International Organizations Law Review, 19(1), 188-214; Ginevra Le Moli (2023), *One Health and the Prevention of Pathogens' Spillover*, Yearbook of International Disaster Law Online, 4(1), 334-357. See also Hélène de Pooter, Gian Luca Burci, Pedro A. Villarreal, *One Health,* ILA White Paper 22 (2022) <https://www.ilaparis2023.org/wp-content/uploads/2022/12/SANTE-EN.pdf>.

[23] *See* WHO Press Release of 20 May 2021, <www.who.int/news/item/20-05-2021-new-international-expert-panel-to-address-the-emergence-and-spread-of-zoonotic-diseases>.

[24] WHO, World Health Assembly Resolution WHA74.7, *Strengthening WHO preparedness for and response to health emergencies*, 31 May 2021. The resolution requested the Director-General, as soon as practicably possible and in consultation with Member States, "to build on and strengthen the existing cooperation among WHO, FAO, OIE and UNEP to develop options, for consideration by their respective governing bodies, including establishing a common strategy on One Health, including a joint workplan on One Health to improve prevention, monitoring, detection, control and containment of zoonotic disease outbreaks."

[25] Global Health Summit, *Rome Declaration*, 21 May 2021, para. 2, <reliefweb.int/report/world/global-health-summit-rome-declaration>.

[26] *See at* <oneworldonehealth.wcs.org/About-Us/Mission/The-Manhattan-Principles.aspx>.

[27] See *Tripartite and UNEP support OHHLEP's definition of "One Health"*, 1 December 2021, <https://www.who.int/news/item/01-12-2021-tripartite-and-unep-support-ohhlep-s-definition-of-one-health>.

17. From the institutional and governance perspectives, the implementation of One Health requires multisectoral institutional involvement and governance mechanisms at the global, regional and national levels. At the international level, its success largely depends on a systematic and coordinated cooperation between the WHO, the World Organisation for Animal Health (WOAH/OIE), the Food and Agriculture Organization (FAO), the UN Environment Programme (UNEP), and other competent United Nations (UN) agencies and international entities such as, for example, bodies under the multilateral conventions addressing environmental drivers of the zoonotic problem such as the UN Framework Convention on Climate Change and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). Synergic cooperation among these key actors and other relevant stakeholders is essential to achieving maximum results in formulating the appropriate regulatory responses, minimising gaps or overlaps in normative regimes, and avoiding duplication of efforts or fragmented outcomes.

18. Putting the One Health vision into practice was facilitated by a formal alliance between WHO, FAO and OIE, which has fostered synergies in expertise, communication, standard setting activities and operational tools. This partnership, also known as the Tripartite, has added a new multilateral dimension to existing relationships based on the bilateral agreements concluded in 1948 (WHO-FAO[28]) and in 2004 (WHO-OIE[29] and FAO-OIE[30]). Based on these and other supplementary agreements, over time the three partners have progressively increased their collaboration on matters of common interest pertaining to the respective fields of competence as defined by their constitutional instruments. They have created governance structures operating in the field of AMR.[31] They have also established a joint early warning system (GLEWS[32]) and developed mechanisms to enhance consultation[33] and coordination, including cooperation among technical experts, the organisation of annual tripartite executive coordination meetings and the appointment of liaison officers at the global level.

19. In 2008, the three collaborating organisations, together with the UN Children's Fund, the World Bank and the UN System Influenza Coordinator, joined forces to produce a strategic document entitled 'Contributing to One World, One Health: A Strategic Framework for Reducing Risks of Infectious Diseases

[28] Agreement between the Food and Agriculture Organization of the United Nations and the World Health Organization, adopted by the First World Health Assembly on 17 July 1948, <apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf#page=62>.

[29] Agreement between the World Health Organization (WHO) and the Office International des Épizooties (OIE), 16 December 2004 (replacing the agreement adopted on 4/8 August 1960), <www.oie.int/en/about-us/key-texts/cooperation-agreements/agreement-with-the-world-health-organization-who/>.

[30] Agreement between the Food and Agriculture Organization of the United Nations (FAO) and the Office International des Epizooties (OIE), 24 May 2004 (replacing a previous bilateral agreement), <www.oie.int/en/about-us/key-texts/cooperation-agreements/agreement-with-the-food-and-agriculture-organization-of-the-united-nations-fao/>.

[31] *E.g.,* the Tripartite Joint Secretariat with rotating chairmanship, the Executive Committee (composed of the three Directors-General), and the Senior Management Group. *See at* <www.who.int/docs/default-source/antimicrobial-resistance/amr-gcp-tjs/tjs-tor-final-october-2019.pdf?sfvrsn=bbd8a3fe_0>.

[32] The Global Early Warning System for Major Animal Diseases, including Zoonoses (GLEWS) is a joint WHO-FAO-OIE initiative launched in 2006 to detect, analyse and assess events through sharing of information on animal disease outbreaks and epidemiological analysis. The response component of GLEWS complements the existing response systems of the three organisations in the field of zoonosis in order to deliver rapid coordinated international response. *See at* <www.oie.int/fileadmin/Home/eng/About_us/docs/pdf/GLEWS_Tripartite-Finalversion010206.pdf>.

[33] *See e.g.* the Report of the WHO/FAO/OIE joint consultation on emerging zoonotic diseases, Geneva, 3-5 May 2004, <www.oie.int/doc/ged/D5681.PDF>.

at the Animal–Human–Ecosystems Interface'.[34] The overarching objective of this Framework was to minimise the global impact of diseases of animal origin, especially those with pandemic potential, through an international, interdisciplinary, cross-sectoral approach to the surveillance, control, prevention and mitigation of EID. This document defined prevention and control of EID as an "international public good", requiring a long-term holistic vision and action building on existing institutions and their mandates.[35] Remarkably, in addressing institutional issues, the document also outlined possible solutions aimed at engaging and strengthening collaboration among key international actors, including by means of a standing coordination mechanism "to garner political support, help ensure continuity of joint operations and encourage increased responsiveness to new outbreaks".[36]

20. By a strategic document issued in 2010 – the Tripartite Concept Note[37] – WHO, FAO and WOAH committed on a long-term basis to working even more closely to ensure coherence of action in the global response to emerging zoonotic and high impact diseases. The Concept Note pointed to strengthening collaboration based on the respective structures and mechanisms, with a view to better managing existing and novel diseases and improving pandemic preparedness and response. Foremost among the objectives set by the Concept Note were the alignment and coherence in global standard setting activities; the realization of complementary work to develop field programs to achieve One Health goals; and the preparation of tripartite protocols for risk assessment, management and communication, including recommendations and guidance for countries. From an institutional point of view, the Concept Note advocated the establishment of a joint Ministerial Conference involving ministers of agriculture and health at the global level to provide a platform to discuss issues related to animal and human health, including zoonoses.

21. To further advance the One Health approach, in 2011 the partner organisations identified three major health threats calling for multisectoral and multi-institutional cooperation: antimicrobial resistance (AMR), rabies and zoonotic influenza.[38] Moreover, pursuant to their renewed strategic vision illustrated in the Tripartite's Commitment of 2017,[39] WHO, FAO and WOAH confirmed their commitment to embrace and strengthen the One Health approach, setting new priorities for joint action. They thus decided to broaden and improve their cooperation in foresight, preparedness and response to emerging, re-emerging

[34] FAO-OIE-WHO-UNSIC-UNICEF-WB, *Contributing to One World, One Health. A Strategic Framework for Reducing Risks of Infectious Diseases at the Animal–Human–Ecosystems Interface*, Consultation document, 14 October 2008, <www.fao.org/3/aj137e/aj137e.pdf>.
[35] *Ibid.*, p. 19.
[36] *Ibid.*, p. 37.
[37] The WHO-FAO-OIE Collaboration. S*haring responsibilities and coordinating global activities to address health risks at the animal-human-ecosystems interfaces, A Tripartite Concept Note*, April 2010, <www.who.int/foodsafety/zoonoses/final_concept_note_Hanoi.pdf>.
[38] Since then, their collaboration has especially developed on AMR. See, for example, the Global Action Plan on AMR (adopted by resolution WHA68.7 of 26 May 2015, <www.who.int/antimicrobial-resistance/global-action-plan/en/>) and the establishment of the Interagency Coordination Group on Antimicrobial Resistance, which was convened by the UN Secretary-General after the UN High-Level Meeting on Antimicrobial Resistance in 2016. The Group completed its mandate on 29 April 2019 upon the handover of its report to the Secretary-General (more information at <www.who.int/antimicrobial-resistance/interagency-coordination-group/en/>). *See also* the Tripartite Joint Secretariat on Antimicrobial Resistance (<www.who.int/docs/default-source/antimicrobial-resistance/amr-gcp-tjs/tjs-tor-final-october-2019.pdf?sfvrsn=bbd8a3fe_0>).
[39] WHO-FAO-OIE, *The Tripartite's Commitment. Providing multi-sectoral, collaborative leadership in addressing health challenges*, October 2017, <www.who.int/zoonoses/tripartite_oct2017.pdf>.

and neglected infectious diseases, and to promote coordinated research and response to the highest priority zoonotic diseases.

22. The Tripartite partnership was further strengthened by the 2018 Memorandum of Understanding (MoU), which complemented the existing interagency agreements with the aim of increasing the tripartite collaboration precisely in the context of the One Health approach.[40] The MoU's purpose was in fact "to provide a formal and legal framework for the longstanding collaboration between the Parties" in order to develop and implement a multisectoral approach to complex health challenges. Along with AMR, one of the three major areas of cooperation referred to "emerging and endemic zoonotic diseases (including foodborne diseases) and information sharing". Interinstitutional coordination for the implementation of tripartite work plans was intended to rely on the practice of the joint executive coordination meetings, reinforced by the establishment of specific task forces, the identification of focal points in each partner institution, and the organisation of additional trilateral meetings at desk-to-desk and expert level within the networks of focal points on each topic area or on *ad hoc* basis.[41]

23. In February 2021, UNEP was invited to join the Tripartite, reaffirming the importance of the environmental dimension in the context of the One Health collaboration. In this regard, at the 28th Tripartite Executive Annual Meeting (TEAM28), on 17 and 18 March 2022, the Principals of the four organisations signed an agreement admitting UNEP as a full and equal partner of the Tripartite thereby effectively constituting a Quadripartite One Health collaboration.[42]

24. In October 2022, the Quadripartite launched the One Health Joint Plan of Action (OH JPA) to set out future shared activities.[43] This five-year plan (2022-2026) was developed through a participatory process and aims to create a framework to integrate systems and capacity to better prevent, predict, detect, and respond to complex health threats at the human-animal-plant-environment interface. It provides a set of actions with a view to strengthening collaboration, communication, capacity building and coordination equally across all relevant sectors, focussing on supporting and expanding capacities in six areas: One Health capacities for health systems, emerging and re-emerging zoonotic epidemics, endemic zoonotic, neglected tropical and vector-borne diseases, food safety risks, antimicrobial resistance and the environment. The plan is a technical document informed by evidence, best practices and existing guidance. It covers a set of actions aimed at advancing One Health at global, regional and national levels.

