



International Economic Law Clinic

A NEW TREATY ON PANDEMICS: SOME KEY ISSUES FROM A GLOBAL SOUTH PERSPECTIVE

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Glossary

§	Section
¶(¶)	Paragraph(s)
ABS	Access and benefits sharing of pathogens
ACT	Access to COVID-19 Tools
AMC	Advance Market Commitment
APAs	Advance purchase agreements
CBD	Convention on Biological Diversity (i.f. 29 December 1993)
CEPI	Coalition for Epidemic Preparedness Innovations
Constitution of the WHO or WHO Constitution	Constitution of the World Health Organization (1946), UNTS I-221
COP	Conference of the Parties
COVAX	COVID-19 Vaccines Global Access
FCTC	WHO Framework Convention on Tobacco Control
GAVI	The Vaccine Alliance
GDP	Gross Domestic Product
GISRS	Global Influenza Surveillance and Response System
GSD	Genetic sequence data
IHR	International Health Regulations (2005) (i.f. 15 June 2007)
ILO	International Labor Organization
IPPPR	The Independent Panel for Pandemic Preparedness and Response
Nagoya Protocol	Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits (i.f. 12 October 2014)
PHEIC	Public Health Emergency of International Concern
PIP Framework	Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and other Benefits
PPE	Personal protective equipment

Review Committee	Review Committee on the Functioning of the International Health Regulations
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures (i.f. 1 January 1995)
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights (i.f. 1 January 1995), amended through the Protocol of the 6 December 2005 (i.f. 23 January 2017)
US	United States of America
WGPR	Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies
WHA	World Health Assembly
WHO	World Health Organization
WTO	World Trade Organization

1. Introduction

Nearly two years after the outbreak of the COVID-19 pandemic, the devastating socio-economic consequences it has caused in all corners of the world are undeniable. Indeed, today it can be noted that after the first biennium, both the effects of the virus and of the response measures adopted to face it have had asymmetric consequences to the detriment of the least favored societies, aggravating the previously existing inequalities. Considering the likely occurrence of future pandemics and in the light of the weaknesses of the international health system, the international community is now discussing major reforms.

In this context, the World Health Organization's (**WHO**) officials, health regulation experts and governments have proposed the negotiation of an international treaty on pandemic preparedness and response and/or the amendment of the existing International Health Regulations (2005) (**IHR**). Given the prevailing situation and the multiple interests at stake, any negotiation on both the form and the content of the necessary reforms is expected to be arduous.

This paper addresses, first, what reforms may be primarily implemented through the adoption of a new international convention under the terms of Article 19 of the Constitution of the World Health Organization (**Constitution of the WHO** or **WHO Constitution**). Second, some of the issues that may be considered key priorities on the agenda of the Global South are discussed. This analysis is not exhaustive; it only addresses a few selected issues and not all that may be relevant to respond to the needs of the countries of the South. The following four cross-cutting questions in relation to each of the six selected issues are examined: (i) Why is each issue relevant for the Global South, (ii) where it is currently regulated, (iii) what are the problems it entails, and (iv) how could a new instrument address them.

The purpose of this paper is to provide elements for the ongoing discussions having in view the lessons learned from the COVID-19 pandemic

and identifying those interests that cannot be overlooked for the sake of the most disadvantaged. Without forgetting that the COVID-19 pandemic is not over, it is argued that the ultimate goal of a new instrument on preparedness and response to pandemics should be to achieve a substantial improvement in cooperation mechanisms at the global level, particularly in a way that allows WHO members States to address pre-existing inequities and the special needs of developing and least developed countries.

2. Background

2.1 The *status quo* is not acceptable to anyone

*"The status quo is not acceptable to anyone".*¹ This clear statement is the very first key starting point noted in the recently published Zero Draft Report of the Member States Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies, and succinctly summarizes the state of affairs described before by multiple international agencies, experts and State representatives when analysing the international health governance in the light of the gaps and shortcomings exposed by the COVID-19 pandemic.²

The current scenario reveals that, in view of the dramatic events the whole world has faced and given that the COVID-19 crisis is not over, everyone

¹ WHO (2021), Zero Draft Report of the Member States Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies, A/WGPR/4/3, ¶¶ 2, 17; The Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies was established in order to work in accordance with the mandates derived from resolutions WHA 74.7 (2021) and WHA 74.16 (2021). A revised version of this Zero draft report published on 12 November 2021 states that "the status quo is unacceptable" (WHO (2021) Draft Report of the Member States Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies, A/WGPR/5/2, ¶ 21). The final version of the Report (which is being discussed at the time of this writing) will be presented at the Special session of the World Health Assembly to be held from 29th November to 1st December 2021 (A74/A/CONF./7, 25th May 2021).

² Independent Panel for Pandemic Preparedness and Response (2021), "COVID-19: Make It the Last Pandemic"; WHO (2021), Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response; Velázquez, G. and Syam, N. (2021), A New WHO International Treaty on Pandemic Preparedness and Response: Can It Address the Needs of the Global South?, South Centre Policy Brief 93; G20 (2021) G20 Rome Leader's Declaration, 4-7.

in the international community seems to agree that the shortcomings in global public health governance cannot be ignored any longer. Substantial changes must be urgently discussed and effectively implemented, since "*the question is not if, but when*"³ the next pandemic will occur.

At the time of this writing, almost two years have passed since the WHO's Country Office in the People's Republic of China picked up a media statement by the Wuhan Municipal Health Commission on cases of an atypical viral pneumonia in that city (31 December 2019), which later turned out to be caused by the COVID-19 virus. By the end of January 2020, the WHO Director-General declared the new coronavirus outbreak a Public Health Emergency of International Concern ('**PHEIC**'), WHO's highest level of alert, and a few weeks later he characterized it as a 'pandemic'.⁴

By November 2021, more than 5 million people had passed away due to the virus,⁵ while tens of millions of people around the world had lost their jobs⁶ and more than a hundred million people were pushed into extreme poverty as a consequence of the crisis unleashed by COVID-19 and some of the corresponding policy responses.⁷

³ WHO (2021), "COVID-19 shows why united action is needed for more robust international health architecture" [<https://www.who.int/news-room/commentaries/detail/op-ed---covid-19-shows-why-united-action-is-needed-for-more-robust-international-health-architecture>, last accessed on 05/11/2021].

⁴ WHO (2021), "Timeline: WHO's COVID-19 response" [https://www.who.int/emergencies/diseases/novel-coronavirus-2019/interactive-timeline?gclid=Cj0KCQjwrJOMBhCZARIsAGEd4VFInfnI4TOM0YDBi6L1aET9DApRBywAJvpNbWWMkrbAt0YssrjhuwaAiFLEALw_wcB#, last accessed on 05/11/2021].

⁵ Ritchie, H. *et al* (2020), "Coronavirus Pandemic (COVID-19)", OurWorldInData.org [<https://ourworldindata.org/coronavirus-data>, last accessed on 05/11/2021].

⁶ ILO (2021), "ILO Monitor: COVID-19 and the world of work - Seventh edition Updated estimates and analysis", [https://www.ilo.org/wcmsp5/groups/public/@dgreports/@dcomm/documents/briefingnote/wcms_767028.pdf last accessed on 03/11/2021]; ILO (2021) "Slow jobs recovery and increased inequality risk long-term COVID-19 scarring", [https://www.ilo.org/global/about-the-ilo/newsroom/news/WCMS_794834/lang-en/index.htm last accessed on 03/11/2021].

⁷ Independent Panel for Pandemic Preparedness and Response (2021), "COVID-19: Make It the Last Pandemic"; World Bank (2021), "Projected poverty impacts of COVID-19 (coronavirus)", [<https://www.worldbank.org/en/topic/poverty/brief/projected-poverty-impacts-of-COVID-19> last accessed on 29/10/2021].

As this traumatic experience has exposed, the shortcomings of the current situation can be characterized as systemic. All the subsequent stages of prevention, preparedness, detection, and response to the outbreak of a PHEIC following its declaration, have shown serious flaws, which resulted in the COVID-19 pandemic having even more devastating effects than it could have had.⁸

Indeed, the international governance of the health system, despite its remarkable interdependence and complexity, proved to be fragile. It failed to prevent foreseeable outbreaks,⁹ to respond in a timely, proportionate and effective manner,¹⁰ and to ensure solidarity in facing the social and economic costs of the pandemic.¹¹

Paradoxically –and dramatically–, the international community is still failing today to distribute vaccines rapidly and equitably, although it is well known that that they are the single most important resource for turning COVID-19 into an endemic disease.¹² What the Independent Panel for Pandemic

⁸ Burci, G. L. *et al.* (2021) “Envisioning an international normative framework for pandemic preparedness and response: issues, instruments and options”, Global Health Centre - The Graduate Institute of International and Development Studies, 4-5., Independent Panel for Pandemic Preparedness and Response (2021) ‘COVID-19: Make It the Last Pandemic’, 36.

⁹ Independent Panel for Pandemic Preparedness and Response (2021) ‘COVID-19: Make It the Last Pandemic’, 15-20.

¹⁰ Independent Panel for Pandemic Preparedness and Response (2021) ‘COVID-19: Make It the Last Pandemic’, 21-36.

¹¹ Guidi, S. & Maisley, N. (2021) “Who Will Pay for COVID-29? (Or, Who Will Pay to Avert It?)”, Bill of Health-Petrie-Flom Center, [<https://blog.petrieflom.law.harvard.edu/2021/11/01/who-will-pay-for-covid-29-or-who-will-pay-to-avert-it>, last accessed on 05/11/2021].

¹² For example, while some developed countries have fully vaccinated more than half of their populations and are implementing third-doses or being forced to discard vaccines due to the lack of volunteers, by the end of October 2021 African countries had only vaccinated an average of 6% of its population. (See WHO-Africa, ‘Less than 10% of African countries to hit key COVID-19 vaccination goal’, [<https://www.afro.who.int/news/less-10-african-countries-hit-key-covid-19-vaccination-goal>, last accessed on 04/11/2021] UN-News (2021) ‘COVID vaccines: Widening inequality and millions vulnerable’ [<https://news.un.org/en/story/2021/09/1100192> last accessed on 04/11/2021]; UNICEF (2021) ‘G20 members have received 15 times more COVID-19 vaccine doses per capita than sub-Saharan African countries’ [<https://www.unicef.org/press-releases/g20-members-have-received-15-times-more-covid-19-vaccine-doses-capita-sub-saharan>, last accessed on 05/11/2021].

Preparedness and Response ('IPPPR') stated in this sense should not be overlooked: “[e]nding the pandemic as quickly as possible goes hand in hand with preparing to avert another one.”¹³ Beyond calling for a change in the regulatory *status quo*, it is essential that those who are still accepting the inequitable dynamics in place make decisions and take measures to change the current situation.

In response to some of these issues, many States and the WHO have begun to analyse the existing possibilities for improving the international health governance, including the option of a new convention on preparedness and response to future pandemics. The assessment of its possible benefits and risks conducted by the WGPR is already establishing an interesting groundwork for the negotiations that will be held by the WHO governing bodies.¹⁴

2.2 Asymmetries and inequalities

The negotiation of a new convention/treaty on pandemics should build on the lessons learned from the COVID-19 experience and reduce the brutal asymmetries and inequalities that the lack of international coordination, "me-first" approaches and the business-as-usual approach by the pharmaceutical industry have fostered. It should, as a matter of necessity, take into account the interests and needs of the Global South.¹⁵

In this sense, the term "Global South" does not reflect a mere geographic characteristic but is intended to encompass a heterogeneous group of countries that share a number of characteristics. Common factors are usually considered to be their lesser economic and institutional development, their lesser relative

¹³ Independent Panel for Pandemic Preparedness and Response (2021) 'COVID-19: Make It the Last Pandemic'.

¹⁴ WHO (2021), Zero Draft Report of the Member States Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies, A/WGPR/4/3, 11

¹⁵ Aginam, O. (2021), "The Proposed Pandemic Treaty and the Challenge of the South for a Robust Diplomacy", *SouthViews* 218 (19), 1; Velázquez, G. & Syam, N. (2021) "A New WHO International Treaty on Pandemic Preparedness and Response: Can It Address the Needs of the Global South?", *South Centre Policy Briefs* 93, 6.

power in the international sphere¹⁶ and their greater dependence on the more industrialized countries.¹⁷

Despite their remarkable heterogeneity and some meaningful exceptions, in comparison to the more developed countries, the countries of the Global South have historically shown the greatest deficiencies in social infrastructure (including fragile health and social security systems) and the highest poverty and informality rates.¹⁸ Also noteworthy is the economic dependence of many of those countries on commodity exports (and its consequent vulnerability to economic shocks),¹⁹ the high level of informality and the relevance of the tourism sector (highly mobility-dependent).²⁰ Therefore, when assessing the possible response measures in the event of a PHEIC or discussing potential holistic policy reforms, in the best interest of the Global South, their pre-existing differential needs and weaknesses should not be overlooked.

However, the COVID-19 experience has shown that this was not the case: preparedness for possible outbreaks was insufficient, the response mechanisms did not consider the different capabilities and, to make matters

¹⁶ Aginam, O. (2021) "The Proposed Pandemic Treaty and the Challenge of the South for a Robust Diplomacy", *SouthViews* 218 (19), 2.

¹⁷ Alcazár, L. *et al.* (2021) "COVID-19 in the Global South: Impacts and policy responses", *Southern Voice Occasional Paper Series* 69, 11; Benabdallah, L. *et al.* (2017) "Global South Perspectives on International Relations Theory", in McGlinchey S. *et al.*, *International Relations Theory*, Bristol, England: E-International Relations Publishing, 125.

¹⁸ OECD/ILO (2019), "Tackling Vulnerability in the Informal Economy, Development Centre Studies", OECD Publishing Ch.1, 27; Roser, M. & Ortiz-Ospina, E. (2013) "Global Extreme Poverty" [<https://ourworldindata.org/extreme-poverty>, last accessed: 18/11/2021]; UNCTAD (2018), *Forging a Path Beyond Borders: The Global South*, UNCTAD/OSG/2018/1, 7.

¹⁹ UNCTAD (2018), *Forging a Path Beyond Borders: The Global South*, UNCTAD/OSG/2018/1, 9; UNCTAD (2021), 'More than 100 countries depend on commodity exports' [<https://unctad.org/news/more-100-countries-depend-commodity-exports>, last accessed: 18/11/2021].

²⁰ Ohnsorge, F. & Shu Y. (2021), "The Long Shadow of Informality: Challenges and Policies. Advance Edition, World Bank Group, 205-208, UNCTAD (2021), "Global economy could lose over \$4 trillion due to COVID-19 impact on tourism" [<https://unctad.org/news/global-economy-could-lose-over-4-trillion-due-covid-19-impact-tourism>, last accessed: 18/11/2021].

worse, the costs of the crisis are being asymmetrically distributed, which ends up widening global inequality.