25. In the face of the increasing number of multidimensional health, water, energy, food security and biodiversity challenges that the world is facing, a shared vision of coherent and coordinated action on all levels is more important than ever. The OH JPA embraces this global vision to further strengthen a

[40] Memorandum of Understanding between the United Nations Food and Agriculture Organization and the World Organization for Animal Health and the World Health Organization Regarding Cooperation to Combat Health Risks at the Animal-Human-Ecosystem Interface in the Context of the One Health Approach and Including Antimicrobial Resistance, 30 May 2018, <www.who.int/zoonoses/MoU-Tripartite-May-2018.pdf>.
[41] *Ibid*., Articles 2-4.
[42] Memorandum of Understanding between the Food and Agriculture Organization of the United Nations and the World Organization for Animal Health and the World Health Organization and the United Nations Environment Programme Regarding Cooperation to Combat Health at the Animal-Human-Ecosystem Interface in the Context of the "One Health" Approach and Including Antimicrobial Resistance, 17 March 2022, <https://www.fao.org/3/cb9403en/cb9403en.pdf>.
[43] FAO-UNEP-WHO-WOAH, *One Health Joint Plan of Action (2022-2026). Working together for the health of humans, animals, plants and the environment*, 2022 <https://www.who.int/publications/i/item/9789240059139>.

comprehensive One Health approach and to foster the change pathways required for successful implementation at all levels.

26. The most recent and consequential action by the Quadripartite has been to publish in 2023 a "Guide to Implementing the One Health Joint Plan of Action at National Level". [44] The Guide builds on the OH JPA and translates the pathways and approaches elaborated therein into actions that countries at any level of development should take to ensure preparedness and capacity to prevent and control zoonotic outbreaks. In light of the complex and intersectoral nature of One Health, the Guide unsurprisingly emphasizes the importance of coordination mechanisms and the adoption of national One Health action plans. The Guide was launched in December 2023 at an event in which Brazil's Global Health Ambassador announced a high-level meeting on One Health to be convened in late 2024 by Brazil in its capacity as G20 president. [45] This type of initiative confirms the strategic importance of One Health for the political agenda of key countries involved in WHO's pandemic law-making negotiations.

27. In the Committee's view, it is evident that a range of environmental conditions play a role in the emergence of disease threats and that a coordinated multi-agency approach, including the integrated participation of national and subnational regulatory systems, is necessary to effectively address the underlying causes for emergence of disease threats, including zoonotic spillovers. In principle, the Committee supports a One Health approach to achieving the requisite coordination, noting that this does not presuppose a particular mechanism to achieve the objectives.

<u>One Health in the Draft Pandemic Agreement[46]</u>

28. Given the likely animal origin of the COVID-19 pandemic and the undeniable increasing risk of zoonotic spillovers for the reasons indicated above, the One Health approach has been included at various level of ambition and detail in the successive drafts of the pandemic agreement between November 2022 and October 2023. To place the proposals in the broader context of the negotiations, it should be recalled that the INB adopted a bottom-up approach whereby it first canvassed a broad range of views in the form of proposals by member States and stakeholders as well as input from expert consultations. Based on those inputs, the Bureau of the INB produced initially a "conceptual zero draft" in November 2022 [47] and subsequently, reflecting the discussions in the INB and more rounds of comments, three more subsequent drafts refining the language and attempting to find compromises and common ground among rather different positions. The production of four drafts in less than a year proved confusing for many delegations and observers who had to constantly adapt their positions. The nature and formulation of substantial parts of the text sometimes changed significantly, including with regard to One Health. The textual references below are based on an informal and unpublished text circulated by the Bureau ahead of the 8th meeting

[44] Available at https://www.who.int/teams/one-health-initiative/quadripartite-secretariat-for-one-health/guide-to-implementing-the-OHJPA-at-national-level

[45] Health Policy Watch, « G20 Plans a One Health Meeting as Zoonotic Threat Grows

[46] This section on One Health in the Draft Pandemic Agreement was principally drafted by Gian Luca Burci.

[47] WHO, "Conceptual zero draft for the consideration of the Intergovernmental Negotiating Body at its third meeting" (25 November 2022), available at https://apps.who.int/gb/inb/pdf_files/inb3/A_INB3_3-en.pdf

of the INB in late February 2024, leaked by an online media outlet. [48] To note that One Health is virtually absent from the amendments proposed to the IHR, so the paragraphs below will focus on the pandemic agreement.

29. While the inclusion of the One Health approach in the broad framework of the pandemic agreement has not been questioned, the priority to assign to that issue and consequentially the scope and level of detail of the corresponding article have proved controversial and led eventually to a relatively short and vague article 5 in the February 2024 draft when compared with previous drafts. A number of reasons account for complicating and politicizing what should have been an uncontroversial issue and for turning it into one of the points dividing developed from developing countries. An overarching issue is what the priorities are for an international pandemic instrument: should it be more narrowly about health security, prioritizing measures that reduce the risk of pandemics and facilitate their control; or about equity and redressing the structural inequalities and imbalances that explain in part the tragic human toll of COVID-19 in developing countries? One Health has been framed during the negotiations as a priority for developed countries and a source of expensive and onerous obligations for developing countries that would divert scarce resources largely for the benefit of the Global North. A concern articulated by African delegations has also been the risk of penalizing tribal and local communities in case of a top-down approach trying to control traditional nutrition habits, and of creating obstacles to their agricultural trade. Another stumbling block has been the linkage with the equally divisive issue of pathogen and benefit sharing, in particular the claim of benefits from the utilization of pathogens discovered through surveillance. For all these reasons and with a view to reaching agreement, the scope and breadth of the provision on One Health has substantially decreased, with the February 2024 text reducing it to a short and rather generic text.

30. From a more conceptual perspective, One Health is an inspiring and holistic concept that moves away from a purely anthropocentric approach and focuses on the human-animal-environmental interface, but at the same time it is a rather vague concept that has to be translated into concrete policy and operational measures. The inclusion of animal health and welfare, food production and trade as well as diverse environmental drivers means that the One Health approach in its totality extends beyond WHO's mandate. In particular, it includes issues falling under the jurisdiction of the other Quadripartite organizations as well as their respective normative instruments. A WHO agreement inevitably focuses predominantly on the protection of human health and can only meaningfully address the broader ecosystem with the participation and coordination of the other organizations that will not, however, participate as such in the agreement. Those organizations have been visibly nervous, at least at the level of their secretariats, at the prospect of WHO purporting to regulate topics such as animal trade and health and stepping on their constitutional mandates. This consideration also raises questions whether an international agreement is the most appropriate normative tool to regulate issues characterized by a high level of regime complexity, or whether more flexible instruments such as joint frameworks among the organizations concerned would be more conducive to a comprehensive approach reducing the risk of gaps or damaging "turf fights".

[48] Health Policy Watch: "EXCLUSIVE: Read Latest Pandemic Agreement Draft Ahead of Monday's Negotiations" (15 February 2024) available at https://healthpolicy-watch.news/exclusive-read-latest-pandemic-agreement-draft-ahead-of-mondays-negotiations/

31. The approach adopted in the latest draft consists of a package of three articles – 4 to 6 – that deal respectively with prevention and surveillance; One Health; and health system preparedness. Even though the three areas can be seen as complementary and synergistic, the balance among them has been the object of intense discussions, in particular for delegations such as the European Union that aimed at strong, broad and operational obligations specifically on One Health. Non-State actors such as animal welfare non-governmental organizations have also been vocal in favour of an approach that would not put too much emphasis on surveillance to the detriment of other obligations – after all, surveillance is not an end in itself but a means to detect and characterize risks that have to be prevented or managed through different policies and measures. Moreover, surveillance is not confined to pathogens of zoonotic potential but also non-animal pathogens and other microorganisms, thus risking to dilute the emphasis on the One Health approach.

32. In synthesis, the picture emerging from draft Articles 4 to 6 points to a few main issues: (a) the establishment of integrated surveillance encompassing animal and human pathogens as well as environmental factors – an uncommon practice so far even in developed countries, which may take time and considerable resources to become mainstreamed; (b) an emphasis on "primary prevention" aiming at reducing the risk of zoonotic spillover rather than limiting itself to detect and control it once diseases emerge in human populations. This translates into the obligation to identify "hot spots" of zoonotic risk and the adoption of resulting measures, in particular for the management of wildlife and farm animals; [49] (c) other national actions, within the context of a multisectoral national action plan, aimed at preventing or reducing the risk of outbreaks in humans, with particular regard to infection prevention and control which is sometimes neglected including in healthcare facilities; (d) the developments of standards and guidelines given how dependent on scientific knowledge and translation are the identification and characterization of emerging pathogens; (e) cooperation with relevant international organizations and bodies, in particular those of the Quadripartite, and reliance on their recommendations, guidelines and policies; (f) development and strengthening by each party of capacities – in particular within their health systems - to implement measures and policies and comply with their obligations; and (g) provision of financial and technical support to developing country parties.

33. An omission from an otherwise rather broad – if not very detailed – scope is a science-policy interface mechanism that can translate and curate pure science into policy-relevant conclusions that can feed into national and international action. The Intergovernmental Panel on Climate Change [50] and the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services [51] are notable examples in the environmental field. The February 2024 draft foresees the establishment of a Scientific Advisory Committee (Article 24) under the aegis of the Governing Body of the agreement that could potentially play this role. However, the provision is within square brackets and thus subject to a request to delete it, and does not mention specifically One Health or Articles 4-6.

[49] This type of prevention has also been dubbed "mainstream deep prevention" and aims at the unregulated space in international law where animals and humans come into close contact. See Ginevra Le Moli, Jorge E Vinuales, Gian Luca Burci, Adam Strobeyko, Suerie Moon, "The deep prevention of future pandemics through a One Health approach: what role for a pandemic instrument?", Geneva Graduate Institute policy brief (September 2022), available at https://repository.graduateinstitute.ch/record/300532.
[50] https://www.ipcc.ch/
[51] https://www.ipbes.net/

34. The Committee notes that provisions in the draft Pandemic Agreement addressing One Health, as with many other portions of the draft text, have been subject to the dilution of specific obligations as the positions of the member States have not been aligned. The Committee supports inclusion of One Health in a final text of the Pandemic Agreement, but it appears that most decisions regarding how the One Health approach will be implemented nationally and internationally remain for future negotiation and elaboration. Perhaps more consideration might have been given at the outset of the negotiations to the fact that WHO, as other international organizations, has a limited mandate. Efforts to expand that mandate into subject matters for which other international organizations are principally responsible was and is likely to face obstacles.