From the point of view of preparedness, although no State was fully prepared to face such a pandemic, the fact is that more than half of those classified as "least prepared" before the pandemic were low- or lower-middle-income countries.²¹ Moreover, even though different pre-existing realities demanded different responses, the lack of preparation meant that improvisation was the only alternative. In the first stage of the crisis, China and European countries were the first to establish massive lockdowns and travel bans. These practices were quickly replicated by many other countries in Asia, Africa and Latin America,²² without taking into account the differences in circumstances that would make some of them ineffective or even more harmful than the virus itself.²³ In fact, the WHO warned from the outset that the disproportionate imposition of extreme measures as primary remedies would be insufficient, and that they would "*disproportionately affect disadvantaged groups*".²⁴

In fact, to be effective, response strategies like shelter-in-place and social-distancing, which have been enforced all over the world, had to be implemented in a robust manner (what entailed very high costs for mobility-dependent economies), while requiring the massive procurement of scarce resources (such as testing kits). That was hardly achievable in low-income countries, as large parts of the population depend on informal income-

²¹ 2019 Global Health Security Index [<https://www.ghsindex.org/>, last accessed on 07/11/2021]

²² Alcazár, L. *et al.* (2021), "COVID-19 in the Global South: Impacts and policy responses", Southern Voice Occasional Paper Series 69, 35.

²³ Bottan, N. *et al.* (2020), "The Unequal Impact of the Coronavirus Pandemic: Evidence from Seventeen Developing Countries", Inter-American Development Bank Working Paper Series IDB-WP-1150; Chowdhury, A. Z., & Jomo, K. S. (2020), "Responding to the COVID-19 pandemic in developing countries: lessons from selected countries of the global south", *Development* 63(2), 166.

²⁴ WHO (2020) "WHO Director-General's opening remarks at the media briefing on COVID-19" [<https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---25-march-2020>, last accessed: 19/11/2021]; WHO (2020) "COVID-19 Strategy Update - 14 April 2020" [<https://www.who.int/publications/i/item/covid-19-strategy-update---14-april-2020>; last accessed on 21/11/2021].

generating activities to escape extreme poverty or hunger.²⁵ Therefore, despite public closures and expanded testing efforts, pre-existing vulnerabilities made it difficult for governments to manage the disease's spread.²⁶

Finally, the problematic distribution of vaccines is yet another example of the asymmetry between the Global North —home of the most important pharmaceutical companies— and the Global South. Indeed, overlooking the Global South's needs will make the pandemic last even longer, affecting the growth and recovery of those most affected, while opening the door to the onset of variants of the virus that could inevitably spread throughout the world.²⁷

All in all, the negative social and economic effects of COVID-19 have been most pronounced in the Global South, and especially in the poorest and most unequal countries.²⁸ If the change in the *status quo* does not address these fundamental asymmetries and injustices, the challenges will continue to grow.

In view of the situation described and the opportunities to come, in the following sections this study aims to provide elements for the discussion of certain issues (though not all the relevant ones) that should be especially considered by the countries of the Global South in future negotiations in the context of the WHO.

²⁵ Bargain, O., & Aminjonov, U. (2020) "Poverty and COVID-19 in developing countries", Bordeaux Economic Working Papers [<https://hal.archives-ouvertes.fr/hal-03258229/document>, last accessed on 05/11/2021]

²⁶ Marczak, J. & Guevara, C. (2021), "COVID-19 Recovery in Latin America and The Caribbean: A Partnership Strategy for the Biden Administration", Atlantic Council, 27 [<https://www.atlanticcouncil.org/in-depth-research-reports/covid-19-recovery-in-latin-america-and-the-caribbean-a-partnership-strategy-for-the-biden-administration/>, last accessed on 07/11/2021].

²⁷ UN-News (2021) "COVID vaccines: Widening inequality and millions vulnerable" [<https://news.un.org/en/story/2021/09/1100192>, last accessed on 04/11/2021]

²⁸ Alcazár, L. *et al.* (2021) "COVID-19 in the Global South: Impacts and policy responses", Southern Voice Occasional Paper Series 69, 12, The Guardian (2021) 'A tale of two pandemics: the true cost of Covid in the global south' [<https://www.theguardian.com/world/2021/nov/23/a-tale-of-two-pandemics-the-true-cost-of-covid-in-the-global-south>, last accessed 23/11/2021].

3. The Critical Need for a New Instrument

In March 2021, 25 Heads of State and the WHO Director-General agreed that a change was needed in order to govern preparedness and response in future pandemics, and suggested a new legally binding treaty. In parallel, other major players —such as the United States (**'US'**)— have proposed amending the existing IHR. Both ideas were motivated by the many gaps and shortcomings that the current international health system has shown during the still ongoing COVID-19 pandemic, and the shared view that the world will go through other major health emergencies.²⁹

The two proposals are essentially different, both in terms of negotiation processes and the substantive issues they may address and would therefore have different outcomes. There is currently no substantial agreement on what decision will be taken, but most States seem to have reached a compromise to discuss a potential new instrument, while seeking to preserve flexibility on the type of agreement that should be adopted.³⁰

3.1 Amending the IHR is Not Enough

The IHR is the instrument –adopted according to article 21 of the Constitution of the WHO– which encompasses the standards relating to prevention, protection, control and response to the international spread of a disease, while avoiding an unnecessary interference with international traffic and trade.³¹

²⁹ WHO (2021) “COVID-19 shows why united action is needed for more robust international health architecture” [<https://www.who.int/news-room/commentaries/detail/op-ed---covid-19-shows-why-united-action-is-needed-for-more-robust-international-health-architecture> last accessed on 18/11/2021].

³⁰ WHO (2021) Draft 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, A/WGPR/5/2, 6.

³¹ International Health Regulations (2005) UNTS I-44861, Article 2.

Since their last amendment in 2005, different diseases have threatened the world, six of them obtaining the declaration of PHEIC.³² According to the IHR, State parties have the obligation to put in place core capacities to detect, assess, report and respond to these potential emergencies.³³ Nevertheless, the implementation of the IHR has fallen short when a health crisis arose. In fact, the Ebola case was a tough test for the IHR; it showed the instruments' many flaws and a lack of leadership by the WHO in addressing it.³⁴ It should also be noted that even though the IHR are a binding instrument, after a PHEIC is declared, the WHO can only issue recommendations, which are not binding, and States can decide not to follow.³⁵

This situation was also evidenced by the current COVID-19 pandemic. Although more than 15 years have passed since the current regulations were approved, at the outbreak of the current pandemic most States still did not have the core capacities required by the IHR and did not comply with the obligation set on article 44 on technical or financial cooperation to other State members to build core capacities.³⁶ Furthermore, the Report of the Review Committee on the Functioning of the International Health Regulations ('**Review Committee**') found that during the COVID-19 response the regulations had failed in the areas of compliance and empowerment, early alert, notification and response, as well as on financing and political commitment.³⁷

³² Wilder-Smith, A. *et al.* (2020) "Public health emergencies of international concern: a historic overview", *J Travel Med*, 23.

³³ International Health Regulations (2005) UNTS I-44861, Annex 1.

³⁴ Gostin, L. *et al.* (2015) "The Normative Authority of the WHO", *Public Health* 129 7, 857.

³⁵ International Health Regulations (2005) UNTS I-44861, Article 1; Velásquez, G. (2020) "The World Health Organization Reforms in the Time of COVID-19", *South Centre Research Paper* 121, 11.

³⁶ Velásquez, G. & Syam, N. (2021) "A New WHO International Treaty on Pandemic Preparedness and Response: Can It Address the Needs of the Global South?", *South Centre Policy Brief* 93, 2.

³⁷ WHO (2021) WHO's work in health emergencies Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005). Annex - Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response. Final Draft, 30 April 2021, 10.

There are many reasons why the IHR were insufficient to control the outbreak of the COVID-19, one of the most important is the lack of an effective compliance system. The WHO stated in this regard that “[a]lthough the IHR (2005) do not include an enforcement mechanism per se for States which fail to comply with its provisions, the potential consequences of non-compliance are themselves a powerful compliance tool. Perhaps the best incentives for compliance are “peer pressure” and public knowledge.”³⁸ Recently some Member States recognized the lack of incentives for implementation and reporting mechanisms of the IHR –in contrast to other legally binding international instruments.³⁹

Notwithstanding this, the US has made a proposal to amend the IHR, arguing against the adoption of a new treaty. According to the US, the recommendations made by the Review Committee and IPPPR could be addressed through targeted amendments to those regulations.⁴⁰ However, the US did not make, so far, a compelling motion on compliance and enforcement. The main formal failure of the IHR would only be addressed through the creation of a “Compliance and Accountability Committee”.⁴¹ Factual evidence has proven that a powerless committee may not be enough to safeguard global public health, and it is clear that amending the IHR only is not enough for the world to be prepared for future pandemics, since they could only address sanitary issues and there are several other elements required for a

³⁸ WHO (2005) Frequently Asked Questions About the IHR [<https://www.who.int/ihr/about/FAQ2009.pdf>, last accessed on 05/11/2021]

³⁹ WHO (2021) Zero Draft Report of the Member States Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies, A/WGPR/4/3, 4; WHO (2021) Draft 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, A/WGPR/5/2, 3; “Non-Paper on Strengthening WHO’s leading and coordinating role in global health With a specific view on WHO’s work in health emergencies and improving IHR implementation”, Prepared by the Governments of Germany and France, August 2020, 3.

⁴⁰ United States of America Proposal on Targeted Amendments to the International Health Regulations (IHR), 1.

⁴¹ United States of America Proposal on Targeted Amendments to the International Health Regulations (IHR), 2.

comprehensive global architecture for emergency preparedness and response that fall outside the scope of the IHR.⁴²

This does not mean that the IHR should be left behind. Even with its current flaws, the IHR provide a broad menu of possibilities for States and the WHO to act during the international spread of a disease. Actually, the IHR will play a foundational role in a new agreement as it is the most widely accepted international health instrument, signed by 196 countries.⁴³ Both the Review Committee and, recently, the WGPR noted that the way forward may include a new convention but also the amendment of the IHR as part of a comprehensive approach.⁴⁴ In fact, article 57 of the IHR states that “*the IHR and other relevant international agreements should be interpreted so as to be compatible*” and the Review Committee has determined that a new pandemic treaty would not only have to be compatible with article 57, but should also aim to strengthen it.⁴⁵ One question, however, is the capacity of some member States to

⁴² WHO (2021) WHO’s work in health emergencies Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005). Annex - Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response. Final Draft, 30 April 2021, 50; WHO (2021) Zero Draft Report of the Member States Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies, A/WGPR/4/3, 6; WHO (2021) Draft 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, A/WGPR/5/2, 2.

⁴³ European Council (2021) “An international treaty on pandemic prevention and preparedness” [<https://www.consilium.europa.eu/en/policies/coronavirus/pandemic-treaty/> last accessed on 10/11/2021]; WHO (2021) “COVID-19 shows why united action is needed for more robust international health architecture” [<https://www.who.int/news-room/commentaries/detail/op-ed--covid-19-shows-why-united-action-is-needed-for-more-robust-international-health-architecture> last accessed on 18/11/2021]

⁴⁴ WHO (2021) WHO’s work in health emergencies Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005). Annex - Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response. Final Draft, 30 April 2021, 50; Zero Draft Report of the Member States Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies, 28th October 2021, A/WGPR/4/3, 9.

⁴⁵ WHO (2021) WHO’s work in health emergencies Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005). Annex - Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response. Final Draft, 30 April 2021, 50.

simultaneously engage in negotiations of a new treaty and amendment of the IHR, and how to ensure consistency between the two processes.

3.2 The Opportunity of an Article 19 Binding Convention

The IPPPR, the Global Preparedness Monitoring Board, the Review Committee, the WGPR,⁴⁶ and the European Council –later supported by WHO’s Director-General, Tedros Adhanom Ghebreyesus– and many WHO Member States,⁴⁷ all seem to agree that the best way forward to regulate future pandemics is a binding convention adopted in accordance with article 19 of the Constitution of the WHO.

In fact, the first article of the Constitution of the WHO enunciates a bold mission for the organization: “*the attainment by all peoples of the highest possible level of health.*”⁴⁸ In order to do so, article 2 grants the WHO extensive normative powers to carry out its mission, notably authorizing the World Health Assembly (‘**WHA**’) to adopt “*conventions, agreements and regulations, and make recommendations with respect to international health matters.*”⁴⁹

These normative prerogatives can be divided in two main categories: binding and non-binding instruments. The first one includes conventions or agreements (under article 19) and regulations (under article 21). As mentioned above, there already exists an instrument adopted as regulations concerning public health response to the international spread of a disease: the IHR. Apart from repetition on this matter, the problem with regulations is that they have a

⁴⁶ WHO (2021) Zero Draft Report of the Member States Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies, A/WGPR/4/3, 2.

⁴⁷ WHO (2021) Draft 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, A/WGPR/5/2, 5.

⁴⁸ Constitution of the World Health Organization (1946) UNTS I-221, Article 1.

⁴⁹ Constitution of the World Health Organization (1946) UNTS I-221, Article 2.

highly restricted normative scope,⁵⁰ which means they cannot serve as a comprehensive framework to address pandemics.

Binding conventions or agreements can be adopted by the WHA by a two-thirds vote. The particularity of these instruments is that Member States have eighteen months to “take action” by accepting or rejecting the convention or agreement.⁵¹ If a Member does not accede to the treaty within the given time, it must furnish a statement of reasons. Moreover, the WHO’s Director-General is given monitoring authority, as Members that accede to a treaty must report annually towards implementation.

Nevertheless, the WHO has rarely used its binding normative powers: only once in accordance with article 19 —the adoption of the Framework Convention on Tobacco Control (**FCTC**) in 2003— and twice in accordance with article 21—the case of the IHR and the Nomenclature Regulations.⁵² On the contrary, it is a common practice for the WHO to govern through other forms of soft-law non-binding norms. Thus, article 23 of the Constitution of the WHO grants the Assembly the authority “*to make recommendations to Members with respect to any matter within the competence of the Organization*”.

The experience of the COVID-19 demonstrated that global health crises cannot be regulated only by non-binding agreements,⁵³ and that it is time for the WHO to use its normative powers to adopt a binding convention or agreement. In this regard, Kickbusch, Nikogosian, Kazatchkine, and Kökény argue that the following general criteria should be considered when deciding

⁵⁰ WHO (1996) Programme on substance abuse – International Strategy for Tobacco Control, WHO/PSA/96.6, 18.

⁵¹ Constitution of the World Health Organization (1946) UNTS I-221, Article 20; Gostin, L. *et al.* (2015) “The Normative Authority of the WHO”, *Public Health* 129 (7), 855.

⁵² WHO (2021) WHO’s work in health emergencies Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005). Annex - Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response. Final Draft, 30 April 2021, 18.

⁵³ WHO (2021) Draft 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, A/WGPR/5/2, 5.

whether a specific problem could be covered by a future global health treaty: (a) the problem should be of a global and growing magnitude; (b) transnational factors play a dominant role; and (c) the existing instruments have proved to be inadequate to tackle the problem.⁵⁴ There is no doubt that pandemics meet the first two criteria, even by its definition. For the latter, it has been shown in the previous section that the IHR proved to be insufficient to deal with the COVID-19 pandemic and questions arise whether amending them would allow to cover all the elements required to implement the substantial improvements that are needed.

It should be noted that the same three criteria mentioned above were also considered by the WHA when discussing the FCTC, which was based on the premise that in the case of certain global health threats, such as tobacco, non-binding instruments are just not enough to solve the problem.⁵⁵ Still, this task is nothing but a challenge.

For a binding convention to be successful, it would need to count with the vast majority of the States' consent, which will be very difficult to obtain. A new regulation on pandemics will also need to cover a wide variety of topics — as will be discussed in the following section— and aiming at a comprehensive binding treaty that would include all of them will be in fact very difficult if not virtually impossible.⁵⁶ First, because some of the issues at stake seem to be, in

⁵⁴ Kickbusch, I. *et al.* (2021) “A guide to global health diplomacy - Things you must know to help you make a decision on a pandemic treaty”, Global Health Centre - The Graduate Institute of International and Development Studies, 88.

⁵⁵ WHO (2003) The Framework Convention on Tobacco Control - A Primer, WHO/NCD/TFI/99.8 Rev.7, 7.

⁵⁶ WHO (2021) Zero Draft Report of the Member States Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies, A/WGPR/4/3, 6; WHO (2021) Draft 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, A/WGPR/5/2, 6.

principle, out of the WHO's competence,⁵⁷ and second, because it will take many years to reach an agreement while urgent action is needed.

As a result, the most politically feasible strategy for securing global support for a new treaty on pandemics and the conclusion of negotiations within a reasonable time, might be to promote a framework convention-protocol approach, since it would allow to draw the essential lines without attempting to resolve all issues in a single instrument.⁵⁸ This does not mean that the convention itself would lack substantial obligations,⁵⁹ but that it would settle a governance regime based on a detailed set of obligations contained in the treaty itself, supplemented by a range of subsequent instruments to be adopted by the parties to address those elements that require more complex negotiations.⁶⁰

The experience of the FCTC has demonstrated that such mechanism can be very successful. Indeed, the main Convention is complemented by protocols and guidelines, which are adopted by the treaty's Conference of the Parties.⁶¹ The guidelines, unlike the protocols, do not create legal obligations themselves, but are part of the legal framework of the Convention and often

⁵⁷ WHO (2021) Draft 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, A/WGPR/5/2, 5.

⁵⁸ Taylor, A. L. (1996) "An International Regulatory Strategy for Global Tobacco Control", *Yale Journal of International Law* 21, 294.

⁵⁹ Zhou, S. (2020) "What Difference Would a Binding International Legal Instrument on Alcohol Control Make? Lessons from the World Health Organization Framework Convention on Tobacco Control's Impact on Domestic Litigation", *European Journal of Risk Regulation* 12(2), 520.

⁶⁰ Zhou, S. & Liberman, J. (2018) "The Global Tobacco Epidemic and the WHO Framework Convention on Tobacco Control – The Contributions of the World Health Organization's First Convention to Global Health Law and Governance", in Burci G. L. & Brigit T., *Research Handbook on Global Health Law*, Edward Elgar Publishing, 346.

⁶¹ Zhou, S. & Liberman, J. (2018) "The Global Tobacco Epidemic and the WHO Framework Convention on Tobacco Control – The Contributions of the World Health Organization's First Convention to Global Health Law and Governance", in Burci G. L. & Brigit T., *Research Handbook on Global Health Law*, Edward Elgar Publishing, 349; Nikogosian, H. & Kickbusch, I. (2016) "The Legal Strength of International Health Instruments - What It Brings to Global Health Governance?", *International Journal of Health Policy and Management* 5(12), 684.

have legal effects flowing from their parent treaty.⁶² Guidelines are intended to help Parties meet their obligations under the respective provisions of the FCTC, by consolidating the views of the Parties on different aspects of its implementation, their experiences and achievements, and the challenges faced.⁶³ Moreover, they allow for non-governmental and non-health sectors to participate in the discussions and the drafting,⁶⁴ a major asset to take into account for the negotiation of a legal framework on preparedness and response to pandemics.⁶⁵

In conclusion, a convention or agreement under article 19 of the Constitution of the WHO could provide for a binding legal foundation to address future pandemics at the global scale. A framework approach would most likely create the conditions for consensus and would expand the scope and feasibility of the adopted instrument. This would accelerate the process for its adoption as well, while also leaving the door open for the adoption of successive instruments —such as protocols or guidelines— to develop or complement the provisions on those issues on which there was no initial agreement or in respect of which more detailed regulation is needed.

⁶² Zhou, S. (2020) “What Difference Would a Binding International Legal Instrument on Alcohol Control Make? Lessons from the World Health Organization Framework Convention on Tobacco Control’s Impact on Domestic Litigation”, *European Journal of Risk Regulation* 12(2), 521.

⁶³ WHO (2013) WHO Framework Convention on Tobacco Control: guidelines for implementation, Article 5.3; Article 8; Articles 9 and 10; Article 11; Article 12; Article 13; Article 14, V.

⁶⁴ WHO (2013) WHO Framework Convention on Tobacco Control: guidelines for implementation, Article 5.3; Article 8; Articles 9 and 10; Article 11; Article 12; Article 13; Article 14, V; Nikogosian H. & Kickbusch I. (2021) “The case for an international pandemic treaty”, *the BMJ*, 1; Nikogosian H. & Kickbusch I. (2016) “The Legal Strength of International Health Instruments - What It Brings to Global Health Governance?”, *International Journal of Health and Policy Management* 5(12), 684.

⁶⁵ WHO (2021) Draft 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, A/WGPR/5/2, 4.

4. Key Issues from a Global South Perspective

As it was clearly shown by the COVID-19 pandemic, the outbreak of a disease may turn into a global health emergency in a short time. Moreover, COVID-19 also made evident that a global health emergency encompasses several multisectoral issues, since a globalized world it impacts trade, migrations, environment, and even investment, among others. Accordingly, a comprehensive answer to a pandemic outbreak requires a legal rationale which addresses that multidimensionality properly.

As discussed above, not all the countries around the globe were able to face the outbreak of a disease in equal terms. It should not be overlooked that countries and even regions are not on an equal footing in front of an international health emergency such as a pandemic. In particular, less developed or developing countries —those of the Global South— have pre-existing differential needs and weaknesses (including preparedness and response capabilities) which place them in an unequal position in the event of a pandemic. Bearing this point in mind, there are some issues deemed essential or of great importance from the point of view of the Global South, which must be considered if the drafting of a new agreement on the matter starts or when discussing amendments to the existing instruments.

Based on the special features that characterises the Global South, six issues have been identified as key to be advanced by negotiators and policy makers of the Global South. These issues include, but are not limited to, the six themes discussed in the following subsections. As noted above, for each of them, four cross-cutting questions are raised and answered in order to allow the reader to explore the scope, importance and complexities of each subject, as well as to consider possible approaches to improve on the current situation.

4.1 The WHO's authority in a pandemic

i. Why is this issue relevant for the Global South?

Since its creation in 1948, the WHO has dealt with difficulties to ensure its leadership and authority.⁶⁶ The situation worsened during the COVID-19 pandemic, when the WHO was accused of not acting properly to face the emergency.⁶⁷ The crisis can be explained in a twofold manner: the WHO's poor funding and its "lack of teeth".

The WHO resources are entirely incommensurate with the scope and scale of global health needs.⁶⁸ In the late 70's, and following the global wave of decolonization, the WHO major contributors –Western States– cut drastically their funding.⁶⁹ They redistributed most of their health budgets to other organisations, while transforming their remaining funding to the WHO as voluntary contributions.⁷⁰ These contributions, unlike the mandatory ones, act like donations that provide the donors, rather than the World Health Assembly as a

⁶⁶ Taylor, A. & Habibi, R. (2020) "The Collapse of Global Cooperation under the WHO International Health Regulations at the Outset of COVID-19: Sculpting the Future of Global Health Governance", ASIL 24 (15), [<https://www.asil.org/insights/volume/24/issue/15/collapse-global-cooperation-under-who-international-health-regulations> last accessed on 30/10/2021]; NBC News (2020) "The pandemic shows WHO lacks authority to force governments to divulge information, experts say" [<https://www.nbcnews.com/health/health-news/pandemic-shows-who-lacks-authority-force-governments-divulge-information-experts-n1203046> last accessed on 30/10/2021]; Gostin, L. (2021) "9 Steps to End COVID-19 and Prevent the Next Pandemic: Essential Outcomes From the World Health Assembly", JAMA Health Forum [<https://jamanetwork.com/journals/jama-health-forum/fullarticle/2781169> last accessed on 30/10/2021]; Gostin, L. (2014) *Global Health Law*, Cambridge: Harvard University Press, 89.

⁶⁷ Health Policy Watch (2021) "Lacking Resources & Authority, WHO Was Too Slow To Act Against COVID-19 – Says Independent Review Panel" [<https://healthpolicy-watch.news/lacking-resources-authority-who-was-too-slow-to-act-against-covid-19-says-independent-review-panel/> last accessed on 30/10/2021]; Independent Panel for Pandemic Preparedness & Response (2020) "Second report on progress", 18; Xiong, Y. (2020) "The COVID-19 Pandemic Witnessed the Weakened Authority of the WHO", California Law Review [<https://www.californialawreview.org/weakened-authority-who/> last accessed on 30/10/2021]

⁶⁸ Gostin, L. *et al.* (2015) "The Normative Authority of the WHO", Public Health 129 (7), 856; The Guardian (2020) "The WHO v coronavirus: why it can't handle the pandemic" [<https://www.theguardian.com/news/2020/apr/10/world-health-organization-who-v-coronavirus-why-it-cant-handle-pandemic> last accessed on 30/10/2021]

⁶⁹ Chorev, N. (2012) *The World Health Organization between north and south*, Ithaca: Cornell University Press, 125.

⁷⁰ The Interpreter (2020) "Covid-19: Why did global health governance fail?" [<https://www.lowyinstitute.org/the-interpreter/covid-19-why-did-global-health-governance-fail> last accessed on 03/11/2021]; Bezruki, A. & Moon, S. (2021) "Always fighting the last war?: Post-Ebola reforms, blindspots & gaps in COVID-19", Global Health Centre Working Paper 26, 28-29.

whole, with control over those funds.⁷¹ Therefore, the WHO cannot dispose of its already low regular budgetary resources to adequately perform some of its expected functions –such as reinforcing developing countries’ health systems for preparedness and response– and address the priorities defined by the membership, but has to comply with the terms and conditions attached to voluntary contributions

As a consequence of their lack of funding independence, the WHO is left with a situation where its authority has been hamstrung by, inter alia, political gridlock, organizational deficiencies and conflicting members States demands.⁷² This is one of the main reasons why, as explained in section 3, the WHO does not use its binding normative powers often and, as explained below, why it also struggles to ensure compliance and accountability to the already existing health law. The WHO issued hundreds of recommendations under the IHR for the COVID-19 pandemic, and most of them were disregarded.⁷³ In other words, the WHO has “no teeth” to enforce the measures it deems necessary to implement (as shown, for instance, by its unheard calls for a more equitable distribution of COVID-19 vaccines).

Moreover, during the outbreak of the COVID-19, the WHO saw in danger its technocratic legitimacy –the assumption that the WHO has the technical knowledge needed to manage a pandemic– and its political legitimacy –the assumption that the decision-making process in the WHO is done with

⁷¹ Chorev, N. (2012) *The World Health Organization between north and south*, Ithaca: Cornell University Press, 125; Gostin, L. (2014) *Global Health Law*, Cambridge: Harvard University Press, 124.

⁷² Gostin, L. *et al.* (2015) “The Normative Authority of the WHO”, *Public Health* 129 (7), 856.

⁷³ WHO (2021) WHO’s work in health emergencies Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005). Annex - Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response. Final Draft, 30 April 2021, 10; Velásquez, G. & Syam, N. (2021) “A New WHO International Treaty on Pandemic Preparedness and Response: Can It Address the Needs of the Global South?”, *South Centre Policy Brief* 93, 2; EurekaAlert! (2020) “Most countries are violating international law during the COVID-19 pandemic: Legal experts” [<https://www.eurekaalert.org/news-releases/780217> last accessed on 05/11/2021]

transparency and accountability–. This, consequently, has called into question the WHO’s international public authority.⁷⁴

This situation reached its peak in May 2020, when the then President of the United States, Donald Trump, announced in a press conference that he would terminate the US membership in the WHO and divert the US funding from it to other health agencies, accusing the WHO of a pattern of misconduct.⁷⁵ Given that the US elected a new Administration in November 2020, this decision was subsequently reversed.

The weakened authority of the WHO deeply affects the Global South. First, because it has led to discoordination in countermeasures, such as procurement of vaccines and the pandemic response funding, which has been disappointingly low.⁷⁶ Second, because the WHO becomes an institution whose action is largely influenced by the weight of donors’ contributions in comparison to regular members’ contributions. If the WHO cannot operate independently, then it cannot safeguard global public health, and those countries with less economic and political power and less sophisticated health systems find themselves alone to deal with pandemics.⁷⁷ There is no other way to truly ensure public health than through cooperation and communal action.⁷⁸

⁷⁴ Xiong, Y. (2020) “The COVID-19 Pandemic Witnessed the Weakened Authority of the WHO”, *California Law Review* [<https://www.californialawreview.org/weakened-authority-who/> last accessed on 30/10/2021]

⁷⁵ Taylor, A. & Habibi, R. (2020) “The Collapse of Global Cooperation under the WHO International Health Regulations at the Outset of COVID-19: Sculpting the Future of Global Health Governance”, *ASIL* 24 (15) [<https://www.asil.org/insights/volume/24/issue/15/collapse-global-cooperation-under-who-international-health-regulations> last accessed on 30/10/2021]; *The Washington Post* (2020) “Trump says U.S. to withdraw from World Health Organization and announces new broadsides against Beijing” [<https://www.washingtonpost.com/business/2020/05/29/trump-china-hong-kong-who/> last accessed on 30/10/2021]

⁷⁶ Erond, N. & Agogo, E. (2020) “What Factors Will Decide the Fate of the Global South in Coronavirus Pandemic?” [<https://theglobalobservatory.org/2020/03/what-factors-will-decide-fate-global-south-coronavirus-pandemic/> last accessed on 30/10/2021]

⁷⁷ Erond, N. & Agogo, E. (2020) “What Factors Will Decide the Fate of the Global South in Coronavirus Pandemic?”, *Global Observatory*” [<https://theglobalobservatory.org/2020/03/what-factors-will-decide-fate-global-south-coronavirus-pandemic/> last accessed on 30/10/2021]

⁷⁸ Gostin, L. (2014) *Global Health Law*, Cambridge: Harvard University Press, 32.

Global governance for health requires developing stable, responsive, democratic political institutions that are focused on good governance and capable of implementing an all-of-government approach to health.⁷⁹ This can only be attained through an empowered WHO with proper authority to implement its goals.⁸⁰

ii. Where is the issue currently regulated?