III. Medical Countermeasures[52]

35. The gap in pandemic preparedness and response that has drawn the greatest public attention is the problem of introducing and scaling up “medical countermeasures”, that is vaccines, diagnostics, therapeutics and medical equipment (including personal protective devices, ventilators and oxygen supplies). The draft Pandemic Agreement seeks to address these gaps by incorporating rights and obligations in respect to research and development, sustainable production, transfer of technology and know-how, and through the establishment of a WHO based supply chain and logistics network. It also addresses the related question of access to pathogen materials and associated genetic sequence data that

[52] This section on Medical Countermeasures was principally drafted by Frederick Abbott. The WHO and its members have used the term "medical countermeasures", sometimes abbreviated as “MCM”, to refer to public health measures taken to prepare for and respond to pandemic threats. See, e.g., Resilient and scalable MCM ecosystem: Regional entities coordination meeting for advancing timely and equitable access to medical countermeasures against pandemic threats, WHO Press Release, March 12-13, 2024. The terminology has been used ubiquitously throughout the INB and IHR negotiating processes, though it is not used “as such” in the draft texts. The term medical countermeasures, or MCMs, was adopted by the US Food and Drug Administration (FDA), at least as early as 2010, with a somewhat broader emergency focus, including “a naturally occurring emerging disease”:

> “Medical countermeasures, or MCMs, are FDA-regulated products (biologics, drugs, devices) that may be used in the event of a potential public health emergency stemming from a terrorist attack with a biological, chemical, or radiological/nuclear material, or a naturally occurring emerging disease.
>
> MCMs can be used to diagnose, prevent, protect from, or treat conditions associated with chemical, biological, radiological, or nuclear (CBRN) threats, or emerging infectious diseases.
>
> MCMs can include:
>
> Biologic products, such as vaccines, blood products and antibodies
> Drugs, such as antimicrobial or antiviral drugs
> Devices, including diagnostic tests to identify threat agents, and personal protective equipment (PPE), such as gloves, respirators (certain face masks), and ventilators”
> (https://www.fda.gov/emergency-preparedness-and-response/about-mcmi/what-are-medical-countermeasures; /https://wayback.archive-it.org/7993/20161022134605/http://www.fda.gov/downloads/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/UCM270750.pdf)

are essential parts of the R&D process, as well as the benefit sharing that would accompany this. There are elements of overlap in the draft provisions which is unsurprising in light of the work that has been done toward consolidating a substantial number of proposals in these areas. The INB has been successful in moving toward a consolidated text of provisions concerned with the development and implementation of medical countermeasures, including those provisions devoted to research and development (R&D), transfer of technology, production, logistics and access to biological materials and genetic resources with pandemic potential.

Article 9. Research and development

36. The draft article on research and development promotes the objectives of geographically diverse R&D capacity through open science approaches, and collaboration in R&D on products needed to address pandemics. The language regarding R&D is hortatory "shall promote". In more obligatory language, "the Parties shall, in accordance with national laws and regulatory frameworks and contexts" increase clinical trial capacities by maintaining a skilled workforce and infrastructure, and by improving policy frameworks. There is an obligation to ensure diversity in clinical trial representation. There is language on developing policies supporting sharing of information, including clinical trial protocols, and the reporting of data. There is a broad set of obligations ("shall, in accordance with national laws" and capacity) to arrange for the publication of information developed with government funding relevant to research inputs, pricing of end products, licensing to enable development, manufacturing and distribution, and terms regarding affordable and equitable access. There are no precise targets established for member action.

37. Recommendations regarding clinical trials and data must take account that trials are usually conducted by private sector enterprises, either directly or by subcontracting with clinics or hospitals, with supervision by physicians. The data that is obtained is protected by patient confidentiality restrictions, and results generated without individual identifications. A more robust approach to the making available of clinical trial results would require action at the national level to mandate the publication of those results, yet the current drafting seems to reflect political limitations. This subject matter has been the object of controversy for many years, with originator pharmaceutical companies contending that clinical trial results constitute valuable confidential commercial information that requires substantial investment to develop. Proponents of open publication of clinical trial results argue that such publication would facilitate external analysis of clinical trial results that might ultimately benefit the health of patients by potentially identifying risks.[53] This long-standing legal and policy debate likely explains why the language in draft Article 9 includes language that provides substantial room for maneuver in terms of implementation.

38. As a policy matter, members of the Committee favor the publication of clinical trial results because such publication may lead to more robust analysis of the effects of pharmaceutical products. Although access to such clinical trial results may work to the benefit of competitors of the originators of that data, if access leads to improving the safety profile of competitive products by identifying potential risks that should be addressed, there would presumably be a net benefit to public health.

Article 10. Sustainable and geographically diversified production

[53] See, e.g., Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTELLECTUAL PROPERTY L. REV. 1 (2009).
Available at: https://scholarship.law.marquette.edu/iplr/vol13/iss1/1

39. Draft Article 10 on sustainable production is drafted in "shall endeavor" language, while encouraging members to "take measures", including to maintain production facilities to produce pandemic related products, as well as to provide for contracting for scaling up. Taking measures includes identifying and maintaining production facilities at national and regional levels, as well as to facilitate production of pandemic-related products, to establish arrangements with third party manufacturers to fill in gaps in supply capacity, and to create predictable demand. The encouragement to establish production facilities ties into the Article 13 supply chain network provision, which more specifically provides for estimating demand for pandemic response products.[54] It is notable that draft articles 10 and 13 do not specifically address whether encouragement to prepare for manufacturing pandemic vaccines is directed toward supply of the national market of the party committing to an obligation, or whether there is some implication that parties with capacity are intended to supply on some type of global basis. It is somewhat difficult to foresee individual parties to the agreement committing to produce sufficient quantities of medical products to supply globally, or even regionally, given the nature of State sovereignty and responsibility for the national territory and population. It appears that the draft pandemic Agreement makes an assumption that the global supply network will be estimating quantities of products that are required.

40. The combination of Articles 10 and 13 appear to contemplate that funding will be provided through the sustainable financing mechanism referred to in Article 20 of the draft Agreement.

41. From a legal standpoint, a directive to parties to the Pandemic Agreement to "endeavor" to "take measures" to maintain production facilities at national and regional levels is useful. However, if the intent of the Pandemic Agreement is to provide a more global response to a future pandemic in the sense of addressing gaps in the supply of vaccines and treatments from a geographic or income level standpoint, it does not necessarily benefit diverse jurisdictions by encouraging major producing countries to produce adequate vaccines. The net results of the provisions on sustainable production are that concrete action is dependent on *ex post facto* development of plans, and financing mechanisms. This is a gap in the draft Pandemic Agreement arrangements. Governments seeking to address the inequitable response to the COVID-19 pandemic should be working on a comprehensive program with financing. That, however, may not be realistic, particularly within the brief time remaining under the plan set out for the negotiations.

Article 11. Transfer of technology and know-how

42. This article on transfer of technology is drafted to provide that the parties "shall collaborate towards" its objectives. This includes facilitating and incentivizing manufacturers to provide relevant technology, and to make available non-exclusive licensing of government owned technology on mutually agreed terms, for the development and manufacturing of products. Parties "shall encourage" R&D institutes and manufacturers, in particular those receiving significant public financing, to waive or otherwise charge reasonable royalties for the use of their technology in developing countries to produce

[54] Article 13 of the draft Agreement calls for the establishment of the WHO Global Supply Chain and Logistics Network (WHO SCL Network) and a directive to the Conference of the Parties to undertake a number of planning operations, including assessing manufacturing capacity, creating databases of potential suppliers and mapping infrastructure. There is a reference to agreement on "sustaining it at all times".

products during pandemics. Parties are encouraged to promote voluntary licensing and transfer of technology by private right holders. The mid-February 2024 draft recognizes that WTO members have the right to makes use of TRIPS Agreement flexibilities, and it provides that parties shall review and update their legislation in order to ensure effective implementation of those flexibilities.

43. WHO created the C-TAP program as a mechanism for receiving voluntary contributions of technology during the COVID-19 pandemic.[55] Most of the licenses to C-TAP came from government research institutions (Spanish and US), with only one license provided after the end of the pandemic emergency for a product ready vaccine. There is no obvious reason to expect that circumstances have changed substantially since the end of the COVID-19 PHEIC. It is not clear that the Pandemic Agreement is adding anything to what WHO already is doing as an internal matter, as it transitions from C-TAP to H-TAP.

Article 12. Access and benefit sharing[56]

44. This article seeks to establish an arrangement similar to that established by the Pandemic Influenza Preparedness (PIP) Framework[57] while directed more generally to pathogens with pandemic potential (not limited to influenza viruses). This new arrangement expressly covers genetic sequence data derived from the relevant pathogens. The text of article 12 relating to a new WHO Pathogen Access and Benefit-Sharing System (WHO PABS System) does not include details regarding the technical mechanisms by which it would operate, but much of that detail is already established with respect to pandemic influenza viruses. This would include the development of a standard material transfer agreement that would be executed by parties receiving biological materials or genetic sequence data under the system. The principal distinction between the new WHO PABS system and the PIP Framework is found in the benefit sharing provisions. As the draft currently stands, recipients of PABS materials would be required to commit to provide 20% (10% as a donation and 10% at affordable prices) of the products based on those materials to WHO on a real time basis, as well as to make an annual financial commitment to the sustainable funding mechanism established by draft article 20 of the Agreement. There is also "soft" reference (i.e., "shall also consider") to encouraging transfers of technology and tiered or other low-cost pricing arrangements to benefit developing countries. A target date of May 31, 2025, is established for bringing this new WHO PABS System into operation. There is also a provision seeking to assure compatibility between this arrangement, the CBD and the Nagoya Protocol.

45. The linking of access to genetic and biological resources representing pathogens with pandemic potential with contributions of the products produced based on those resources is intended as a pragmatic solution to a problem faced by countries lacking capacity to undertake the R&D and production necessary to address pandemic outbreaks. It recognizes the sovereignty of the countries where pandemic outbreaks originate and their stewardship with respect to the genetic and biological resources. There is an incongruity between the risks presented by pathogens of pandemic potential, on one hand, and limiting access to the materials needed to address it, on the other. From a purely philosophical standpoint, viruses, bacteria and other pathogens might be viewed as global public goods, including because they are likely to migrate quickly from the country where an initial outbreak occurs to other sovereign territories. Moreover,

[55] WHO COVID-19 Technology Access Pool, https://www.who.int/initiatives/covid-19-technology-access-pool.
[56] The mid-February 2024 leaked text, supra n. [], did not include a revised Article 12.
[57] The Pandemic Influenza Preparedness (PIP) Framework, https://www.who.int/initiatives/pandemic-influenza-preparedness-framework.

the host countries that provide the resources themselves require the resulting products to address a pandemic. However the low- and middle-income countries that demanded an exchange of value for providing access to resources did not perceive themselves to have another solution. The *quid pro quo* proposal addresses the reality of international economic relations and that the interests of LMICs may not be accommodated unless they hold some leverage in dealing with the countries where medical countermeasures are developed and produced.

46. Of course, there is no assurance that a *quid pro quo* arrangement such as envisaged by the PABS system will actually be carried out in a real time pandemic. As exemplified, for example, by India's imposing restrictions on exports of vaccines during the COVID-19 pandemic, nation States tend to prioritize the national interest in situations of emergency. What this may mean is that proposals for establishing production facilities in geographically diverse locations is a more practical solution to the problem of access to medical countermeasures during a pandemic, as compared with commitments to supply those vaccines to WHO. There would, however, remain the question of technology transfer. During the negotiation of the PIP Framework, LMIC negotiators demanded that concrete proposals for technology transfer be included. Instead, private producers in their home countries were given the option of providing products to WHO stockpiles and financial contributions. Technology transfers have not taken place under that PIP Framework system.

47. Under the circumstances, a commitment by a recipient of genetic or biological materials under the PAB system to supply products to WHO by donation and at discounted prices may well be the “best solution available”, recognizing it remains an imperfect one.

Article 13. Global Supply Chain and Logistics Network

48. The global response to the COVID-19 pandemic was characterized by substantial gaps in information regarding the available vaccine suppliers and the materials needed to rapidly scale up production of vaccines. In addition, there were substantial limitations on the transport, storage and other infrastructure needed to efficiently and rapidly distribute vaccines, as well as a “last mile” problem in providing those vaccines to patients. Draft article 13 is laudably directed toward addressing these gaps by providing for the mapping of the global supply chain and logistics network, and by providing for the relevant information to be accessible. This includes establishing price transparency and more generally transparency with respect to the terms and conditions of agreements. It encourages the establishment of pooled procurement mechanisms and the creation of stockpiles.

49. Draft article 13 is based on an understanding that responsibility for different elements of the international supply and logistical framework are handled by different institutions, and that cooperation among the various institutions and members will be required, all within the framework of WHO. It is not clear how this aspect of WHO management would fit within the management structures of the other relevant organizations.

50. Draft article 13 represents efforts to address very important concerns. At the outset of the COVID-19 pandemic the extent of gaps in information regarding vaccine production capacity and capacity to produce personal protective equipment was remarkable. Those gaps were not rapidly filled. Even by the end of the pandemic emergency (PHEIC) cataloging of potential material suppliers, logistics capabilities

and production facilities had not been adequately compiled. At the 2nd WHO World Local Production Forum meeting in The Hague in November 2023, one of the principal recommendations was for the creation of comprehensive databases identifying potential sources of the materials and equipment, production facilities, logistics capacities, and so forth for addressing public health requirements. In this case, not limited to pandemic preparedness and response.

51. The Committee broadly endorses establishing a Global Supply Chain and Logistics Network. In order for such an effort to be truly successful it will require the cooperation of both the private and public sectors because much of the information regarding pharmaceutical manufacturing is in private hands, and the private sector may perceive commercial advantages in maintaining information regarding capacity confidential. Incentives are likely needed to encourage cooperation.

Article 20. Financing

52. This article provides for the establishment of a sustainable financing mechanism within 12 months following entry into force of the Agreement. The mechanism refers back inter alia to article 12 and the funds that may be generated through annual contributions under the WHO PAB system. There is no specific provision for determining the amount of contributions to the financing mechanism other than through *ex post facto* agreement by the Governing Body of the Agreement.

General Observation

53. As of February 2024, the negotiating process for the Pandemic Agreement has evidenced a continuous scaling back of specificity and of the extent of potential binding obligations. This may reflect the level of distrust currently affecting the international political arena, and the suspicion of international institutions among the public in many countries of the world. The WHO established a very ambitious timeframe for negotiations that has created pressure for reaching "some agreement" at the May-June 2024 World Health Assembly. As demonstrated at the WTO in the context of its TRIPS waiver negotiations, the desire of "WHO management" to portray an institution capable of acting might lead to the conclusion in Geneva of a Pandemic Agreement with few enumerated rights or obligations. It might have been better to focus post-pandemic activities on a few specific programmatic achievements.

54. The Committee broadly endorses the conclusion of a Pandemic Agreement mainly as a demonstration of multilateral political commitment in addressing potential future pandemics. But a serious question remains whether it might be preferable to extend the time frame initially proposed for concluding the negotiations. This might entail a decision to negotiate subject matter areas in more discrete "blocks", and to incorporate elements such as financing in more concrete ways than is currently contemplated.

IV. Amendments to the International Health Regulations (2005)[58]

54. When the COVID-19 pandemic emerged, the International Health Regulations (IHR) of 2005 were the main legally binding international law instrument dealing with the cross-border spread of disease. Its object and purpose under article 2 is to "prevent, protect against, control and provide a public health

[58] This section on Amendments to the International Health Regulations (2005) was principally drafted by Pedro Villarreal.

response to the international spread of disease in ways… commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade". Given the belated and uncoordinated response from the international community of States to the pandemic, major questions emerged both amongst policymakers[59] and in academic commentary[60] on whether the IHR (2005) were fit for achieving its own object and purpose.

55. The global debacle caused by COVID-19 was far from being the first instance where the IHR (2005) was subjected to critical scrutiny. Ever since the first public health emergency of international concern was declared due to H1N1 Influenza in 2009, and notably during the West African Ebola crisis of 2014, the implementation of the IHR (2005) has been the subject of external, independent inquiries commissioned for examining its shortcomings.[61] Particular attention had been given to failures in three sets of obligations, namely: failure to report, in a timely – ie within 24 hours after assessment of an event – and transparent fashion, all events in their territories which may constitute a public health emergency of international concern to the WHO, in accordance with article 6; failure to develop and strengthen minimum core capacities, as required in articles 5 and 13 as well as Annex 1, and notably to assist other States parties in meeting these obligations, as foreseen in article 44; and failure to refrain from public health measures that excessively restrict international travel and trade, as established in article 43. All of these obligations are intertwined, composing either a virtuous or a vicious circle where fulfillment of one will necessarily have an impact on the other two.[62] Until 2020, however, there had been no effort to overhaul the IHR (2005) in these key areas. In fact, two previous IHR Review Committee Reports – one on the West African Ebola crisis,[63] and one in the wake of the COVID-19 pandemic[64] – had advised against "opening up" the IHR for reforms due to the political and economic costs. Despite these recommendations to the contrary, States parties are currently undertaking the most ambitious reforms since the approval of the IHR in 2005, and the third ones after a minor addition to Annex 7 concerning yellow fever vaccination certificates in 2014,[65] and a number of "technical amendments" approved in 2022.

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[59] The Independent Panel for Pandemic Preparedness & Response, *COVID-19: Make it the Last Pandemic, report to the Seventy-fourth World Health Assembly*, May 2021, p. 16.

[60] Gian Luca Burci and Mark Eccleston-Turner, ´Preparing for the Next Pandemic: The International Health Regulations and World Health Organization during COVID-19´ (2021) 2 *Yearbook of International Disaster Law* 259-282.

[61] Among others, see WHO, Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009, A64/10 (5 May 2011), hereinafter "IHR Review Committee Report on H1N1 Influenza"; WHO, *Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response*, A69/21 (13 May 2016), hereinafter "IHR Review Committee Report on Ebola"; United Nations General Assembly, ´Protecting Humanity from Future Health Crises. Report of the High-level Panel on the Global Response to Health Crises´, A/70/723 (9 February 2016); Suerie Moon et al, ´ Will Ebola change the game? Ten essential reforms before the next pandemic. The report of the Harvard-LSHTM Independent Panel on the Global Response to Ebola´, 386 *The Lancet* 2204-2221.

[62] Pierre Dorolle, ´Old Plagues in the Jet Age´ (1968) 4(5634) *British Medical Journal* 789-792; Pedro Villarreal, Roojin Habibi and Allyn Taylor, ´Strengthening the Monitoring of States´ Compliance with the International Health Regulations´ (2022) 215-240.

[63] *IHR Review Committee Report on Ebola*, 6.

[64] WHO, *Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response, Final Draft*, A/74/9 Add. 1 (30 April 2021), hereinafter "IHR Review Committee Report on COVID-19", 60.

[65] WHO, *World Health Assembly Resolution WHA67.13, Implementation of the International Health Regulations (2005)* (24 May 2014).

56. The procedure for amending the IHR (2005) is currently prescribed under its article 55. States parties must submit their proposals to the WHO Director-General, who will then circulate them to all States parties at least four months before the Health Assembly where amendments will be considered for approval. This is meant to give sufficient time for discussing and pondering the contents of amendments, thus avoiding last-minute, take-it-or-leave-it proposals. Such a procedure should be understood against the background of the peculiar nature of the entry into force, which removes the need for ratification through the approval of other national bodies, for instance the legislative branch, enshrines the possibility of amendments to the IHR (2005) becoming binding after a statutory period of time for States who do not reject them or issue reservations.

57. In January 2022, the United States of America put forward several proposals for amending the IHR (2005). These proposals included, among others, creating new review mechanisms for assessing the development of minimum core capacities as defined in article 5; an obligation for States parties to assess events in their territory which may constitute a Public Health Emergency of International Concern (PHEIC) within 48 hours; removing the requirement under article 9 for the WHO to consult with States parties when receiving reports from non-official sources before taking any action; creating a multi-tiered system of different types of emergencies and an intermediate health alert within article 12; allowing for the WHO to recommend the deployment of expert teams as temporary recommendations under article 15; creating a new Compliance Committee on the basis of article 53; and shortening the period for expressing rejections and reservations, as well as for the entry into force of amendments to the IHR (2005).

58. The amendment proposals submitted by the United States were hotly discussed at the 75th World Health Assembly of May 2022. Due to their complex nature, delegates requested extending the time for their consideration. Only a few amendments were approved, namely to Articles 55, 59, 61, 62 and 63 IHR (2005), themselves regulating amendments. Under the new formulation of Article 55 IHR (2005), the period of 18 months for either expressing rejections or reservations ("opt out") to amendments to the IHR (2005), and of 24 months for their entry into force for those States parties that did not express reservations or rejections, was reduced to 10 and 12 months, respectively. At the same time as these amendments were approved by a World Health Assembly resolution, a Working Group was created by a separate decision in that resolution (WHA75(9)) to gather further amendments submitted by other States parties until an agreed upon deadline in September 2022. This decision led to the initiation of current negotiations.

59. By the time the deadline of September 2022 elapsed, States parties had submitted over 300 amendments, many of them overlapping. In order to deal with this complexity, the WHO Director-General convened, on the basis of article 50 IHR (2005), an IHR Review Committee composed of experts in multiple fields correlated to international law, international relations and communicable diseases. In February 2023, the Review Committee on amendments to the IHR (2005) ("IHR Review Committee on amendments") published its report, offering a series of recommendations on how to harmonize several of the proposals.[66] Although according to article 50 (1) IHR, neither States parties nor the WHO are obliged

[66] WHO, *Report of the Review Committee regarding amendments to the International Health Regulations (2005)*, A/WGIHR/2/5 (6 February 2023) hereinafter "IHR Review Committee Report on amendments".

to accept these technical recommendations, they constitute a valuable and authoritative source meant to aid delegates when making sense of the many, overlapping provisions.

60. The following lines focus on a few of the conclusions and recommendations of the IHR Review Committee´s report on the three sets of obligations mentioned above, namely: surveillance with and through timely and transparent notification and information-sharing; refraining from implementing health measures more restrictive of international travel and trade than necessary; and developing and strengthening minimum core capacities to "detect, assess, notify and report" events that may constitute a PHEIC.

61. Multiple subjects fall within the purview of both the Pandemic Agreement and amendments to the IHR (2005). Perhaps the most divisive aspect between delegates negotiating both instruments is the call for more equity, particularly what it means in terms of access to medical countermeasures, on the one hand; and collaboration and assistance in the strengthening of minimum core capacities under the IHR (2005), on the other hand. The IHR Review Committee considered that equity goes beyond the distribution of medical countermeasures, and the transfer of technology;[67] instead, it can be a guiding term meant to offset disparities in capacities of States to identify and respond to future disease outbreaks.

62. One clear instance in which equity is at stake in the IHR (2005) is in the obligation to collaborate with and assist countries in the development of minimum core capacities mandated in articles 5 and 13 and enumerated in Annex 1. Accordingly, several States parties to the IHR (2005) have submitted amendment proposals of article 44. Among them, access to medical countermeasures is a particular source of contention. The IHR Review Committee noted how this aspect overlaps considerably with the proposals under draft articles 10 and 12 of the Pandemic Agreement, which also focuses on questions of equitable access to medical countermeasures. At the moment of writing, no decision has been made between negotiators of both instruments on where exactly provisions concerning this equitable access would be located. This is due to the importance of the subject matter for multiple countries, especially from the Global South.[68] The shadow of the global distributive failures during the COVID-19 pandemic looms large. Agreement on this subject matter is likely to be one of the most difficult to achieve, with uncertainty prevailing over the final outcome of these negotiations so far.