As noted above, article 1 of the Constitution of the WHO states that its objective “*shall be the attainment by all peoples of the highest possible level of health.*” Article 2 follows by spelling out the Organization’s functions to achieve such a goal. It should be noted that many of the provisions in the Constitution do not create binding obligations for the Member States, either because they use “soft” verbs or because they specify the need of consent by them.⁸¹

Chapter XII of the Constitution deals with Budget and Expenses. The drafting of the WHO’s budget is a process between the Director-General, the Executive Board and the WHA.⁸² Once approved, the WHA “*shall apportion the expenses among the Members in accordance with a scale*” that it shall fix.⁸³ Article 57 provides for the possibility of donations and article 58 allows for a special fund to meet emergencies and unforeseen contingencies and that the Executive Board can use at its discretion. The biennial budget can be found in the WHO’s website, and it is usually approved a year in advance.

The IHR give power to the Director-General to determine the existence of a public health emergency of international concern.⁸⁴ This ability triggers the application of the whole mechanism of the IHR. However, the WHO can only

⁷⁹ Gostin, L. (2014) *Global Health Law*, Cambridge: Harvard University Press, 17.

⁸⁰ WHO (2021) Draft 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, A/WGPR/5/2, 3.

⁸¹ Constitution of the World Health Organization (1946), UNTS I-221, Article 2.

⁸² Constitution of the World Health Organization (1946), UNTS I-221, Article 55.

⁸³ Constitution of the World Health Organization (1946), UNTS I-221, Article 56.

⁸⁴ International Health Regulations (2005), UNTS I-44861, Article 12.

issue recommendations once a PHEIC is declared.⁸⁵ This, as the COVID-19 experience showed, deprives the WHO of its authority, since the States are not compelled to follow their guidance. Furthermore, the instrument – being a regulation in terms of article 21 of the Constitution– does not allow for a special funding system to be created, nor does it give the WHO any other special power.

The situation is quite different with the FCTC. First of all, it should be remarked that this Convention creates a new body for its implementation: the Conference of the Parties (**'COP'**),⁸⁶ which is the FCTC's governing body, comprised of all Parties.⁸⁷ In addition, Parties established the Convention Secretariat, the permanent executive arm, which functions within WHO but is directly accountable to the COP on treaty matters.⁸⁸

Therefore, the FCTC entrusts the COP with a series of tasks, such as assisting developing country Parties and Parties with economies in transition, at their request, in meeting their reporting and exchange of information obligations.⁸⁹ This clause, although still requiring the State's consent, grants the COP with power over the implementation of the treaty. Moreover, the FCTC has also a detailed article on financing, thereby recognizing the role that funding has on the achievement of the Convention's objectives.⁹⁰ It also contemplates the provision of advice on financial assistance and funding from international institutions for developing countries or countries with economies in transition to

⁸⁵ International Health Regulations (2005), UNTS I-44861, PART III - RECOMMENDATIONS.

⁸⁶ WHO Framework Convention on Tobacco Control (2003) I-41032, Article 23.

⁸⁷ Nikogosian, H. & Kickbusch, I. (2016) "The Legal Strength of International Health Instruments - What It Brings to Global Health Governance?", *International Journal of Health Policy and Management* 5(12), 684.

⁸⁸ WHO Framework Convention on Tobacco Control (2003) I-41032, Article 24.

⁸⁹ WHO Framework Convention on Tobacco Control (2003) I-41032, Article 21(3).

⁹⁰ WHO Framework Convention on Tobacco Control (2003) I-41032, Article 26(1).

meet their conventional obligations.⁹¹ The Parties also agreed to mobilize and use all available sources of financing for the benefit of all State Parties.⁹²

iii. What are the problems it entails?

There are two main problems with regard to the authority of the WHO that relate to the inherent nature of international organizations, their funding and competences. International organizations, such as the WHO, enjoy a legal personality different from its members. However, their monetary resources and, consequently, its survival depend on them.⁹³ Sometimes, when States dislike the actions the organizations are taking, they proceed to cut their financing. The WHO suffered this in the 70s, when the Alma Ata Declaration was signed recognizing health as a human right and the deep health inequalities between developed and developing countries. The developed countries were concerned about potential redistributive demands and proceeded to cut the funding to the WHO.⁹⁴ History repeated itself in 2020 when, as mentioned above, the US President announced it would divert American financing to other health organisations.

Therefore, pushing for an enhanced WHO's authority in a pandemic preparedness and response treaty might fire back with a wealthy States' decision to defund. Also, although creating a specialised governing body for the the new convention will require additional funding, it can grant the pandemic treaty legitimacy. This, again, might encounter resistance from developed countries.

On the other hand, a pandemic treaty will need to cover a whole variety of issues in order to address the multiple effects of a global health crisis. Given

⁹¹ WHO Framework Convention on Tobacco Control (2003) I-41032, Articles 26(4), 26(5)(a).

⁹² WHO Framework Convention on Tobacco Control (2003) I-41032, Articles 26(5)(a).

⁹³ Amerasinghe, C. F. (2009) *Principles of the institutional law of international organizations*, Cambridge: Cambridge University Press, 352.

⁹⁴ The Interpreter (2020) "Covid-19: Why did global health governance fail?" [<https://www.lowyinstitute.org/the-interpreter/covid-19-why-did-global-health-governance-fail> last accessed on 03/11/2021]

its core functions, the WHO cannot exercise its competence over all the matters at stake. There will be many issues that will need for the WHO to act in collaboration with other specialised international entities, but States need to be very careful that this does not reduce the WHO's authority on fundamental health matters.

iv. How should the treaty address this issue?

There are many steps that could strengthen the WHO's authority in pandemic preparedness and response. Firstly, States should strongly consider the possibility that the pandemic treaty creates a COP or an equivalent body to govern the application of the convention.⁹⁵ The WHO could provide support and work closely with it relying on the technocratic legitimacy of the Organization.⁹⁶

Secondly, a very important question at stake is the application *ratione materiae* of the treaty. As with the IHR, action under that instrument should be triggered once a pandemic is declared (although some provisions on preparedness of health systems can be continual obligations).⁹⁷ Therefore, the declaration of a pandemic must be an important element to be regulated and the WHO should be at the centre of the decision.⁹⁸

Once a health emergency is declared, the governing body of the treaty should work closely –as indicated above– with the WHO to establish the

⁹⁵ WHO (2021) Draft 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, A/WGPR/5/2, 4; Zhou, S. (2020) "What Difference Would a Binding International Legal Instrument on Alcohol Control Make? Lessons from the World Health Organization Framework Convention on Tobacco Control's Impact on Domestic Litigation", *European Journal of Risk Regulation* 12(2), 520.

⁹⁶ Burci, G. L. *et al.* (2021) "Envisioning an international normative framework for pandemic preparedness and response: issues, instruments and options", *Global Health Centre - The Graduate Institute of International and Development Studies*, 13.

⁹⁷ Nikogosian, H. (2021) "A guide to a pandemic treaty - Things you must know to help you make a decision on a pandemic treaty", *Global Health Centre - The Graduate Institute of International and Development Studies*, 16-17.

⁹⁸ WHO (2021) Zero Draft Report of the Member States Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies, A/WGPR/4/3, 6.

procedure States shall take to countermeasure the health emergency.⁹⁹ Given that the IHR experience of issuing recommendations was proven not to be adequate, States should consider the possibility that the new pandemic treaty addresses this issue differently. In fact, in some exceptional situations, the convention could introduce the possibility of using the same system that the Constitution of the WHO has established to adopt regulations. A sort of “opt out” mechanism¹⁰⁰ could provide for this exceptional guidance announced by the COP and the WHO to be mandatory –and would need a statement of motives to obtain this status–, unless in a certain –and short, considering the importance and urgency of the matter– period of time, States decide not to adhere to that norm. This would give the WHO more authority in a pandemic situation, but still leave room for the States’ consent, which is key in order to achieve consensus in the negotiation of the treaty and for its effective implementation. Issuance of such recommendations can be attributed to special committees so as to take actions in an expeditious manner as needed.

Thirdly, it is crucial that the new instrument allows for the COP-like body and the WHO to take action, even before a pandemic is declared. This could take the form of permission to a delegation to make site visits to States,¹⁰¹ which is further explained in the following sections. Also, it is very important that these institutions are granted the authority to implement countermeasures in an equitable manner, such as vaccine distribution, mentioned in detail in section 4.5 below.

Lastly, the treaty should have a financing system of its own. As stated before, the funding issue is key to the development and appropriate functioning

⁹⁹ Nikogosian, H. (2021) “A guide to a pandemic treaty - Things you must know to help you make a decision on a pandemic treaty”, Global Health Centre - The Graduate Institute of International and Development Studies, 26.

¹⁰⁰ Gostin, L. *et al.* (2015) “The Normative Authority of the WHO”, Public Health 129 7, 857.

¹⁰¹ Nikogosian, H. (2021) “A guide to a pandemic treaty - Things you must know to help you make a decision on a pandemic treaty”, Global Health Centre - The Graduate Institute of International and Development Studies, 15.

of the instrument.¹⁰² Without its own budget, there will be no possible improvement on the global preparedness and response to a pandemic. The fact that this is a new treaty in which States will all have a voice in its negotiation will most certainly grant it legitimacy,¹⁰³ which will prone States to contribute financially. Moreover, since fighting a pandemic is a global responsibility, the new instrument should include a similar clause to article 26(5)(a) of the FCTC mentioned above, which recognises that the financing of the Convention needs to be used to strengthen every State's health system.

4.2 Compliance mechanisms and dispute settlement system

i. Why is this issue relevant for the Global South?

The experience of the COVID-19 pandemic demonstrated the lack of observance from the States to the current international health law. Most of them did not –either partially or completely– follow the non-binding recommendations issued by the WHO (in accordance with the power given by the IHR) nor comply with the binding articles of the IHR that require for State's action in situations of health crisis.¹⁰⁴ As shown in section 3, the IHR do not have an effective enforcement system.¹⁰⁵ The IHR premise is that States would comply because of peer-pressure and public visibility. However, when States were confronted with a critical situation that surpassed every health system in the world, their

¹⁰² WHO (2021) Draft 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, A/WGPR/5/2, 3.

¹⁰³ WHO (2021) Draft 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, A/WGPR/5/2, 4.

¹⁰⁴ WHO (2021) WHO's work in health emergencies Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005). Annex - Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response. Final Draft, 30 April 2021, 10; Velásquez, G. & Syam, N. (2021) "A New WHO International Treaty on Pandemic Preparedness and Response: Can It Address the Needs of the Global South?", South Centre Policy Brief 93, 2; EurekaAlert! (2020) "Most countries are violating international law during the COVID-19 pandemic: Legal experts" [<https://www.eurekaalert.org/news-releases/780217> last accessed on 05/11/2021]

¹⁰⁵ WHO (2005) Frequently Asked Questions About the IHR [<https://www.who.int/ihr/about/FAQ2009.pdf> last accessed on 05/11/2021]

first reaction was to protect themselves and disregard international health law and their duty of cooperation.

This led to a situation of global discoordination to face the pandemic. Overcoming the virus' effects was in the hands of each State political leadership, and in many cases not even regional blocks decided on joint strategies. Consequently, many countries of the Global South which have a limited capacity to respond to the immediate fallouts of the pandemic, were left to do so alone.¹⁰⁶

A new health crisis cannot be confronted in this way. In order to avoid devastating results, States must comply with the procedures to overcome a pandemic as prescribed in international health law. Since governing pandemics is a global issue, the failure to comply with a new treaty -if adopted- might affect the public health of all State parties—and the countries of the Global South disproportionately- as was the case with COVID-19.

It should be noted that most States from the Global South do not have the capacity to negotiate as equals with industrialized States from the Global North,¹⁰⁷ even less in times of crisis, when a health emergency is already declared. Therefore, they must seize the opportunity opened up in the context of WHO, join forces and, if a new pandemic treaty is negotiated, ensure that it includes (i) proper compliance mechanisms that can guarantee the State parties' compliance,¹⁰⁸ and (ii) a dispute settlement system that States can rely on, but that would also discourage the parties from breaching the treaty, taking into account, however, differences in the countries' level of development, health

¹⁰⁶ Alcazár, L. *et al.* (2021) "COVID-19 in the Global South: Impacts and policy responses", Southern Voice Occasional Paper Series 69, 24.

¹⁰⁷ Aginam, O. (2021) "The Proposed Pandemic Treaty and the Challenge of the South for a Robust Diplomacy", SouthViews 218 (19), 2.

¹⁰⁸ WHO (2021) Zero Draft Report of the Member States Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies, A/WGPR/4/3, 6; WHO (2021) Draft 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, A/WGPR/5/2, 3.

systems and capacity to implement the treaty provisions.¹⁰⁹ Measures to strengthen such a capacity should be a critical component of the proposed treaty.

ii. Where is the issue currently regulated?

In order to address this issue, two instruments can be regarded so as to understand the approach that global health law has taken with compliance mechanisms and dispute settlement systems: the IHR and the FCTC. As previously stated, currently the IHR do not have any compliance mechanism. The only procedure they contemplate is a static self-assessment report on core capacities and a WHO Secretariat annual implementation report to the World Health Assembly, which do not demonstrate either the States or the WHO performance under the IHR's obligations.¹¹⁰ In the words of the Review Committee, as noted, "*the IHR has no teeth*".¹¹¹

However, the IHR do contain a specific dispute settlement clause. Article 56 requires Parties to resort firstly to diplomatic peaceful means of dispute settlement. In case of failure, parties need to refer the dispute to the Director-General, who shall make every effort to settle it. Moreover, arbitral procedures under the Permanent Court of Arbitration Optional Rules for Arbitrating Disputes between Two States are also an option, or any other dispute settlement mechanism of other intergovernmental organizations or established under any international agreement to which the States are also parties. In case

¹⁰⁹ WHO (2021) WHO's work in health emergencies Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005). Annex - Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response. Final Draft, 30 April 2021, 50-51.

¹¹⁰ WHO (2021) WHO's work in health emergencies Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005). Annex - Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response, Final Draft, 30 April 2021, 52.

¹¹¹ WHO (2021) WHO's work in health emergencies Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005). Annex - Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response, Final Draft, 30 April 2021, 52; Velásquez, G. (2020) "The World Health Organization Reforms in the Time of COVID-19", South Centre Research Paper 121, 15.

the dispute is between a State and the WHO, the matter shall be submitted to the Health Assembly.

The FCTC includes multiple enforcement elements, such as regular reporting and progress monitoring; technical assistance; resource mobilisation; and normative guidance on conflicts of interest, links to human rights and sustainable development and the design and implementation of regulatory measures.¹¹² Furthermore, in 2018, the FCTC COP adopted a pilot project for an Implementation Review Mechanism, which involves peer-review of Parties' biannual implementation reports, with an eye to identifying and sharing good practices, helping Parties understand where they might improve their tobacco control policy formulation, implementation or enforcement, and providing a focus for follow-up assistance.¹¹³

Additionally, the FCTC provides for a quite brief dispute settlement article. Article 27 resorts to diplomatic channels as the principal way to resolve conflicts, and it adds the possibility for the parties to accept the jurisdiction of *ad hoc* arbitration but leaves the decision of the procedural rules to the Conference of the Parties.

iii. What are the problems it entails?