63. Another amendment related to equity concerns the creation of new financing mechanisms available for States to help them strengthen their minimum core capacities under articles 5 and 13 and Annex 1 IHR (2005). It is arguably a question of equity, considering the expectation that countries with more developed economies would financially contribute more and in proportion to their capacities. This is not an unusual constellation within international law. One of the proposed amendments to insert an article 44A IHR (2005) would be to create a concrete financial mechanism, which would address what was arguably a constantly neglected obligation of collaborating and assisting in the current article 44 IHR (2005). This though raises two core questions: 1) which States parties will qualify for obligations to financially contribute to the mechanism, and which will be the criteria of eligibility for developing countries to be deemed recipients; and, 2) which body will administer the fund. In its report, the IHR Review

[67] Ibid., paras. 17-18.
[68] Kerry Cullinan, "WHO IHR Negotiators Agree on Special Session on Equity", *Health Policy Watch* (12 February 2024) https://healthpolicy-watch.news/who-ihr-negotiators-agree-on-special-session-on-equity/.

Committee had diverging opinions on whether the WHO is an adequate organization for administering new funds, while also noting that the World Bank has already established a Financial Intermediary Fund or "Pandemic Fund".[69] At the moment of writing, the Pandemic Fund has become operational, having implemented a first round of grants, and is in its second round. Several of these projects, though not all,[70] have an explicit link to the IHR (2005).

64. Whereas the WHO is not per se a financial organization, it is also no stranger to the deployment of funding for technical assistance. Its programmes, funded by the overall budget, are partly composed of country-based assistance, albeit not through the direct transfer of funds. Ongoing discussions at the 154th session of the WHO´s Executive Board in January 2024 addressed the question of how the organization´s programmes are funded, with investment rounds being proposed as a modality for sustainable financing.[71] Participation in these investment rounds by donors will be voluntary, and the WHO Secretariat will be responsible for managing the implementation of those rounds, including through publishing calls for financial contributions by interested parties.[72] These discussions, however, cover areas beyond those of disease outbreak prevention, preparedness and response, and are thus parallel to those of the Pandemic Agreement and amendments to the IHR (2005). Nevertheless, there is a future potential for synergies between different financial sources, considering how e.g. the WHO's existing Emergency Programme could be deployed to cover events under both the IHR (2005) and the Pandemic Agreement.

65. Determining which institution will manage funding related to the IHR (2005) will depend on the question of how finances will be structured. An open question in this regard is whether financing under collaboration and assistance within the IHR (2005) would be project-based, similar to those of the World Bank´s Pandemic Fund; or more open-ended, consisting of structural investments in the overhead of day-to-day operational costs of healthcare systems provided they are related to the IHR (2005)´s minimum core capacities under articles 5 and Annex 1 IHR (2005). The former is likelier to be managed at the international level. If and when the nature and structure of financing in the IHR (2005) is agreed upon, it will be more feasible to clarify the administering entity, be it an existing body or a new one created for that purpose.

66. Should financing mechanisms be created in both the IHR (2005) and the Pandemic Agreement, it is in principle possible to institute a common administering body. Precedents exist in the field of international environmental law. The Global Environmental Facility is tasked with providing administrative financing services for five conventions: the Convention on Biological Diversity (CBD), the United Nations Framework Convention on Climate Change (UNFCCC), the Stockholm Convention on Persistent Organic

[69] Ibid., 70.

[70] For instance, several projects are focused on a One Health Approach, which so far falls beyond the purview of the IHR (2005). See World Bank, "Pandemic Fund Allocates First Grants to Help Countries Be Better Prepared for Future Pandemics", *Press Release* (20 July 2023), https://www.worldbank.org/en/news/press-release/2023/07/20/pandemic-fund-allocates-first-grants-to-help-countries-be-better-prepared-for-future-pandemics.
It can be argued that the holistic potential of One Health contributes to the human health dimension of surveillance objectives.

[71] WHO, *Sustainable financing: WHO investment round. Report of the Director-General*, EB/154/29 Rev. 1 (21 December 2023) https://apps.who.int/gb/ebwha/pdf_files/EB154/B154_29Rev1-en.pdf.

[72] Ibid., para. 17.

Pollutants, the UN Convention to Combat Desertification, and the Minamata Convention on Mercury. All of these conventions have a different number of States parties. Nevertheless, the possibility to have a common financial administration shared between the Pandemic Agreement and the IHR (2005) will depend on the extent to which negotiators manage to achieve synergies in terms of obligations. The nature of financial assistance under article 44 IHR (2005) is similar to that of article 20 of the draft Pandemic Agreement, in so far as both would emphasize the strengthening of disease outbreak and pandemic prevention, preparedness and response capacities. The sources of available financing would likely differ, as the Pandemic Agreement is supposed so far to include, first, a capacity development fund, operational through mandatory and voluntary contributions by Member States as well as funds collected through contracts with pharmaceutical manufacturers within the so-called Pathogen-Access and Benefit Sharing System; and second, an endowment drawing from mandatory and voluntary contributions by Member States and donations and contributions by non-State actors. By contrast, the IHR (2005) so far would rely exclusively upon contributions by States parties and possibly international institutions like the World Bank. As mentioned above for the Pandemic Agreement, so far any discussion on actual amounts to be furnished in the IHR (2005) has yet to take place.

67. The strengthening of core capacities under the IHR (2005) is directly linked to, and will arguably determine, the fate of amendments aimed at enhancing the global health surveillance system. Notification obligations under articles 6 and 7, in particular, will be affected by what States consider to be feasible for them to fulfill. This affects, especially, the introduction of a mandatory public health assessment period after an event has emerged in the territory of a State Party to the IHR (2005). Currently, the statutory period of 24 hours to notify the WHO commences once the event has been assessed, whereas for the latter there is no timeframe. In events such as the H1N1 Influenza pandemic,[73] the West African Ebola crisis[74] and even the COVID-19 pandemic,[75] weeks and even months elapsed since the first emergence of the pathogen and until national authorities were able to detect their spread across the population. Any and all changes in the current legally binding obligations to assess events that may constitute PHEICs and report them promptly to the WHO must take into account the capacities and needs of all current 196 parties to the IHR (2005).

68. Another issue being discussed in negotiations to amend the IHR (2005) is the type of declarations the WHO Director-General, in particular, can make, and on what basis. Under current article 12, the Director-General may declare that an event constitutes a PHEIC. S/he may only do so after consulting an Emergency Committee, a group of experts selected from an IHR Roster with the mandate under article 49 to provide expert advice on the subject matter of whether a particular event may constitute a PHEIC. The final authority to declare or not rests upon the Director-General, who may in theory even disregard the advice of the Emergency Committee. According to practice under the IHR (2005) so far, Director-Generals have paid heed to the Committee advice in the vast majority of cases – with one exception. During the declaration of the multinational spread of monkeypox as a PHEIC in June 2022, the Emergency Committee was divided on whether the Director-General should issue the declaration or not. The majority opinion

[73] *Report of the IHR Review Committee on amendments*, para. 9.
[74] *Report of the IHR Review Committee on Ebola*, para. 59.
[75] Allyn Taylor et al, "Solidarity in the Wake of COVID-19: Reimagining the International Health Regulations" (2020) 396 *The Lancet* 82-83.

considered that the criteria had not been met.[76] The WHO Director-General took the initiative and declared the PHEIC. In the view of some commentators, this represented a governance shift within the WHO.[77]

69. Article 49 IHR (2005) is silent on instances when there is no consensus within Emergency Committees on whether an event should be declared a PHEIC or not. One proposal would be to establish the possibility of Emergency Committee Members to publicly express their dissenting opinions. While none of the proposals explicitly remove the Director-General´s authority to declare a PHEIC under article 12, some of them include the possibility for Emergency Committee members to issue their recommendations to "relevant WHO bodies", including the Standing Committee on Health Emergency Prevention, Preparedness and Response. This proposal was considered by the IHR Review Committee on amendments to be in conflict with the existing procedure for issuing PHEIC declarations.[78]

70. The matter of mechanisms to monitor compliance by States parties is of key importance for the future effectiveness of legal obligations in both the IHR (2005) and the Pandemic Agreement. Which body will have the authority to oversee compliance is still a matter of debate. So far, in proposed amendments to articles 53 and 54 IHR (2005), the creation of a new compliance committee delves upon the issue of who will compose it, and what its terms of reference will be. On the one hand, representatives of States parties could be tasked with being members of such a compliance committee, which would grant it political pedigree in the eyes of governments[79] as it would be them, and not international officials from the WHO, who would oversee each other. On the other hand, another modality would be to have a smaller body of six experts, one from each of the WHO regions, who would be appointed by the WHO Director-General. Still another matter is whether a compliance committee would be an expert advisory body under the authority of the WHO Director-General, or a subsidiary body within the World Health Assembly. When pondering these open issues, the IHR Review Committee emphasized that "form should follow function", that is, the choice of which body is the best suited to supervise compliance should be taken only after the actual reach and scope of current and new obligations under the IHR (2005) has been agreed upon.[80]

71. So far, none of the existing perspectives on compliance has relied upon more stringent enforcement mechanisms, such as sanctions.[81] This is a welcome change from past public statements in media outlets by both the WHO Director-General and national officials.[82] Neither the WHO as an

[76] WHO, *Second meeting of the International Health Regulations (2005) (IHR) Emergency Committee regarding the multi-country outbreak of monkeypox* (23 July 2022) https://www.who.int/news/item/23-07-2022-second-meeting-of-the-international-health-regulations-(2005)-(ihr)-emergency-committee-regarding-the-multi-country-outbreak-of-monkeypox

[77] Clare Wenham and Mark Eccleston-Turner, "Monkeypox as a PHEIC: implications for global health governance" (2023) 400 *The Lancet* 2169-2171.

[78] *IHR Review Committee Report on amendments*, 74-75.

[79] Similar arguments made in Eyal Benvenisti, "The WHO—Destined to Fail?: Political Cooperation and the COVID-19 Pandemic" (2020) 114 *American Journal of International Law* 588-597.

[80] *IHR Review Committee Report on amendments*, 76-77.

[81] Contrary to what was proposed in Johnathan Duff et al, "A global public health convention for the 21st century" (2021) 6 *The Lancet Public Health* e429.

[82] Sarah Wheaton and Carlo Martuschelli, "WHO, Berlin float sanctions if countries suppress information on pandemics", https://www.politico.eu/article/who-berlin-float-sanctions-if-countries-suppress-information-on-pandemics/

organization, nor the current trends in multilateralism broadly speaking, would support the idea of granting a new body or even States parties to both the IHR (2005) and the Pandemic Agreement the power to sanction states whenever non-compliance is at stake. That said, there is still an open point on whether a new body for overseeing compliance would be able to name-and-shame States when they are deemed to be in breach of their obligations under the IHR (2005).

72. One issue closely related to compliance, or lack thereof, is dispute settlement. While the IHR (2005) allow States parties to declare that they wish to submit their differences to binding arbitration at the Permanent Court of Arbitration, it does not grant compulsory jurisdiction. None of the amendment proposals currently being considered would change this. Similarly, good offices mediation by the WHO would not be overhauled. Nevertheless, the organization´s role as an intermediary could be developed further. One of the amendment proposals would allow the WHO to communicate complaints submitted by States parties against the adoption of additional health measures by other States that restrict international travel and trade, a matter currently falling under the purview of article 43 IHR (2005). This does not represent a forum where States can resolve their differences without having to actually invoke dispute settlement. A similar model exists in the World Trade Organization. Its thematic committees hold periodic meetings between Member States in which they discuss specific measures adopted by other States, including instances where they disagree with their adoption and encourage their removal.[83]

73. It is worth shedding light upon the overarching political context both at the multilateral level, as well as across multiple national settings. The multilateral landscape is currently experiencing major upheavals due to ongoing military conflicts and geopolitical tensions, which are unfolding in the principal United Nations bodies. Moreover, the stark North-South divide on issues involving equity and information- and pathogen-sharing persists, with different groups of States being entrenched in their negotiating positions.

74. At the same time, major political transitions across multiple countries have become noticeable. Major elections will take place during the year, including in the United States of America, the Russian Federation and in the European Union. There is a skepticism of resorting to the multilateral landscape for solutions to current challenges, including in those that are literally global in nature like pandemics. Indeed, a few States parties have already opted out of the amendments approved in 2022,[84] which would have shortened the periods for both expressing rejection or reservations to amendments, as well as their entry into force. Considering their rather procedural nature, such rejections are a bad omen for States parties´ willingness to compromise on contentious issues.

75. Moreover, media outlets have reported on how the negotiations on amendments to the IHR (2005) and of a new Pandemic Agreement are being tagged as a lightning rod for stoking fears of loss of national sovereignty.[85] The contents of accusations of loss of sovereignty, however, have no basis on the

[83] World Trade Organization, *WTO Organization Chart*, https://www.wto.org/english/thewto_e/whatis_e/tif_e/org2_e.htm
[84] Marc Daalder, "International warning over Govt´s ´rare´ stance on WHO", *newsroom* (30 January 2024) https://newsroom.co.nz/2024/01/30/documents-detail-international-concern-over-govts-who-policy/
[85] Sophia Tulp, "WHO ´pandemic treaty´ draft doesn´t sign over US sovereignty", *AP Fact Check* (24 February 2023) https://apnews.com/article/fact-check-world-health-organization-pandemic-treaty-212446302001

actual published draft texts for negotiation. It is, moreover, worth underscoring that the Pandemic Agreement has included a so-called "guiding principle" of sovereignty, which restates States´ prerogatives in choosing their public health measures in response to future pandemics. Against this backdrop, the WHO Director-General has repeatedly cautioned against the spread of misinformation related to these two legal instruments.[86] Time will tell whether these warnings are heeded.

76. The Committee considers that some amendments to the IHR are desirable, and perhaps necessary, such as making it more difficult for members to prevent or delay the dissemination of essential technical data, and enshrining stronger and more concrete commitments to support States parties – under clear eligibility criteria – in the strengthening of their minimum core capacities for disease surveillance and outbreak response. The Committee does not consider that attempting to broadly extend the subject matter scope of the IHR negotiations to other areas of member State concern – e.g., the establishment of pharmaceutical manufacturing facilities -- is likely to be successful and may be counterproductive in the sense of inhibiting agreements on IHR amendments that can be accepted by specific States parties with a strong pharmaceutical sector, who are needed to make the system useful.

V. The Human Right to the Social and Environmental Determinants of Mental Health[87]

Introduction: the social determinants of health

77. This section stresses the need to frame the social determinants of mental health in terms of human rights. This approach is grounded in the recognition that compromised mental health is closely associated with the psychosocial impact of structural factors that consistently put some groups in a vulnerable situation. Before doing so, a general introduction will be given to the social determinants of health, and what it means to frame these as a matter of human rights.

78. In March 2005 the World Health Organization (WHO) established a Commission on the Social Determinants of Health (CDSH) with a three year mandate to collect, collate, and synthesize global evidence on the social determinants of health, i.e. the non-medical conditions of life that determine whether or not a person is able to realise a high level of health.[88] The Commission's findings were published in a 247-page report in 2008, which was endorsed by the World Health Assembly in 2009.[89]

79. The CDSH report concluded that '[t]he conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life' are more influential in

[86] "WHO chief warns against misinformation over global pandemic Agreement", *UN News* (23 March 2023), https://news.un.org/en/story/2023/03/1134967; WHO, "Governments continue discussions on pandemic agreement negotiating text", *News Release* (7 December 2023) https://www.who.int/news/item/07-12-2023-governments-continue-discussions-on-pandemic-agreement-negotiating-text

[87] This section on The Human Right to the Social and Environmental Determinants of Mental Health was principally drafted by Siobhan Wills.

[88] WHO, Commission on the Social Determinants of Health (CDSH), Final Report, *Closing the gap in a generation Health equity through action on the social determinants of health,* Note from the chair Michael Marmot

[89] Resolution WHA62.14 (2009).

determining health outcomes overall than any other[90] and that '[s]ocial injustice is killing people on a grand scale.' [91] Moreover:

> unequal distribution of health-damaging experiences is not in any sense a 'natural' phenomenon but is the result of a toxic combination of poor social policies and programmes, unfair economic arrangements, and bad politics. Together, the structural determinants and conditions of daily life constitute the social determinants of health and are responsible for a major part of health inequities between and within countries.[92]

80. The CDSH report set out in detail a range of social and environmental conditions that are prerequisite for the realisation of high level of health, commonly referred to as the social and environmental determinants of health. These determinants include: safe, secure, and fairly paid work and a healthy work–life balance for all; social protection policies that support a level of income sufficient for healthy living for all; policies to counter the gender biases that currently exist in the structures of society; a socially inclusive framework for policy-making; and the establishment of routine monitoring systems for health equity and the social determinants of health ensuring that they are in place, locally, nationally, and internationally.[93]

81. In 2011 the World Conference on Social Determinants of Health adopted the Rio Political Declaration on Social Determinants of Health which recognised that 'the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition' and expressed a global 'determination to achieve social and health equity through action on social determinants of health and well-being by a comprehensive intersectoral approach.'[94] The Declaration set out seven pages of commitments to address global inequities in access to and enjoyment of the social determinants of a high level of health.[95] The Rio Declaration was endorsed by the World Health Assembly.[96] A World Report on the Social Determinants of Health is due to be published in 2024.[97] However, despite these commitments and those made in subsequent World Health Assembly meetings, the recommendations put forward by the CDSH have not yet been widely or effectively translated into policy or implemented in practice. [98] This is acknowledged to have been a key factor in the inequitable impact of the COVID pandemic.[99]

82. The international human rights community has reached similar conclusions to those reached by social medicine communities as to the critical importance of the social and environmental determinants

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[90] CDSH, *Closing the gap in a generation Health equity through action on the social determinants of health,* (n. 1*)* Executive Summary, page 1.
[91] Ibid, Preamble.
[92] Ibid, page 1.
[93] Ibid, pages 4-30.
[94] Rio Political Declaration on Social Determinants of Health, 21 October 2011, paras 3 and 1.
[95] Ibid, para. 10 and throughout the text.
[96] Resolution WHA69.11 (2016).
[97] https://www.who.int/initiatives/action-on-the-social-determinants-of-health-for-advancing-equity/world-report-on-social-determinants-of-health-equity
[98] U. Gopinathan and K. Buse, 'How can WHO transform its approach to social determinants of health?' *BMJ* 2022, page 376.
[99] Ibid; Director General WHO, Report on the Social determinants of health, EB148/24, 6 January 2021.

of health to reducing health inequities. Crucially, under human rights law enjoyment of the social and environmental determinants of a high level of health is a legal right and has been formally recognised as such for over twenty years.[100] States can and should be held accountable for failure to implement policies necessary to advance protection of the right to enjoy the social and environmental determinants of health.[101] However, whilst the 2008 CDSH report stressed that the human right to health 'presents a compelling case for action on the social determinants of health'[102] very little of it specifically addressed how the international human rights framework might be harnessed to try and achieve the milestones set out in it. Paul Hunt, UNSR on the right to health from 2002-2008, commented that 'Despite the multiple, dense connections between social determinants and human rights, the report's human rights content is disappointingly muted. The human rights analysis is not absent, but underdeveloped and understated.'[103] Fifteen years on it is still the case that the potential benefits of a more focused interaction between social medicine communities and human rights communities remains underutilized.

83. In 2000, the Committee on Economic Social and Cultural Rights (CESCR) formally stated that whilst the International Covenant on Economic, Social and Cultural Rights (ICESCR) provides for progressive realization of the right to health due to the limits of available resources, State parties have immediate obligations to take 'deliberate, concrete and targeted' steps towards the full realisation of the right of everyone to enjoy the social and environmental determinants of a high level of health.[104] The CESCR added that 'Judges and members of the legal profession should be encouraged by States parties to pay greater attention to violations of the right to health in the exercise of their functions.'[105]

84. Successive UN Special Rapporteurs on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, (henceforth UNSRs on the right to health), – including Paul Hunt (2002-2008), Dainius Puras (2014-2020) and the current rapporteur Tlaleng Mofokeng (2020-) – have highlighted the importance of harnessing human rights law in order to implement the WHO recommendations on the social and environmental determinants of health. UN treaty-monitoring bodies and Special Procedures have clearly articulated in detailed formal documents the nature, scope and content of states' obligations to respect, protect and fulfil the right of everyone within their jurisdiction to enjoy the social and environmental determinants of health. These reports have been presented to the General Assembly, published on UN websites and incorporated into law textbooks.

85. Despite this, for many marginalised communities, groups and individuals the right to enjoy the social and environmental determinants of a high level of health remains a theoretical right only. Regrettably, it is still the case that States parties to the ICESCR are rarely held to account by judges or members of the legal profession, or even by human rights monitoring bodies, for failure to take 'deliberate,

[100] CESCR General Comment 14 *The Right to the Highest Attainable Standard of Health (Art. 12)* E/C.12/2000/4, 11 August 2000.
[101] Ibid.
[102] CDSH, *Closing the gap in a generation Health equity through action on the social determinants of health,* (n. 1*)* Final Report, page173.
[103] P. Hunt, (2009) 'Missed opportunities: Human rights and the Commission on Social Determinants of Health,' 16 *Global Health Promotion*, 1, 36, at 36. See also A. Chapman, (2011) 'Missed Opportunities: The Human Rights Gaps in the Report of the Commission on Social Determinants of Health', 10 *Journal of Human Rights* 2, 132.
[104] CESCR General Comment 14 *The Right to the Highest Attainable Standard of Health (Art. 12)*, (n 13.) para. 30.
[105] Ibid, para. 61.

concrete and targeted' steps towards the full realisation of the right to the social and environmental determinants of health. This is particularly true of the right to enjoy the social and environmental determinants of mental health. As Dr. Dainius Puras, who was UNSR on the right to health from 2014 to 2020, stated in his final report:

> As the third decade of the millennium begins, nowhere in the world has achieved parity between mental and physical health and this remains a significant human development challenge. An important message within that collective failure is that without addressing human rights seriously, any investment in mental health will not be effective.[106]

State Parties' Obligations to Respect, Protect and Fulfil the Social and Environmental Determinants of Health under International Human Rights Law

86. Every State has ratified at least one human rights treaty recognizing the right to health.[107] Foremost among the many international human rights treaties that recognise health as a human right are the International Covenant on Economic, Social and Cultural Rights (ICESCR, 1966) with 171 state parties and the Convention on the Rights of the Child (CRC, 1989) with 196 state parties. The ICESCR recognises that all human beings, and the CRC recognises that all children, have a right to enjoy the 'highest attainable' standard of physical and mental health.[108] Similar provisions are set out in the 1965 International Convention on the Elimination of All Forms of Racial Discrimination (ICERD), the 1979 Convention on the Elimination of All Forms of Discrimination against Women (CEDAW), and the 2006 Convention on the Rights of Persons with Disabilities (CRPD).