States are highly reluctant to have their sovereignty limited.¹¹⁴ This is clearly reflected in their cautious approach to adopt binding international conventions. As noted repeatedly before, the IHR are a binding instrument

¹¹² Zhou, S. (2020) "What Difference Would a Binding International Legal Instrument on Alcohol Control Make? Lessons from the World Health Organization Framework Convention on Tobacco Control's Impact on Domestic Litigation", *European Journal of Risk Regulation* 12(2), 524.

¹¹³ Framework Convention Alliance (2018) "Parties Strengthen WHO FCTC at COP8 by Adopting Global Strategy" [<https://fctc.org/cop8/> last accessed on 17/10/2021]

¹¹⁴ Pauwelyn, J. *et al.* (2014) "When Structures Become Shackles: Stagnation and Dynamics in International Lawmaking", *The European Journal of International Law* 25 (3), 740; Burci, G. L. *et al.* (2021) "Envisioning an international normative framework for pandemic preparedness and response: issues, instruments and options", *Global Health Centre - The Graduate Institute of International and Development Studies*, 9.

whose lack of compliance has been high in the COVID-19 pandemic.¹¹⁵ Therefore, many States may resist a system that will oblige and make them accountable for their actions, either by forcing them to comply with a new set of rules or by providing other State parties with diplomatic or jurisdictional channels to use in case of breach of their obligations. Not even a binding instrument can guarantee States' effective compliance.¹¹⁶

iv. How should the treaty address this issue?

There are two different sets of rules that need to be considered: (i) compliance mechanisms and (ii) dispute settlement systems.

(i) On the first matter, the options should be approached strategically. Experience has demonstrated that States do not comply because they are forced to, but because the instrument has effective mechanisms for monitoring or accountability, responds to actual and widespread needs, is perceived as authoritative and legitimate, and there is strong and coordinated civil society movement behind the instrument in question pushing states to abide by it.¹¹⁷ In short, this means that States obligations to comply with the pandemic treaty can be incorporated in the binding convention articles –such as the obligation to report the implementation of the FCTC–¹¹⁸ and further developed in subsequent non-binding guidelines which could be drafted by States, following consultations with health specialists and other actors from the civil society.¹¹⁹

¹¹⁵ Health Policy Watch (2020) “WHO’s Legal Mandate Is Weak In Responding To COVID-19 Emergency; But Changes Are Up To Member States” [<https://healthpolicy-watch.news/whos-legal-mandate-is-weak-in-responding-to-covid-19-emergency-but-changes-are-up-to-member-states/> last accessed on 17/10/2021]

¹¹⁶ Burci, G. L. *et al.* (2021) “Envisioning an international normative framework for pandemic preparedness and response: issues, instruments and options”, Global Health Centre - The Graduate Institute of International and Development Studies, 10.

¹¹⁷ Burci, G. L. *et al.* (2021) “Envisioning an international normative framework for pandemic preparedness and response: issues, instruments and options”, Global Health Centre - Graduate Institute of International and Development Studies, 10.

¹¹⁸ WHO Framework Convention on Tobacco Control (2003) I-41032, Article 21.

¹¹⁹ Zhou, S. (2020) “What Difference Would a Binding International Legal Instrument on Alcohol Control Make? Lessons from the World Health Organization Framework Convention on Tobacco Control’s Impact on Domestic Litigation”, European Journal of Risk Regulation 12(2), 523.

This will grant such guidelines legitimacy and eventually lead to a higher rate of observance.

The individual measures that can be taken are many, but all revolve around two concepts: peer-review mechanisms and WHO's technical assistance to strengthen each State's weak points.¹²⁰ The former has been used for several years in human rights systems, and –as noted above– has also been recently adopted by the FCTC.¹²¹ The peer-review process is an open, transparent and participatory process in which States elaborate on the action taken to comply with the treaty's obligations.¹²² It can also include expert's reports on the matter, and the participation of other relevant stakeholders from civil society. The WHO, or a further designated committee by the convention itself, will then proceed to elaborate recommendations on the States' performance. As this procedure is continuous, States will have to report on further progress in a designated period of time, and their work and improvement can be also further assessed.

The former suggestion strongly relies on the WHO's technical expertise. The agency could provide guidance on how to structure rigorous and all-inclusive, whole-of-government assessments and other preparedness activities. Moreover, it could also have the task of carrying verification and inspection procedures for monitoring, especially, the States' response mechanisms to pandemics. Site visits could complement the peer-review process, and they can be designed to take place with previous consent from

¹²⁰ WHO (2021) Zero Draft Report of the Member States Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies, A/WGPR/4/3, 6-7.

¹²¹ Zhou, S. (2020) "What Difference Would a Binding International Legal Instrument on Alcohol Control Make? Lessons from the World Health Organization Framework Convention on Tobacco Control's Impact on Domestic Litigation", *European Journal of Risk Regulation* 12(2), 523.

¹²² WHO (2021) WHO's work in health emergencies Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005). Annex - Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response, Final Draft, 30 April 2021, 53.

the States.¹²³ This would enhance the compliance system but without compromising States' sovereignty.

(ii) For dispute settlement, the future pandemic treaty should include both diplomatic and jurisdictional channels of conflict resolution. The first ones were already mentioned in point (ii) of this section. In fact, both the IHR and the FCTC mention them.¹²⁴ It might be interesting that the new convention appoints –as the IHR does– the WHO or a subsequently created committee, as the focal point for conflict resolution in case that no settlement is reached by the parties. Since the WHO or the respective Committee would have technical expertise, this would provide for legitimacy on the process.

Jurisdictional channels entail further difficulty. Formal dispute settlement systems are often perceived by states as adversarial and resource-intensive, and therefore not often used.¹²⁵ However, the possibility of States engaging in these procedures can work as a deterrent for them to comply with the treaty, so such clause should be incorporated into the instrument. Again, in this case, the IHR article is the most comprehensive one, designating arbitral procedures but leaving space for other jurisdictional mechanisms to be used.¹²⁶ In order to grant legitimacy to the process, this dispute settlement formula could repeat the FCTC clause by leaving the decision of the arbitral procedural rules to a future designated committee of the parties.¹²⁷

¹²³ Nikogosian, H. (2021) "A guide to a pandemic treaty - Things you must know to help you make a decision on a pandemic treaty", Global Health Centre - The Graduate Institute of International and Development Studies, 15.

¹²⁴ International Health Regulations (2005), UNTS I-44861, Article 56; WHO Framework Convention on Tobacco Control (2003) I-41032, Article 27.

¹²⁵ Zhou, S. (2020) "What Difference Would a Binding International Legal Instrument on Alcohol Control Make? Lessons from the World Health Organization Framework Convention on Tobacco Control's Impact on Domestic Litigation", *European Journal of Risk Regulation* 12(2), 523.

¹²⁶ International Health Regulations (2005) UNTS I-44861, Article 56.

¹²⁷ WHO Framework Convention on Tobacco Control (2003) I-41032, Article 27.

4.3 Access and benefit sharing of pathogens and genetic sequence data

i. Why is this issue relevant for the Global South?

One of the lessons that the COVID19 pandemic has revealed is that a new pathogen with pandemic potential could emerge at any time and, in this regard, that there are gaps in preparedness and response which need an urgent rectification to be better prepared for future outbreaks.¹²⁸ It has been pointed out that the access and benefits sharing ('**ABS**') of pathogens and genetic sequence data ('**GSD**') is one of the main and highly discussed topics regarding a new pandemic treaty.¹²⁹ A primary issue is the fair, reliable and rapid international sharing of pathogens and GSD, which allows the development of diagnostic assays, therapeutic interventions, vaccine development and prophylactic measures.¹³⁰ However, it is crucial that in addition to sharing access to pathogens and GSD in a timely manner, a system for the fair and equitable sharing of the benefits generated as a result of sharing be contemplated including, for instance, timely access to products developed with the shared samples/GSD.¹³¹ In its report, the Review Committee noted that

¹²⁸ Independent Panel for Pandemic Preparedness & Response (2021) "COVID-19: Make it the Last Pandemic", 50-51.

¹²⁹ Velásquez, G. & Syam, N. (2021) "A New WHO International Treaty on Pandemic Preparedness and Response: Can It Address the Needs of the Global South?", South Centre Policy Brief 93, 6; Nikogosian, H. (2021) "A guide to a Pandemic Treaty - Things you must know to help you make a decision on a Pandemic Treaty", Global Health Centre - The Graduate Institute of International and Development Studies, 11; WHO (2021) Zero Draft Report of the Member States Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies, A/WGPR/4/3, 6.

¹³⁰ Risk, A. *et al.* (2020) 'Everybody knows this needs to be done, but nobody really wants to do it': Governing Pathogen- and Benefit Sharing (PBS)", Global Health Centre Working Paper 23, 13; WHO (2021) WHO's work in health emergencies Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005). Annex - Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response, Final Draft, 30 April 2021, 49-50.

¹³¹ Switzer, S. *et al.* (2020) "Biodiversity, Pathogen Sharing and International Law" in Negri, S. (Ed.), *Environmental Health in International and EU Law: Current Challenges and Legal Responses*, New York: Routledge, 271; WHO (2017) Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications – Study by the Secretariat, 6 [Implementation](#)

the strategies for the development of effective countermeasures during a pandemic should include provisions for equitable access globally to benefits arising from sharing pathogens and GSD, not only for maintaining the global supply chain, but also for prevention and management of zoonotic risks.¹³² The sharing of pathogen samples and/or GSD and benefit-sharing of scientific and biomedical inventions as a result from such access serves all of humanity for the enjoyment of the highest attainable standard of health, which is one of the fundamental rights of every human being.¹³³ From a Global South perspective, the pandemic treaty should promote and support the interests and take into account the special needs of these countries, as the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits (“**Nagoya Protocol**”) does.¹³⁴ An instrument for a pandemic must seek to design measures to counter the prevalence of corporate and commercial interests in negotiations, especially with respect to benefit sharing arrangements related to biomedical innovations derived from shared pathogens and GSD.¹³⁵ The instrument should also support capacity building in surveillance, genomics and infrastructure for countries of the Global South.

Furthermore, it is essential for the Global South to address this issue having in view the need to facilitate fast access to samples/GSD for timely developing countermeasures and, at the same time, recognition of the right to benefit sharing. In disease outbreaks contexts, pathogens and GSD become

[of the Nagoya Protocol and Pathogen Sharing: Public Health Implications \(who.int\)](#) last accessed on 20/11/21].

¹³² WHO (2021) WHO’s work in health emergencies Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005). Annex - Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response. Final Draft, 30 April 2021, 52.

¹³³ Aginam, O. (2021) “The Proposed Pandemic Treaty and the Challenge of the South for a Robust Diplomacy”, *SouthViews* 218 (19), 3; Constitution of the World Health Organization (1946), UNTS I-221, Preamble.

¹³⁴ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, (2010), UNEP/CBD/COP/DEC/X/1.

¹³⁵ Aginam, O. (2021) “The Proposed Pandemic Treaty and the Challenge of the South for a Robust Diplomacy”, *SouthViews* 218 (19), 4.

“hot items to acquire and highly valued internationally”,¹³⁶ which may lead to reservations around sample-sharing, often to retain negotiating power over potential benefits. In this context, many countries have reported that their ability to negotiate favourable terms and conditions are constrained or even inhibited; particularly in global health policy, developing states are the weaker party when it comes to negotiation.¹³⁷

ii. Where is the issue currently regulated?

There is no regulation within the framework of the WHO, since the ABS was not explicitly envisaged by the IHR.¹³⁸ It has been noted that the IHR only remotely encompass this issue, and even though there are articles related to, such as Article 6 –notification–, Article 44 –collaboration and assistance– and Article 46 –transport and handling of substances and materials– they seem only loosely linked to, and not used in practice regarding ABS.¹³⁹

However, in response to Indonesia’s position in 2007 regarding samples of H5N1 influenza during the avian influenza A(H5N1) outbreaks, in 2011 the WHO adopted an instrument for the sharing of influenza viruses and ABS:¹⁴⁰

¹³⁶Risk, A. *et al.* (2020) “‘Everybody knows this needs to be done, but nobody really wants to do it’: Governing Pathogen- and Benefit Sharing (PBS)”, Global Health Centre Working Paper 23, 31-32.

¹³⁷Risk, A. *et al.* (2020) “‘Everybody knows this needs to be done, but nobody really wants to do it’: Governing Pathogen- and Benefit Sharing (PBS)”, Global Health Centre Working Paper 23, 31-32.

¹³⁸Fidler, D. P., & Gostin, L. O. (2011) “The WHO pandemic influenza preparedness framework: a milestone in global governance for health”, *Jama* 306(2), 200; Bezruki, A. & Moon, S. (2021) “Always fighting the last war?: Post-Ebola reforms, blindspots & gaps in COVID-19”, Global Health Centre Working Paper 26, 18; Nikogosian, H. (2021) “A guide to a Pandemic Treaty - Things you must know to help you make a decision on a Pandemic Treaty”, Global Health Centre - The Graduate Institute of International and Development Studies, 18. New initiatives such as the establishment of BioHub in collaboration between WHO and individual governments (such as Switzerland) do not have a framework on the question of ABS.

¹³⁹Nikogosian, H. (2021) “A guide to a Pandemic Treaty - Things you must know to help you make a decision on a Pandemic Treaty”, Global Health Centre - The Graduate Institute of International and Development Studies, 18.

¹⁴⁰Risk, A. *et al.* (2020) “‘Everybody knows this needs to be done, but nobody really wants to do it’: Governing Pathogen- and Benefit Sharing (PBS)”, Global Health Centre Working Paper No. 23, 17; Fidler, D. P., & Gostin, L. O. (2011) “The WHO pandemic influenza preparedness framework: a milestone in global governance for health” *Jama* 306(2), 200.

the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and Access to vaccines and other benefits (“**PIP Framework**”).¹⁴¹ Even though this is not a legal binding instrument, it provides an ABS regime in the context of a pandemic and, what is more, it encompasses a mode of virus and benefit sharing that applies to both, public and private actors. Accordingly, the PIP Framework was created with the objective of improving pandemic influenza preparedness and response, by strengthening the WHO’s Global Influenza Surveillance and Response System (“**GISRS**”). With its objective of a fair, transparent, equitable, efficient and effective system for, it establishes –on an equal footing–: (i) the sharing of influenza viruses with human pandemic potential; and (ii) access to vaccines and the sharing of other benefits.¹⁴² Still, this framework only operates sharing H5N1 and other influenza viruses with human pandemic potential and the sharing of benefits, and it does not apply to seasonal influenza or non-influenza biological materials.¹⁴³

From a Global South perspective, it is interesting and relevant that this framework contemplates, in a sense, the special difficulties of the developing countries by giving certain recognition to their situation regarding the ABS and the response to a pandemic. To name a few examples, the WHO Member States note the continuing risk of an influenza pandemic with potentially devastating health, economic and social impacts, particularly for developing countries, which are more vulnerable and suffer a higher disease burden.¹⁴⁴

¹⁴¹WHO (2021) Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and Access to vaccines and other benefits.

¹⁴² WHO (2021) Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and Access to vaccines and other benefits, 6; Switzer, S. et. al. (2019) “Biodiversity, Pathogen Sharing and International Law” in Negri, S. (Ed.), *Environmental Health in International and EU Law: Current Challenges and Legal Responses*, Routledge, 272; WHO (2017), Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications – Study by the Secretariat, 6 [last accessed on 20/11/21]

¹⁴³WHO (2021) Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and Access to vaccines and other benefits, 7; Fidler, D. P., & Gostin, L. O. (2011) “The WHO pandemic influenza preparedness framework: a milestone in global governance for health”, *Jama* 306(2), 200.

¹⁴⁴ WHO (2021) Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and Access to vaccines and other benefits, 3-4.

Specifically, it includes the goal of reducing the gap between potential vaccine demand and supply during an influenza pandemic by expanding the global capacity to produce influenza vaccines. In this sense, it is recognized the importance of access to relevant technologies in respect of influenza vaccine, diagnostics, and pharmaceuticals and of making specific efforts to transfer these technologies, skills, knowledge and know-how to countries, particularly developing countries, that do not currently have access to these technologies, skills, knowledge and know-how.¹⁴⁵ Finally, another interesting feature of the PIP Framework is that it provides models for standard agreements for laboratories and manufacturers, which would create legal consequences for contracting parties.¹⁴⁶ Its Annex I foresees a model of an “Standard Material Transfer Agreement”, which envisages a general provision establishing that the parties will consider support to the strengthening of the laboratory and surveillance capacity of the networks of developing countries.¹⁴⁷

In this sense, the Framework’s greatest accomplishment for equity is to require private sector contributions, and to consider developing countries’ need of increasing access to technologies and resources for capacity-building.¹⁴⁸ However, Gostin and Fidler highlight that the absence of even soft norms encouraging developed countries to make specific equity-enhancing contributions to developing countries –such as donating portions of purchased vaccines– is the most glaring omission.¹⁴⁹ Still, the PIP Framework has been

¹⁴⁵ WHO (2021) Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and Access to vaccines and other benefits, 4-5.

¹⁴⁶ Fidler, D. P. & Gostin, L. O. (2011) “The WHO pandemic influenza preparedness framework: a milestone in global governance for health”, *Jama* 306(2), 200; WHO (2021) Draft Report of the Member States Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies, A/WGPR/5/2, 4; Ravelo, J. L. (2021), Uncertainties over a treaty persist ahead of WHA special session , [last accessed on 21/11/21].

¹⁴⁷ WHO (2021) Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and Access to vaccines and other benefits, Annex I, Article 3.

¹⁴⁸ Fidler, D. P. & Gostin, L. O. (2011) “The WHO pandemic influenza preparedness framework: a milestone in global governance for health”, *Jama* 306(2), 201.

¹⁴⁹ Fidler, D. P. & Gostin, L. O. (2011) “The WHO pandemic influenza preparedness framework: a milestone in global governance for health”, *Jama* 306(2), 201.

pointed out as a successful model and an innovative instrument, that is credited for injecting principles of equity and distributive justice that are missing in the IHR.¹⁵⁰

The Nagoya Protocol¹⁵¹ is of particular importance in considering this issue. This Protocol is a supplementary agreement to the Convention on Biological Diversity ('**CBD**'). Among its objectives, the CBD aims to achieve the fair and equitable sharing of benefits arising from the utilization of genetic resources, and particularly the Nagoya Protocol was adopted to provide an international regime and innovative provisions regarding this objective of the CBD.¹⁵²

Although the ABS originally was developed in the area of international environmental law, its implications have gone beyond, influencing other areas of international law such as health.¹⁵³ As a matter of fact, the Nagoya Protocol introduced a number of principles and rules as well some flexibilities that have been discussed in the context of the WHO .¹⁵⁴

Among the incorporated relevant flexibilities, the main ones are: (i) the recognition in Article 4(4) that the Nagoya regime shall not apply to the parties to specialized international ABS instruments consistent with the Protocol; (ii)

¹⁵⁰ Risk, A. *et al.* (2020) "‘Everybody knows this needs to be done, but nobody really wants to do it’: Governing Pathogen- and Benefit Sharing (PBS)", Global Health Centre Working Paper 23, 66

¹⁵¹ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, (2010), UNEP/CBD/COP/DEC/X/1 [Nagoya Protocol]

¹⁵² Nagoya Protocol, introduction; Morguera, E. *et al.* (2013) *The 2010 Nagoya Protocol on Access and Benefit-sharing in Perspective Implications for International Law and Implementation Challenges*, Leiden: Martinus Nijhoff Publishers, 21; WHO (2021), The public health implications of implementation of the Nagoya Protocol, Report by the Director-General, 2. The CBD and the Nagoya Protocol create legally binding treaty obligation for its contracting Parties, who comprise the majority of WHO member States.

¹⁵³ Morguera E. *et al.* (2013) *The 2010 Nagoya Protocol on Access and Benefit-sharing in Perspective Implications for International Law and Implementation Challenges*, Leiden: Martinus Nijhoff Publishers, 21-22.

¹⁵⁴ Risk, A. *et al.* (2020) "‘Everybody knows this needs to be done, but nobody really wants to do it’: Governing Pathogen- and Benefit Sharing (PBS)", Global Health Centre Working Paper 23, 20.

the requirement in Article 8(b) that States parties, in developing their ABS legislation, shall “*pay due regard*” to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally and consider the need for quick access to genetic resources and related benefits, including access to countermeasures (e.g. drugs, diagnostics, vaccines); and (iii) the encouragement to the development of model contractual clauses, voluntary codes of conduct, guidelines, and best practices in Articles 19 and 20, to harmonize and smooth the terms of ABS.¹⁵⁵

iii. What are the problems it entails?

Sharing the access to samples of pathogens and GSD has the capacity to enhance disease surveillance activities necessary for global health security, build and bolster diagnostic capacity, assisting in risk assessment, as well as the development of countermeasures such as vaccines and treatments like antivirals.¹⁵⁶ Nonetheless, as it has been previously stated, it is crucial to share the benefits arising from access to those materials and information.¹⁵⁷ The absence of clear and coherent international governance arrangements and regulations may determine the success or failure of the management of the disease outbreaks; and it may pose a problem in future outbreaks.¹⁵⁸

The fundamental nature of this issue was reflected in the COVID-19 pandemic. China's sharing of the genetic sequence of the new pathogen with

¹⁵⁵ Nagoya Protocol, Articles 4(4), 8(b), 19 and 20; Risk, A. *et al.* (2020) “‘Everybody knows this needs to be done, but nobody really wants to do it’: Governing Pathogen- and Benefit Sharing (PBS)”, Global Health Centre Working Paper 23, 20.

¹⁵⁶ Switzer, S. *et al.* (2019) “Biodiversity, Pathogen Sharing and International Law” in Negri, S. (Ed.), *Environmental Health in International and EU Law: Current Challenges and Legal Responses*, Routledge, 271; Bezruki, A. & Moon, S. (2021) “Always fighting the last war?: Post-Ebola reforms, blindspots & gaps in COVID-19”, Global Health Centre Working Paper 26, 18

¹⁵⁷ WHO (2017) *Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications – Study by the Secretariat*, 6 [last accessed on 20/11/21]; Switzer, S. *et al.* (2019) “Biodiversity, Pathogen Sharing and International Law” in Negri, S. (Ed.), *Environmental Health in International and EU Law: Current Challenges and Legal Responses*, Routledge, 271

¹⁵⁸ Risk, A. *et al.* (2020) “‘Everybody knows this needs to be done, but nobody really wants to do it’: Governing Pathogen- and Benefit Sharing (PBS)”, Global Health Centre Working Paper 23, 31-2; Bezruki, A. & Moon, S. (2021), “Always fighting the last war?: Post-Ebola reforms, blindspots & gaps in COVID-19”, Global Health Centre Working Paper 26, 19

WHO and the global scientific community facilitated the rapid development of diagnostic tests and ultimately guided the development of vaccines.¹⁵⁹ However, this behaviour is not the rule. Previous situations of health emergencies have shown that countries may refuse or delay the sharing of pathogen samples if appropriate benefit sharing is not provided for.¹⁶⁰ In late 2006, during the avian influenza outbreak, Indonesia stressed it was inequitable to give pharmaceutical industries access, given that then –based on the shared samples by developing countries– companies would patent vaccines and antiviral medications that later Indonesia would not be able to afford, and also were less likely to be available to developing countries.¹⁶¹ Another relevant case was during the West African Ebola epidemic, as pathogen sample movement was not regulated during the initial stages of the disease outbreak; it has been reported that some samples were taken to other countries in the absence of arrangements to ensure adequate benefit sharing with the originating countries.¹⁶²

Besides these stresses inter-states and/or with the industry regarding the ABS of pathogens and GSD, uncertainty surrounds the application of existing regulations. On the one hand, the PIP Framework has a limited scope and the possibility of extending into a broader framework applicable to other pathogens has not received much support. Whether using the PIP Framework as a model

¹⁵⁹ WHO (2021) WHO's work in health emergencies Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005). Annex - Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response. Final Draft, 30 April 2021, 29.

¹⁶⁰Risk, A. *et al.* (2020) "‘Everybody knows this needs to be done, but nobody really wants to do it’: Governing Pathogen- and Benefit Sharing (PBS)", Global Health Centre Working Paper 23, 13, 17. It is to be noted, however, that under the CDB and the Nagoya Protocol, countries have the sovereign right over their genetic resources, including pathogens, and can condition access to such resources to benefit-sharing.

¹⁶¹Fidler, D. P. & Gostin, L. O. (2011) "The WHO pandemic influenza preparedness framework: a milestone in global governance for health", *Jama* 306(2), 200; Nicholson, A. *et al.* (2019), *Exploring Lessons Learned from a Century of Outbreaks: Readiness for 2030: Proceedings of a Workshop*, Washington D.C.: National Academies Press U.S., 92

¹⁶² Bezruki, A. & Moon, S. (2021) "Always fighting the last war?: Post-Ebola reforms, blindspots & gaps in COVID-19", Global Health Centre Working Paper 26, 19

may help to solve the tensions with the Nagoya Protocol remains an open question.¹⁶³

On the other hand, The Nagoya Protocol still does not offer a solution. Despite it being a highly valuable source of international law from a Global South perspective –since it broke with “neo-colonialist” behaviour by developed countries and their industries and gave more leverage to source countries and enshrined fundamental notions of equity in international law–¹⁶⁴the ABS of pathogens and GSD was not foreseen for public health purposes in particular with regard to disease outbreaks. Certainly, the bilateral, rather than multilateral and transactional approaches in ABS enshrined in the CBD and Nagoya Protocol may not be fit to address public health emergencies given that its provisions do not guarantee an unfettered and quick multilateral sharing.¹⁶⁵

Still, it has been argued that given the flexible normative structure of the Nagoya Protocol, there is no inherent conflict with public health needs. Nonetheless, regardless of the different points of view about the suitability of the Nagoya Protocol to disease outbreaks, there is a shared vision with regard to the fact that national implementation is uneven and fragmented and not always consistent across countries due to the significant flexibilities provided by the Nagoya Protocol.¹⁶⁶ In any case, the CBD and the Nagoya Protocol did not impede or delay the sharing of pathogen samples or data during COVID-19. In fact, samples were rapidly shared, vaccines were rapidly developed. The

¹⁶³ Risk, A. *et al.* (2020) “‘Everybody knows this needs to be done, but nobody really wants to do it’: Governing Pathogen- and Benefit Sharing (PBS)”, Global Health Centre Working Paper 23, 67

¹⁶⁴ Risk, A. *et al.* (2020) “‘Everybody knows this needs to be done, but nobody really wants to do it’: Governing Pathogen- and Benefit Sharing (PBS)”, Global Health Centre Working Paper 23, 67

¹⁶⁵ Risk, A. *et al.* (2020) “‘Everybody knows this needs to be done, but nobody really wants to do it’: Governing Pathogen- and Benefit Sharing (PBS)”, Global Health Centre Working Paper 23, 67-8

¹⁶⁶ Risk, A. *et al.* (2020) “‘Everybody knows this needs to be done, but nobody really wants to do it’: Governing Pathogen- and Benefit Sharing (PBS)”, Global Health Centre Working Paper 23, 67-8; Nikogosian, H. (2021) “A guide to a Pandemic Treaty. Things you must know to help you make a decision on a Pandemic Treaty”, Global Health Centre - The Graduate Institute of International and Development Studies, 19

benefits of those vaccines have however not been available equitably to all countries.

iv. How should the treaty address this issue?

With a view to strengthening the global coordination and collaboration during global health emergencies and pandemics, the emergency response shall include a structured system of sharing information and samples of pathogens, GSD and the resulting benefits for public health purposes.¹⁶⁷ Hence, in order to develop an international framework capable of strengthening global preparedness and response in front of a pandemic, information on the pathogen and its GSD must be shared immediately for research and development of medical countermeasures. In addition, this framework for the rapid exchange should include subsequent equal benefit sharing, e.g. the production and distribution of vaccines, the availability of the resulting know-how to expand manufacturing capacity and ensure affordable access to various medical and health products.¹⁶⁸ The long term capacity building for developing countries to produce their own sequence studies -rather than depending with the need to share samples for sequencing to be done in laboratories in developed countries could be explored.

In accordance with the vision of some authors, a prospective pandemic treaty could potentially resolve the mentioned problems by specifying and streamlining ABS measures pertinent to pandemics.¹⁶⁹ As noted, the Nagoya Protocol is compatible with specialized regimes of ABS.

¹⁶⁷ WHO (2021) WHO's work in health emergencies Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005). Annex - Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response, Final Draft, 30 April 2021, 49-50.

¹⁶⁸ Velásquez, G. & Syam, N. (2021) "A New WHO International Treaty on Pandemic Preparedness and Response: Can It Address the Needs of the Global South?", South Centre Policy Brief 93, 6; Burci, G. *et al.* (2021) "What could a "Pandemic Treaty" govern?: criteria and other considerations on scope and content, Draft for Discussion", Global Health Centre - The Graduate Institute of International and Development Studies, 7.

¹⁶⁹ Nikogosian, H. (2021) "A guide to a Pandemic Treaty. Things you must know to help you make a decision on a Pandemic Treaty", Global Health Centre - The Graduate Institute of International and Development Studies, 19.

By virtue of article 4(4) of the Protocol, an ABS regime may address extraordinary situations, such as the outbreak of a disease, through a pandemic treaty or other instrument. In this manner, a conflict between the Nagoya Protocol and a pandemic treaty would be prevented. Furthermore, another possibility for establishing an ABS procedure for all pathogens and GSD of pandemic potential could be discussed in parallel with negotiations of the treaty or, once the treaty is in force,¹⁷⁰ it could be regulated through a “soft” law instrument deriving from the parent treaty such as guidelines (as mentioned in section 3.b) above).