87. The right to health is also recognised in regional treaties. The Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social, and Cultural Rights provides that 'Everyone shall have the right to health, understood to mean the enjoyment of the highest level of physical, mental and social well-being' and that 'in order to ensure the exercise of the right to health, the States Parties agree to recognize health as a public good.'[109] States parties are explicitly required to ensure 'satisfaction of the health needs of the highest risk groups and of those whose poverty makes them the most vulnerable.'[110] Article 11 states that 'everyone shall have the right to live in a healthy environment[111] and 'States Parties shall promote the protection, preservation, and improvement of the environment.'[112] The right to health is also explicitly recognized in the African Charter on Human and Peoples' Rights which has been ratified by all members of the African Union and also in the African Charter on the Rights and Welfare

[106] *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, (A/HRC/44/48), 15 June 2020, para. 1.
[107] UN Office of the High Commissioner for Human Rights (OHCHR), *Fact Sheet No. 31, The Right to Health*, June 2008, No. 31, page 1; Committee on Economic Social and Cultural Rights (CESCR) General Comment 14 *The Right to the Highest Attainable Standard of Health (Art. 12)* E/C.12/2000/4, 11 August 2000.
[108] International Covenant on Economic, Social and Cultural Rights (ICESCR), Article 12; Convention on the Rights of the Child (CRC,) Article 24.
[109] Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social, and Cultural Rights, 1988, Article 10
[110] Ibid
[111] Ibid
[112] Ibid

of the Child. The former states that 'Every individual' and the latter 'Every Child' shall have the right 'to enjoy the best attainable state of physical and mental health.'[113] The (Revised) European Social Charter adopted under the umbrella of the Council of Europe recognizes the right to protection of health and the right to social and medical assistance.[114]

88. Clearly a right to a high level of health can only be realised if the conditions necessary to enjoy high levels of health are met. Given the logicality of this premise it is unsurprising that there is a consensus amongst human rights experts, human rights treaty-monitoring bodies and UN special procedures that the conditions necessary for the realisation of a high level of health are a core element of the right to health. As the CESCR stated in its General Comment 14 on *The Right to the Highest Attainable Standard of Health*, the right to health is 'an inclusive right extending not only to timely and appropriate health care but also to the underlying determinants of health.'[115] In the two decades since General Comment 14 was promulgated, the CESCR's assessment of the scope of the right to health and of states' obligations and of potential violations has been reiterated and expanded upon over and over by human rights bodies and experts and in human rights law textbooks.[116] Today it is axiomatic within the human rights law field that the social and environmental conditions of life that are necessary to realise a high level of health are an integral component of the right to health and that the right of everyone to enjoy the social and environmental determinants of health - without discrimination on the basis of race, ethnicity, sex, gender, social condition, disability or any other prohibited ground - is as enforceable and justiciable as any other economic, social or cultural human right.

89. In the early days of the development of human rights law, economic, social and cultural rights were commonly viewed as non-justiciable (in contrast to civil and political rights) because implementing them involved political decisions regarding the distribution of economic resources. This view has long since fallen into desuetude. UN human rights treaty monitoring bodies and special procedures have made it clear that states have a tripartite obligation to respect, protect and fulfil all the human rights set out in the treaties to which they are party, regardless of their economic, social and cultural or civil and political character. As explained by the Office of the High Commissioner for Human Rights (OHCHR) on the UN website:

> By becoming parties to international treaties, States assume obligations and duties under international law to respect, to protect and to fulfil human rights. The obligation to respect means that States must refrain from interfering with or curtailing the enjoyment of human rights. The obligation to protect requires States to protect individuals and groups against human rights abuses. The obligation to fulfil means that States must take positive action to facilitate the enjoyment of basic human rights.[117]

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[113] African Charter on Human and Peoples' Rights, 1981, Article 16; African Charter on the Rights and Welfare of the Child, 1990, Article 14.

[114] (Revised) European Social Charter, 1961, Articles 11 and 13.

[115] CESCR General Comment 14 *The Right to the Highest Attainable Standard of Health (Art. 12)* (n 13), paras. 4 and 11.

[116] E.g., B. Saul, D. Kinley, J. Mowbury, *The International Covenant on Economic, Social and Cultural Rights:Commentary, Cases and Materials* (Oxford University Press 2014), at 986

[117] https://www.ohchr.org/en/instruments-and-mechanisms/international-human-rights-law.

90. In General Comment no. 2 on *The nature of States parties' obligations* to uphold the ICESCR, the CESCR stated that:

> even where the available resources are demonstrably inadequate, the obligation remains for a State party to strive to ensure the widest possible enjoyment of the relevant rights under the prevailing circumstances. Moreover, the obligations to monitor the extent of the realization, or more especially of the non-realization, of economic, social and cultural rights, and to devise strategies and programmes for their promotion, are not in any way eliminated as a result of resource constraints.[118]

Addressing the right to health specifically the CESCR stated in 2000 that 'the Covenant proscribes any discrimination in access to' the 'underlying determinants of health, as well as to means and entitlements for their procurement.'[119] These points were reiterated by Paul Hunt, who was UN Special Rapporteur on the right to health from 2002-2008. In his 2004 report he reminded states that 'The right to health encompasses the underlying determinants of health, including its social and psychosocial determinants.'[120] He emphasised that State's obligations to respect, protect and fulfil the right to enjoy these underlying determinants 'include progressive realization, obligations of immediate effect, maximum available resources and international assistance and cooperation.'[121] Moreover the human right to health, including its underlying determinants,'requires that all duty-holders be held to account for their conduct,' e.g., in an 'examination by a human rights treaty body of a State's periodic report' and in examinations by special rapporteurs when conducting country missions.[122]

91. The current UNSR on the right to health, Tlaleng Mofokeng, affirms that 'accountability is essential if the right to health is to be more than a mere aspiration' explaining that:

> Accountability's constituent components of monitoring, review and redress help to identify where progress has been made and where progress is lacking. In addition, accountability constitutes a way for duty bearers to explain their actions and make adjustments. It also provides a means for rights holders to engage in the promotion and protection of their rights with those responsible for the realization of rights, and it allows rights holders to seek redress for violations where they have occurred.[123]

This means that if a community is denied enjoyment of a recognised underlying determinant of health (e.g., access to clean water) and the state fails to take effective action to remedy this, the state will be in violation of its obligations to respect the right to health of the residents of that community. Lawyers planning to bring an action against the state on behalf of residents of communities would need to be able to present information as to the nature and content of the underlying determinant that is inaccessible to

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118 CESCR, General Comment 3, The nature of States parties' obligations (Fifth session, 1990), U.N. Doc. E/1991/23, annex III at 86 (1991), paragraph 11.

[119]CESCR, General Comment No. 14 on *The Right to the Highest Attainable Standard of Health (Art. 12)* (n 13), para. 18.

[120] Report by the UN Special rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Paul Hunt A/59/422, 8 October 2004, paras. 19 and 26.

[121] Ibid, paras. 19 and 26.

[122] Ibid, paras. 36 and 40.

[123] Report by the UN Special rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Tlaleng Mofokeng A/HRC/47/28, 7 April 2021, para. 36.

the community bringing the claim (e.g., as to what level of purity constitutes 'clean water'). The CESCR has said that States are required:

> To adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population; the strategy and plan of action shall be devised, and periodically reviewed, on the basis of a participatory and transparent process; they shall include methods, such as right to health indicators and benchmarks, by which progress can be closely monitored;[124]

These obligations apply to all aspects of health and the CESCR has stressed that 'the process by which the strategy and plan of action are devised, as well as their content, shall give particular attention to all vulnerable or marginalized groups.'[125]

92. However for many racially and socially marginalised communities - and for many discriminated groups e.g., women, LGBTQI, refugees and migrants - the right to the living conditions necessary to realise a high level of health is severely compromised due in part to discriminatory and sometimes violent forms of social, political and economic control resulting in high levels of stress that are known to have the potential to severely compromise both mental and physical health.[126] As UNSR Tlaleng Mofokeng reports:

> adverse health outcomes are not only about individual predisposition or genetics, but also about oppressive systems that established racial hierarchies, which enable enduring social discrimination beyond formal colonial structures and continue to perpetuate health inequalities.[127]

Moreover 'the health consequences of racism and discrimination can be persistent and passed from one generation to the next through the body's "biological memory" of harmful experiences.'[128]

<u>The Human Right to the Underlying Determinants of Mental Health</u>

93. In his annual reports Dainius Puras (who was UNSR on the right to health from 2014-2020) repeatedly stressed the importance of improving access to and enjoyment of the underlying determinants of health, especially mental health which he made a core focus of his mandate. Noting the strength of the findings of the CDSH and subsequent WHO health action plans, he expressed concern that much of this work on the underlying determinants of health has not been framed in terms of human rights, commenting on this as 'a missed opportunity.'[129]

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[124] CESCR, General Comment No. 14 on *The Right to the Highest Attainable Standard of Health (Art. 12)* (n 13), para. 43 (f).
[125] Ibid.
[126] A. Geronimus, *Weathering: The Extraordinary Stress of Ordinary Life on the Body in an Unjust Society* (Virago 2023), page 3.
[127] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Tlaleng Mofokeng, A/HRC/47/28, 7 April 2021, para. 26.
[128] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Tlaleng Mofokeng, A/77/197 20 July 2022, para 7.
[129] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Dainius Puras, A/HRC/41/34, 12 April 2019, para. 3 citing his earlier report A/71/304, 5 August 2016.

94. In his 2017 report Dainius Puras expressed concern that 'the widening of disease boundaries has medicalized normal human experience (e.g., "social anxiety disorder"), resulting in expanded markets for treatment and diverting attention away from the cultural, socioeconomic and political context of emotional distress.'[130] In his 2019 report he expressed frustration that global efforts to improving responses to mental health challenges 'are still dominated by targeting individuals and their mental health conditions, such as calls to scale up services that provide treatment' rather than on addressing the underlying determinants of mental health.[131] He reminded states that right to health requires 'that no one be denied access to a healthy psychosocial environment to sustain their well-being, and that everyone be entitled to a life with respect, social connection, equal opportunities and dignity.'[132] Therefore:

> States must facilitate, provide and promote conditions in which mental health and well-being can be realized; that requires the provision of interventions that can protect populations from key risk factors for poor mental health. It requires action outside the traditional health sector in homes, schools, workplaces and communities. It also requires the therapeutic focus (alongside structural efforts by duty bearers) to extend beyond the individual to social healing, community strengthening and the promotion of a healthy society.[133]

95. This report sets out 19 pages of observations explaining in detail the content and scope of the social and environmental determinants of mental health and states obligations to respect, protect and fulfil them. This includes taking progressive action to reduce 'key risk factors, such as violence, disempowerment and social exclusion.'[134] Paragraph 26 of the report states that:

> Determinants of mental health and measures taken to promote mental health must be accessible without discrimination, particularly for those in vulnerable situations. This includes physical and economic accessibility to determinants, such as non-violent school and home environments, healthy workplaces that respect the full spectrum of labour rights, and a robust and active civil society supporting the struggles of those furthest behind.[135]

paragraph 41 of the report states that:

> Inequality is a key obstacle to mental health globally. Many risk factors for poor mental health are closely associated with inequalities in the conditions of daily life…and the psychosocial impact of structural factors that consistently put some groups in a vulnerable situation…The outcomes of structural inequality not only have a negative individual impact, but are also detrimental to societal health, as they break down key

[130] Toebes, B., & Puras, D. (2017). Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/72/137, 14 July 2017, para. 71.
[131] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Dainius Puras, A/HRC/41/34, 12 April 2019, para. 6.
[132] Ibid, para. 5
[133] Ibid, para. 67
[134] Ibid, para. 41
[135] Ibid, para. 26.

protective factors, such as trust, social inclusion and the healthy development of young people.[136]

In his 2020 annual report he reminded member States that they 'have a tripartite obligation to respect, protect and fulfil the right to mental health, including the underlying determinants to promote mental health'[137] and that 'action that focuses only on strengthening failing mental health-care systems and institutions is not compliant with the right to health.' [138]

96. Professor Puras' reports, and those of his predecessor Paul Hunt, consistently emphasise that the right to health encompasses obligations on states to address the social and environmental determinants of health, including mental health - and that compromised mental health is 'closely associated' with 'the psychosocial impact of structural factors that consistently put some groups in a vulnerable situation.'[139] UNSR Tlaleng Mofokeng has reiterated these observations and developed them further to specifically address the impact of coloniality and the legacy of slavery on the right to health. She has produced reports on, among other things, the impact of violence on health, the impact of racism on health and the impact of inequalities in access to food and nutrition on the right to health.