4.4 Supply of and equitable access to medical products and other technologies

i. Why is this issue relevant for the Global South?

Even though the COVID-19 pandemic was –and still is– primarily a health crisis, it has become clear that it had ramifications that extend to many aspects of national realities (such as poverty, unemployment, access to education) and the international order, such as international trade.¹⁷¹ In the context of disease outbreaks, international trade plays an extremely important role in the response and development of countermeasures. One of the aspects of world trade regarding the COVID19 pandemic that has already received substantial attention is the effect on access to essential medical supplies.¹⁷² Furthermore, it has been of great significance from a Global South perspective, given that for these countries how the trade policies are applied by States –

¹⁷⁰ Nikogosian, H. (2021) “A guide to a Pandemic Treaty. Things you must know to help you make a decision on a Pandemic Treaty”, Global Health Centre - The Graduate Institute of International and Development Studies, 19.

¹⁷¹ Barlow, P. *et. al.* (2021) “COVID-19 and the collapse of global trade: building an effective public health response”, *The Lancet Planetary Health* 5(2), e102

¹⁷² Barlow, P. *et. al.* (2021) “COVID-19 and the collapse of global trade: building an effective public health response”, *The Lancet Planetary Health* 5(2), e102

notably restricting exports of goods and services— amplified the negative effects of the pandemic.¹⁷³

Mainly in the early days, the health emergency generated a serious and unprecedented degree of demand and made products such as personal protective equipment (“**PPE**”), like face masks, ventilators, some medicines and mechanical ventilators scarce and highly sought-after commodities.¹⁷⁴ Some of these medical supplies have been listed within the WHO s’ list of tools that encompasses key components that are essential to managing COVID-19.¹⁷⁵ Hence, shortages and increased global demand for sanitary products created tensions around the world.¹⁷⁶

In the face of a possible shortage of medical supplies, many States reacted at the beginning of the pandemic by applying restrictions on exports of these products.¹⁷⁷ In this manner, health-care providers and governments have engaged in a frantic scramble to obtain medical supplies, and the problem was exacerbated by often chaotic purchasing arrangements.¹⁷⁸

Although the challenge of scaling up supply rapidly to meet demand and resulting price rises is a global issue, it is more so for the Global South, and in some countries, this has been worsened by trade barriers affecting medical goods. As it has been previously stated, importing countries can impose tariffs

¹⁷³ Zelicovich, J., & Romero, C. (2020) “El impacto del COVID-19 en las relaciones comerciales internacionales”, *Relaciones Internacionales en tiempos de Pandemia*, IRI Rosario, 42.

¹⁷⁴ Barlow, P. *et al.* (2021) “COVID-19 and the collapse of global trade: building an effective public health response”, *The Lancet Planetary Health* 5(2), e102; Zelicovich, J. & Romero, C. (2020) “El impacto del COVID-19 en las relaciones comerciales internacionales”, *Relaciones Internacionales en tiempos de Pandemia*. IRI Rosario, 42.

¹⁷⁵ WHO (2021) “Diagnostics, therapeutics, vaccine readiness, and other health products for COVID-19”, *COVID-19: Essential health services*, 2.

¹⁷⁶ Gozzer, S. (11 de abril de 2020) Coronavirus: cómo afecta a América Latina la pugna entre países por conseguir respiradores, ventiladores y mascarillas. *BBC News Mundo* [<https://www.bbc.com/mundo/noticias-america-latina-52233577> last accessed on 30/10/2021].

¹⁷⁷ Zelicovich, J. & Romero, C. (2020) “El impacto del COVID-19 en las relaciones comerciales internacionales”, *Relaciones Internacionales en tiempos de Pandemia*. IRI Rosario, 45

¹⁷⁸ Barlow, P. *et al.* (2021) “COVID-19 and the collapse of global trade: building an effective public health response”, *The Lancet Planetary Health* 5(2), e103.

to restrict trade, and these difficulties are especially acute in countries dependent on imports of medical products, such as Armenia, Brazil, and Colombia.¹⁷⁹ At the beginning of the COVID-19 outbreak, it was highlighted that the high concentration of imports in certain products makes developing countries extremely vulnerable to changes in policies by exporters.¹⁸⁰ In that sense, as a result of export restrictions on key COVID-19 products, access to medical supplies and other critical products can be disrupted particularly for developing countries that need them urgently.¹⁸¹

Additionally, health systems in many countries are weak, even in normal times. To date, most countries remain poorly prepared, even many health systems in Europe and North America have faced major shortages of doctors, respirators/ventilators, basic infection prevention gear, PPE and testing kits.¹⁸² Therefore, international trade plays a crucial role in ensuring the availability of these tools in countries, especially developing ones, which are scarce and urgently needed.¹⁸³

COVID-19 exposed the inequalities that the trade system creates in the response and development of countermeasures in disease outbreaks, not only because the market for certain health products depends on a small number of developed countries, but also because of their behaviour. The dominance of suppliers from these countries over the aforementioned products allowed their

¹⁷⁹ Barlow, P. *et al.* (2021) "COVID-19 and the collapse of global trade: building an effective public health response", *The Lancet Planetary Health* 5(2), e103

¹⁸⁰ Chowdhury, A.Z. & Jomo, K.S. (2020) "Responding to the COVID-19 Pandemic in Developing Countries: Lessons from Selected Countries of the Global South", *Development* 63, 167; Espitia, A. *et al* (2020) "Trade and the COVID-19 crisis in developing countries", [<https://voxeu.org/article/trade-and-covid-19-crisis-developing-countries>] last accessed on 21/11/21].

¹⁸¹ Espitia, A. *et al.* (2020) "Trade and the COVID-19 crisis in developing countries", [<https://voxeu.org/article/trade-and-covid-19-crisis-developing-countries>] last accessed on 21/11/21].

¹⁸² Chowdhury, A.Z. & Jomo, K.S. (2020) "Responding to the COVID-19 Pandemic in Developing Countries: Lessons from Selected Countries of the Global South", *Development* 63, 167.

¹⁸³ ECLAC (2020) "Restrictions on the export of medical products hamper efforts to contain coronavirus disease (COVID-19) in Latin America and the Caribbean", *COVID-19 Reports*,1.

governments to determine prices and adopt trade measures, ergo conditioning the distribution of such products.

ii. Where is the issue currently regulated?

International trade law regulates the flow and exchange of goods and services between and across States, regional trade areas, or trade regions, and is characterized by a large number of multilateral and bilateral treaties, customary international law, and an increasing *corpus* of case law.¹⁸⁴ Accordingly, and also as an effect of globalization, evidence of its ongoing development is the establishment of regional trade areas among a number of States within a particular region. The most significant multilateral agreement is the General Agreement on Tariffs and Trade (**'GATT'**), signed in 1947, which is the precursor of the creation of the World Trade Organization (**'WTO'**).¹⁸⁵ The WTO is the only global trade organization¹⁸⁶ and it provides the institutional basis for global trade relations. Its principal objectives are to reduce existing trade barriers, expand international trade, and secure an adequate share in the growth of international trade for developing countries.¹⁸⁷ Along with the GATT, the institutional system of the WTO operates a global system of trade rules, administrates a number of trade agreements.¹⁸⁸ Specifically the application of certain provisions in health emergencies, such as import/export bans and

¹⁸⁴ Oesch, M. (2014), "Commercial Treaties", Max Planck Encyclopedia of Public International Law, 2; O'Donoghue, A. (2021) "Trade Law", Oxford Bibliographies [<https://www.oxfordbibliographies.com/view/document/obo-9780199743292/obo-9780199743292-0057.xml?rskey=hXkLgC&result=9&q=international+trade+law#firstMatch> last accessed on 21/11/21]

¹⁸⁵ O'Donoghue, A. (2021) "Trade Law", Oxford Bibliographies [<https://www.oxfordbibliographies.com/view/document/obo-9780199743292/obo-9780199743292-0057.xml?rskey=hXkLgC&result=9&q=international+trade+law#firstMatch> last accessed on 21/11/21]

¹⁸⁶ O'Donoghue, A. (2021) "Trade Law", Oxford Bibliographies [<https://www.oxfordbibliographies.com/view/document/obo-9780199743292/obo-9780199743292-0057.xml?rskey=hXkLgC&result=9&q=international+trade+law#firstMatch> last accessed on 21/11/21]

¹⁸⁷ Herdegen, M. (2020) "International Economic Law", Max Planck Encyclopedia of Public International Law, 2

¹⁸⁸ Herdegen, M. (2020) "International Economic Law", Max Planck Encyclopedia of Public International Law, 2

restrictions, may arise in the context of the Agreement on the Application of Sanitary and Phytosanitary Measures (**'SPS Agreement'**) and the Agreement on Technical Barriers to Trade (**'TBT Agreement'**).¹⁸⁹ Finally, a cornerstone of this system is the Trade-Related Aspects of Intellectual Property Rights Agreement (**'TRIPS Agreement'** or **'TRIPS'**).

As a matter of fact, there is other key issue related to international trade, which is the access to vaccines and the obstacles that intellectual property law causes. Since its adoption, TRIPS has generated concerns from affected countries, in particular because of the impact on access to medicines in the midst of public health crises, as was the case with the HIV/AIDS epidemic. This reaction led to some clarifications, as illustrated by the Doha Ministerial Declaration, adopted in 2001, which deals with TRIPS and public health.¹⁹⁰

Patents protecting vaccine formulations signify exclusive rights that imply restrictions on the production and distribution of vaccines by states. Thus, the demand to eliminate barriers of intellectual property protection arose, and in October 2020 India and South Africa submitted a proposal to the WTO requesting a temporary exemption from intellectual property rights for vaccines and other medical countermeasures during the pandemic.¹⁹¹ At the TRIPS Council, almost a hundred States expressed full or general support for the waiver proposal. However, a group of countries, notably the European Union, opposed it, blocking the possibility of a consensus decision.¹⁹² Nevertheless,

¹⁸⁹ Nikogosian, H. (2021) "A guide to a Pandemic Treaty. Things you must know to help you make a decision on a Pandemic Treaty", Global Health Centre - The Graduate Institute of International and Development Studies, 19.

¹⁹⁰ Primo Braga, C. & Hoekman, B. (2017) *Future of the Global Trade Order*, 2nd. Edition, European University Institute, 18; Nikogosian, H. (2021) "A guide to a Pandemic Treaty. Things you must know to help you make a decision on a Pandemic Treaty", Global Health Centre - The Graduate Institute of International and Development Studies, 19.

¹⁹¹ Herrero, M. & Lombardi, S. (2021) "Pandemia, debate en la OMC y la imperiosa necesidad de liberar las patentes", BLOG FLASCO-Argentina [<http://rrii.flasco.org.ar/liberar-patentes-que-implica-donde-estamos-y-hacia-donde-podemos-ir/> last accessed on 30/10/2021]

¹⁹² Amnistía Internacional (2020) "Información para los Estados Miembros de la OMC sobre la propuesta de exención de los ADPIC en relación con la prevención, contención y tratamiento de la COVID-19", Amnesty International, 2-4.

the WTO framework has the potential to achieve progress on the exemption of patent rights, which could consequently accelerate the development, manufacture, and supply of vaccines and increase access to vaccines in developing countries. Therefore, international trade multilateralism is an extremely relevant factor in the face of disease outbreaks.

iii. What are the problems it entails?

The health systems resilience is tested by the availability of and access to essential vaccines, diagnostics, medicines, and equipment. Lack of access to these tools is compounded by other critical challenges faced by health systems in many countries of the Global South, including deficient health services, and hospital capacity in particular, and challenges of governance and financing, including the coordination between primary and hospital services.¹⁹³

Access to products needed to address COVID 19 has been extremely challenging for most developing countries. This certainly applies to vaccines, as noted above, but also to other products.¹⁹⁴ Thus, in the year 2020, the WHO warned of severe and mounting disruption to the global supply of PPE, caused by rising demand, panic buying, hoarding and misuse; therefore, it *called on industry and governments to increase manufacturing to meet rising global demand*. The WHO emphasised that healthcare workers rely on PPE to protect themselves and their patients from being infected and infecting others, and due to shortages and the limited access to medical supplies, such as PPE, doctors, nurses and other frontline workers were put in a dangerous position. In that regard the WHO Director-General stated that *“Without secure supply chains, the risk to healthcare workers around the world is real. Industry and governments must act quickly to boost supply, ease export restrictions and put measures in place to stop speculation and hoarding. We can’t stop COVID-19*

¹⁹³ Nikogosian, H. (2021) “A guide to a Pandemic Treaty. Things you must know to help you make a decision on a Pandemic Treaty”, Global Health Centre - The Graduate Institute of International and Development Studies, 13

¹⁹⁴ Muhammad Abbas (2021) ‘Access to Medical Equipment in a Pandemic Situation: Importance of Localized Supply Chains and 3D Printing’, SouthViews No. 213, South Centre, <https://www.southcentre.int/wp-content/uploads/2021/02/SouthViews-Abbas.pdf>.

without protecting health workers first".¹⁹⁵ Furthermore, a critical factor was that the production and supply of medical supplies, such as masks, respirators and ventilators are highly concentrated in industrialized countries and a small number of developing countries, mainly in Asia.¹⁹⁶

iv. How should the treaty address this issue?

Certainly, there is not just one answer regarding how the treaty should address this issue given the complexities of the fragmentation of the international law and the specific rules regarding international trade and their domestic nature. In countries where the is production of medical products, in the context of a pandemic, national governments are understandably under pressure to satisfy the demand of their local population first. Nonetheless, the pandemic treaty represents an opportunity to reassess globalisation and discuss how to coordinate a global action. In order to achieve an answer to this issue, it will have to be a recognition of the explicit link between trade and health and should also consider carefully the wide-ranging links between trade, trade policy, and the determinants of health and health inequalities that this issue reveals.¹⁹⁷

In fact, regarding the reforms for the current global health system, Member States of the WHO have raised the topic of "equity" as a priority, and in that regard, agree that *"...equity is critically important for global health both as a principle and as an outcome [and they] emphasized that equity is essential in particular in prevention, preparedness and response to health emergencies, including with respect to capacity building, equitable and timely access to and distribution of medical countermeasures and addressing barriers to timely access to and distribution of medical countermeasures, as well as related*

¹⁹⁵ Chaib, F. (2020), "Shortage of personal protective equipment endangering health workers worldwide", WHO News, [<https://www.who.int/news/item/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide>, last accessed on 21/11/2021]

¹⁹⁶ ECLAC (2020) "Restrictions on the export of medical products hamper efforts to contain coronavirus disease (COVID-19) in Latin America and the Caribbean", COVID-19 Reports, 1

¹⁹⁷ Barlow, P. *et al.* (2021) "COVID-19 and the collapse of global trade: building an effective public health response", The Lancet Planetary Health 5(2), e105

*issues such as research and development, intellectual property, technology transfer and empowering/scaling up local and regional manufacturing capacity during emergencies to discover, develop and deliver effective medical countermeasures and other tools and technologies.”*¹⁹⁸ Therefore, an effective global governance of trade and health will be crucial, and it will *require* a more coordinated global response.¹⁹⁹

To conclude, the development of equitable and effective purchasing mechanisms are needed to enable all countries to timely obtain medical or other life-saving materials and any vaccines or treatments that are found to be effective.²⁰⁰ Although the issue is complex, it has been noted that the supply of –and access to– vaccines and other essential products could be resolved by the treaty.²⁰¹

4.5 Multilateral governance to ensure equitable distribution of vaccines

i. Why is this issue relevant for the Global South?