97. All three UNSRs on the right to health – Hunt, Puras and Mofokeng – have focused their attention primarily on addressing the underlying determinants of health rather than on a biomedical model. Taken together, over the last twenty years UN treaty-monitoring bodies and successive UNSRs on the right to health have produced a wealth of detail setting out States legal obligations under human rights law to respect, protect and fulfil the right to the social and environmental determinants of health, including mental health – set out in lengthy reports fully referenced to legal sources and academic analysis.[140]

98. However, all of this is largely ignored in practice, even by UN human rights monitoring bodies themselves, when it comes to holding states accountable under the periodic review process. To date there has been very little attempt by human rights treaty monitoring bodies to question states as to whether they have monitored the impact of their security, social, economic or environmental policies on the right of everyone to enjoy the social and environmental conditions necessary to realise a high level of physical and mental health, or to require States to produce disaggregated data on how these policies impact on the mental health of different communities, groups, genders and ages. Nor has there been any significant attempt to require States to reform state policies that are known to pose high risks to mental health - e.g., violence by police or violence by nonstate actors that is effectively condoned by the State through failure to respond - in order to meet their obligations to respect, protect and fulfil the right to the social and environmental determinants of mental health. As a result the right to the social and environmental determinants of mental health currently exists in theory only, at least for marginalised communities and groups, which are the ones most exposed to the major risk factors for compromised mental health.

[136] Ibid, para. 41.
[137] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Dainius Puras, A/HRC/44/48, 15 April 2020, para. 18.
[138] Ibid, para. 10.
[139] Ibid, paras. 41 and 4.
[140] For an elaborate study on the right to mental health see Natalie Abrokwa, *The Right to Mental Health: A human rights approach*, Intersentia human rights series No. 100, 2023.

Conclusion

99. It is widely accepted within both the social medicine and human rights communities that everyone in the world has a right to a high level of physical and mental health and that mitigating the gross inequities in enjoyment of this right globally will only be possible through sustained targeted action to ensure equality in access to and enjoyment of the right to the social and environmental determinants of health. Human rights treaty-monitoring bodies and special rapporteurs have stressed that whilst realisation of the right to the social and environmental determinants of a high level of health may be achieved progressively, State parties have immediate obligations to take 'deliberate, concrete and targeted' steps towards its full realisation. These steps include monitoring of the State's progress on ensuring equal enjoyment of the right to health without discrimination, including through the production of disaggregated data on all prohibited grounds of discrimination e.g., race, ethnicity, sex, gender, social status, age, and disability and on potential differences in enjoyment of the right to health across different communities, e.g., rural traditional communities, including Indigenous and Quilombola communities, who have their own distinct culture and beliefs that are important for their mental and physical health.

100. The Committee stresses that if progress is to be made States should be held to account by the responsible human rights treaty bodies for any lack of progress in achieving these goals. It should be a standard expectation that when States face periodic review of their compliance with their obligations under the ICESCR, CRC, or any other treaty that recognises the right to health, they must report on their progress on advancing equal enjoyment of the right to the social and environmental determinants of health to everyone within their jurisdiction and States should expect to be questioned in depth by the relevant treaty-monitoring body on the actions they have taken to achieve this. Currently this is not happening, at least not in a sustained and reliable manner.

In particular States should be questioned, e.g., in periodic review by treaty-monitoring bodies or in-country review by special rapporteurs, as to the steps they have taken to reduce known risks to health, such as violence, whether it is perpetrated by the State or condoned by the State through inaction, whether it is armed violence, or sexual violence, or violence against children or structural violence.

101. If these processes were implemented as routine in all reviews that pertain to monitoring compliance with the right to health, it would enable civil society and lawyers representing marginalised communities that are currently not benefitting from equal enjoyment of the right to the social and environmental determinants of health to bring these to the attention of state courts and national, regional and international human rights tribunals. This is especially important in situations where communities are being subjected routinely to known risk factors for compromised health such as racialised police violence, or the violence experienced by Indigenous and Quilombola communities in the context of the ecowars in the Amazon, Cerrado and other areas of Brazil that are home to traditional communities whose lifestyle is under threat from violent invasions by agribusiness, mining and logging interests.

102. These steps offer a means of pressuring States to take action to respect, protect and fulfil the right to the social and environmental determinants of health to communities, groups and individuals within their jurisdiction. Doing so would not only advance realisation of the right to human health but also the

realisation of other human rights and even of better planetary health, given that all human rights are indivisible, interdependent, interrelated and inalienable.[141]

103. The Committee concludes that the right to health embraces State obligations to address the social and environmental determinants of health, including mental health. And, that compromised mental health is strongly connected with the impact of structural factors putting individuals in vulnerable situations. Human rights treaty bodies should question States in depth on their progress on advancing equal enjoyment of the right to the social and environmental determinants of health to everyone within their jurisdiction.

VI. The Interplay of Foreign Investment and Global Health in International Investment Law: Support for Mental Health[142]

104. Investment and health are separate fields of international law and are regulated by distinct legal instruments, whether binding or non-binding. The Covid-19 pandemic impacted on international investment law under three main perspectives: first, as a potential reason for conflicts of interest and disputes before international investment treaty-based arbitral tribunals between host States and foreign investors, due to a host State's domestic restrictive regulatory measures aimed at the control and prevention of the spread of the contagion; second, as a further reason for keeping typical open-ended definitions of investment in international investment treaties, rather than limiting their scope of application to sustainable investments, in terms of investments having a qualitative substantial impact on a host State's local social development, including the safeguard of public health; and third, as a boost for investments, both public and private, not only in the health sector, but also in health determinants, like clean air, safe food and water, as well as rural and urban redevelopment.

105. The design of a complementary interplay between international legal instruments on health and those on investment – beyond diversification typical of international law – could be an appropriate tool for not only preventing conflict of interests, respectively public and private ones, and arbitral cases, but also facilitating special investments in health protection.

106. Considering the 'social determinants of mental health and related subject matter', several international organizations, such as the World Bank and WHO, underlined the importance of 'investing in mental health', on account of the burden of mental health and its social costs, even before the Covid-19 pandemic. In 2004 WHO published a comprehensive report on this topic to invite States to employ special human, financial and technical resources to prevent and treat mental disorders, particularly depression, alcohol and drug abuse, as these could affect people in any country, whether developed or not.[143] Besides, WHO focused on the relationship between mental health and poverty because mental disorders, by affecting social capital, undermine poverty alleviation strategies and hinder social development. This can also matter from an intergenerational perspective, as mental disorders affect family contexts, by bringing about child and adolescent developments problems, and then impacting on the participation of new

[141] https://www.ohchr.org/en/what-are-human-rights.

[142] This section on The Interplay of Foreign Investment and Global Health in International Investment Law: Support for Mental Health was principally drafted by Pia Acconci.

[143] See, in particular, WHO, *Investing in Mental Health*, 2004, especially 21-24 (available online).

generations in the society. The Pan-American Health Organization also underlined the importance of special human, financial and technical resources, by showing the need of policy measures, such as the reallocation of investment from large hospitals to primary health care and community mental health care.[144]

107. The Covid-19 pandemic exacerbated mental disorders and highlighted their impact on the effective realization of sustainable development, in terms of social development. During this pandemic, international technical assistance and special actions have been required to cope with this issue under an equity-based approach. Specialized international organizations continue to call for dedicated investments in mental health. OECD highlighted the impact of the pandemic on both physical and mental health through research activities, by underlining the need of special investments in this respect, but, as other international organizations, without specifying what investments might be more adequate than others.[145] Hence, the Covid-19 pandemic has brought about one further specific issue, from a narrow international law standpoint, that is to understand what foreign investments would be strategic for the protection of mental health and, for this reason, should be promoted by international investment agreements.

108. Foreign private investment projects in local development would be an appropriate tool for the safeguard of mental health, provided that they take the protection of the interests of the community and territory involved in the implementation of the investment into account. In particular, mental health of local peoples would benefit from sustainable foreign private investments, as these are expected to improve local living conditions. The emergence from Covid-19 has showed the need of a drastic renewal in the utilization of large portions of land, degraded areas in urban suburbs and/or wastelands places. Rural and urban renewal from a *pro*-sustainable development standpoint appeared to be desirable, as open-air recreational and social activities were allowed during the second and third waves of the Covid-19 pandemic, but many places were ill-suited for this purpose, mostly because of abandonment and environmental degradation. Foreign private investments in the regeneration of numerous abandoned rural and urban spaces or locations, including small villages or mountain communities subject to depopulation phenomena, would improve living conditions, contribute to open-air socialization and thus to mental health.

109. This would be in line with what stated by the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Dainius Puras, in his annual reports. He has reiterated that diseases are mainly "managed through medical treatment, rather than through addressing the underlying, social, psychosocial and environmental conditions which contribute to poor health".[146]

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[144] See, in particular, PAHO, *Plan of Action on Mental Health 2015-2020*, 3 October 2014, CD53/8, Rev. 1, especially paragraphs 1, 18, 31, 33, 54 (available online).

[145] For instance, see OECD, *Ready for the Next Crisis? Investing in Health System Resilience*, Paris, 23 February 2023; OECD, *COVID-19 and Well-Being: Life in the Pandemic*, Paris, 22 February 2022; OECD, *Tackling the Mental Health Impact of the COVID-19 Crisis: an integrated, whole-of-society response*, Paris, 12 May 2021 (all these publications are available online).

[146] See, in particular, the Reports of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Dainius Puras, A/HRC/41/34, 12 April 2019, para. 6; and A/75/163, 16 July 2020, para. 46; as well as his report on *A human rights-based global agenda for mental health and human*

110. A further revision of the legal layout of 'new generation' investment treaties would be desirable to enhance the interplay of health and foreign private investment in international law.

VII. Committee Work Program

In regards to its future work program the Committee intends: (1) to follow and analyze negotiation of new instruments at the WHO, including any potential developments regarding implementation; (2) to address the interrelationship between climate change and health, and the role of international law in addressing the mitigation of and response to health impacts of climate change, including 'planetary health'; (3) to continue its research regarding the role of artificial intelligence in the public health sector; and (4) to explore the complex interface between the UN drug control system and human rights.

rights, A/HRC/44/48, 15 April 2020, especially paragraphs 32-33. See also the *Analytical study on the relationship between climate change and the human right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, Report of the Office of the UN High Commissioner for human rights, A/HRC/32/23, 6 May 2016.