The countries from the Global South, as noted, are being unequally affected by the COVID-19 pandemic. One of the main reasons for this is the absence of multilateral governance to ensure equitable distribution of vaccines.

On the one hand and as stated above,²⁰² most of these countries have weak national core capacities to give effective response to a pandemic, resulting in numerous avoidable deaths. On the other hand, such States lack

¹⁹⁸ WHO (2021) Draft 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, A/WGPR/5/2,

¹⁹⁹ Barlow, P. *et. al.* (2021) “COVID-19 and the collapse of global trade: building an effective public health response”, *The Lancet Planetary Health* 5(2), e105

²⁰⁰ Barlow, P. *et. al.* (2021) “COVID-19 and the collapse of global trade: building an effective public health response”, *The Lancet Planetary Health* 5(2), e103

²⁰¹ Nikogosian, H. (2021) “A guide to a Pandemic Treaty. Things you must know to help you make a decision on a Pandemic Treaty”, *Global Health Centre - The Graduate Institute of International and Development Studies*, 16

²⁰² See *supra* § 2(2).

resources to invest in research and development for vaccines and financial resources to negotiate pre-purchase agreements with the pharmaceutical companies to ensure priority in the queue for vaccines. As of November 2021 only 5% of the population of low-income countries have received at least one dose of the COVID-19 vaccines, while 73.4% of the population of high-income countries have received at least one dose.²⁰³

Hence, the Global South needs a multilateral mechanism to address the inequalities in the distribution and access to vaccines that allows the international community to act timely, globally and in coordinated manner, thereby diminishing the developing disadvantages for the sake of their population and the international community in general.

ii. Where is the issue currently regulated?

The multilateral governance for the equitable access to vaccines for pandemics is not regulated by the international law, but subject to market mechanisms. During the COVID-19 pandemic there have been certain attempts to organize the global distribution of vaccines, but these are not binding rules for the States. In September 2020, after the mandate received from the 73rd World Health Assembly, the WHO issued non-binding principles for fair allocation mechanism for COVID-19 vaccines.²⁰⁴ In a few words, a fair allocation of vaccines consists in an initial proportional allocation of doses to countries until all countries reach enough quantities to cover 20% of their population and a follow-up phase to expand coverage to other populations.

The COVAX was established as an ad-hoc mechanism outside the WHO as an initiative aimed at supporting access to vaccine doses, especially for lower income countries, during the COVID-19 pandemic. It became one of the three pillars of the Access to COVID-19 Tools ('**ACT**') Accelerator initiative

²⁰³ Ritchie, H. *et al.* (2020) "Coronavirus Pandemic (COVID-19)" [<https://ourworldindata.org/coronavirus> last accessed on 23/11/2021].

²⁰⁴ WHO (2020) Concept for fair access and equitable allocation of COVID-19 health products, Final working version 9 September 2020, 18.

coordinated by Gavi —the Vaccine Alliance—, the Coalition for Epidemic Preparedness Innovations (**‘CEPI’**) and the WHO, with the mission of providing a platform to support the research, development, manufacturing and procurement of several COVID-19 vaccine candidates and negotiate their pricing.²⁰⁵ CEPI coordinates vaccine research and development work, while Gavi deals with procurement and large-scale delivery. A model of Advance Market Commitment (**‘AMC’**) supports the up-front financing for the purchase of vaccines for 92 low-income countries.

COVAX has been created as a mechanism to promote vaccine access in all countries, by engaging the international community to join in. The aim was to benefit all countries regardless of their income’s levels. Through the AMC, COVAX should mainly serve countries that otherwise may be unable to afford vaccines. COVAX also should support higher middle-income self-financing countries that have no bilateral advance purchase agreements (**‘APAs’**) by allowing them to pre-order vaccines through the mechanism at fixed prices. Lastly, COVAX sought to entice participation for wealthiest self-financing countries -most of which may have already negotiated APAs with vaccine manufacturers-, to enhance its purchasing power by increasing their chances of securing vaccine doses if they are also pre-ordered through COVAX.

iii. What are the problems it entails?

Despite its fair efforts, one basic problem with COVAX is that it lacks multilateral governance. According to the WHO, at the outburst of the COVID-19 pandemic, 173 economies have engaged in conversations to potentially participate in COVAX.²⁰⁶ The initial goal was to have 2 billion doses of vaccines available by the end of 2021, which should have been enough to protect high

²⁰⁵ GAVI, the Vaccine Alliance (2020) “COVAX explained” [<https://www.gavi.org/vaccineswork/covax-explained>, last accessed on 20/11/2021].

²⁰⁶ WHO News (2020) “172 countries and multiple candidate vaccines engaged in COVID-19 vaccine Global Access Facility” [<https://www.who.int/news/item/24-08-2020-172-countries-and-multiple-candidate-vaccines-engaged-in-covid-19-vaccine-global-access-facility>, last accessed on 20/10/2021].

risk and vulnerable people, as well as frontline healthcare workers.²⁰⁷ Nevertheless, such goal is unlikely to occur.²⁰⁸

The collective action approach of COVAX Facility was undermined mostly because of the “vaccine nationalism” driven by high-income states that rather than committing to this global initiative rushed to individually sign APAs, thereby competing against other countries and COVAX Facility.²⁰⁹ On the basis of public records, governments in high-income states, representing 16% of the global population, have secured at least 70% of doses available in 2021 of five leading vaccine candidates, on the basis of known agreements.²¹⁰ The incentives to procure vaccines through APAs increased, including in middle-income states, after positive trial results were announced, which reduced the risk of purchasing vaccines under development.²¹¹ Most of the APAs imply a preferential right of the purchaser *vis-à-vis* third parties. This indeed led to an unfair situation where the population of one State (purchaser) acquired more than the doses needed by its population, leaving behind other late purchasers. Hence, the first purchaser may have vaccinated a vast number of its population before groups at higher risk from the latter purchaser got any dose.²¹² According

²⁰⁷ GAVI, the Vaccine Alliance (2020) “COVAX explained” [<https://www.gavi.org/vaccineswork/covax-explained> , last accessed 20/10/2021].

²⁰⁸ AMC Engagement Group Meeting (2021) [<https://www.gavi.org/sites/default/files/covid/covax/governance/COVAX-AMC-Engagement-Group-2021-Mtg-03-Approved-Minutes.pdf> , last accessed on 28/10/2021].

²⁰⁹ Brown, R. (2021) “COVAX, Global Health Governance and the Failure of Multilateralism”, ILA Reporter [<https://ilareporter.org.au/2021/05/covax-global-health-governance-and-the-failure-of-multilateralism-rebecca-brown>], last accessed on 25/10/2021].

²¹⁰ Wouters, O. J. *et al.* (2021) “Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment”, *The Lancet health files* 397, 1029.

²¹¹ Wouters, O. J. *et al.* (2021) “Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment”, *The Lancet health files* 397, 1029.

²¹² Lobo, F. (2021) “Restructuring the Global Vaccine Industry”, *South Centre Research Paper* 134, 70.

to Brown, COVAX has been reduced to a vessel for financial contributions to lower-income states.²¹³

Further, COVAX has been criticized for many reasons including the negotiation of prices that include profit—rather than vaccines at cost as a global public good—, the lack of transparency of contracts entered with vaccine manufacturers, the limits imposed to civil society participation, the failure to address potential impacts of intellectual property rights on pandemic vaccines, the limited experience procuring vaccines for middle-income countries and high-income countries and governance questions, including the role of WHO.²¹⁴ Other reasons include COVAX overambition, the limited portfolio of vaccines it invested in (CEPI portfolio), the fact that some of these vaccine candidates did not develop into effective vaccines and having attempted to supply rich countries as well.

iv. How should the treaty address this issue?

An equitable distribution of vaccines for future pandemics requires ensuring every State has the capacity to access them. As stated in the recent Draft Report of the WGPR, equity is critically important: “[b]oth as a principle and as an outcome”.²¹⁵ Some scholars agree that the optimal solution for future pandemics “would be full multilateralism with global AMCs covering all populations at risk from the beginning”.²¹⁶ In this regard, a new pandemic treaty could include the mandate of the WHO to subscribe global AMCs with the vaccines manufacturers. Such proposal would be the ideal solution as it would allow the WHO to allocate and distribute the vaccines needed in future

²¹³ Brown, R. (2021) “COVAX, Global Health Governance and the Failure of Multilateralism”, ILA Reporter [<https://ilareporter.org.au/2021/05/covax-global-health-governance-and-the-failure-of-multilateralism-rebecca-brown>], last accessed on 01/11/2021].

²¹⁴ Phelan, A. L. *et al.* (2020) “Legal agreements: barriers and enablers to global equitable COVID-19 vaccine access”, *The Lancet* 396, 801.

²¹⁵ WHO (2021) Draft Report of the Member States Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies, A/WGPR/5/2, 2.

²¹⁶ Lobo, F. (2021) “Restructuring the Global Vaccine Industry”, *South Centre Research Paper* 134, 70.

pandemics, following the principles and criteria to be established by the WHO, similar to the non-binding principles for fair allocation mechanism for COVID-19 vaccines.²¹⁷ However, this proposal would face at least two problems: the first one would be the resistance of most of the high-income and middle-income countries to resign a portion of their sovereignty²¹⁸ and rely on a multilateral authority to procure the vaccines and distribute them; the second one is the lack of financial mechanisms within the WHO to deal with the procurements of low-income countries.

To achieve more consensus and given the fact that it is generally accepted that there is a need for a financial mechanism for the WHO,²¹⁹ a new agreement on preparedness and response to pandemics could establish an independent multilateral facility informed by the experience of the COVAX coalition with an institutional link to the very instrument.²²⁰ Under this scenario, States could opt to procure vaccines through the facility or to subscribe their own APAs with the vaccine manufacturer companies. The new instrument could establish a reporting mechanism for allocation and distribution of the vaccine doses to be received by each State Party²²¹, even if such vaccine doses have been acquired through the facility or independently by the State Parties. There should be information and reporting obligations to State Parties as provided in the FCTC.²²² Such reporting obligations could consist of quantity of doses acquired, quantity of doses available, population at risk, and/or total population.

²¹⁷ WHO (2020) Concept for fair access and equitable allocation of COVID-19 health products, Final working version 9 September 2020.

²¹⁸ Burci, G. L. *et al.* (2021) “Envisioning an international normative framework for pandemic preparedness and response: issues, instruments and options”, Global Health Centre - The Graduate Institute of International and Development Studies, 9

²¹⁹ WHO (2021) Draft Report of the Member States Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies, AWGPR/5/2, 3.

²²⁰ Kummer Peiry, K. (2021) “International treaty features potentially applicable to a future pandemic treaty” Global Health Centre - The Graduate Institute of International and Development Studies, 6.

²²¹ Phelan, A. L. *et al.* (2020) “Legal agreements: barriers and enablers to global equitable COVID-19 vaccine access”, *The Lancet* 396, 802.

²²² WHO Framework Convention on Tobacco Control (2003) I-41032, Article 20 and Article 21.

This governance mechanism would ensure that each vaccine dose, as it becomes available, may be distributed timely, globally and under equity principles. Lastly, and as mentioned before, no multilateral governance could be reached without the cooperation and trust among State Parties.²²³

4.6 Equitable standards to address the liability limitations of vaccine manufacturers

i. Why is this issue relevant for the Global South?

The previous section stressed the need for the Global South to get timely and equitable access to vaccines. Nevertheless, an important aspect regarding access to vaccines is the negotiation capacity with the vaccine manufacturers. In this sense, the emergence of unknown viruses demands the pharmaceutical companies to deploy vaccines at an unusual speed. Under such circumstances, manufacturers may not receive the insurance needed to cover potential product risks.²²⁴ Consequently, they may not deploy the novel vaccines in the market at the speed the global community demands.

The way to overcome such obstacles is the issuance of emergency authorization of vaccines. Another feasible measure is limiting the liability of the vaccine manufacturers from adverse effects associated to a multilateral mechanism so as to avoid shifting the burden to purchasing governments. Moreover, vaccine manufacturers may seek indemnity from the countries (purchasers) to cover any losses they may incur as a result of the deployment and use of those vaccines.²²⁵ As already underlined, the countries from the

²²³ Further analysis will be needed regarding policies about price fixing and transparency for purchased vaccine doses.

²²⁴ Geneva Health Files (2021) "COVAX & the question of liability: COVID-19 vaccines" [<https://genevahealthfiles.substack.com/p/covax-and-the-question-of-liability>, last accessed on 05/11/2021].

²²⁵ Geneva Health Files (2021) "COVAX & the question of liability: COVID-19 vaccines" [<https://genevahealthfiles.substack.com/p/covax-and-the-question-of-liability>, last accessed on 05/11/2021].

Global South may lack the financial or judicial capacities to address such claims.

There should be a global solution to deploy vaccines speedily while balancing the risks and especially limiting the unequitable burden to the Global South. Consequently, global cooperation among States rather than individual contractual negotiations with vaccine manufacturers is needed in times of health crisis.²²⁶ There are several issues regarding contractual negotiations that particularly affect the Global South such as vaccine prices, confidential information, jurisdiction and liability. This paper will address only the latter issue, focusing on the liability limitations of vaccines manufacturers.

ii. Where is the issue currently regulated?

The liability arising from adverse effects from vaccines, tort or negligence from the vaccine manufacturers or developers is regulated under the domestic legal systems of States. As Lobo states: “[t]he central idea is that the supplier of a product is responsible for the damages that may arise insofar as it has put the good in the market. No tort or negligence from his part is required nor has to be proved”.²²⁷ In many countries, the injured consumer should seek relief through a lawsuit, what is sometimes discouraged by the legal and procedural difficulties and the associated costs. Under many legal systems, without evidence of clear negligence, it is difficult for injured consumers to obtain compensation.²²⁸

In the US for example, before 1987 consumers had to directly sue the vaccine manufacturers. Under that scenario, manufacturers, and their insurers increased the prices based on worst-case estimates, there was a decrease of

²²⁶ Fairgrieve, D. *et al.* (2020) “Products in a Pandemic: Liability for Medical Products and the Fight against COVID-19”, *European Journal of Risk Regulation* 11, 599.

²²⁷ Lobo, F. (2021) “Restructuring the Global Vaccine Industry”, *South Centre, Research Paper* 134, 70.

²²⁸ Looker, C.& Heath, K. (2011) “No-fault compensation following adverse events attributed to vaccination: a review of international programmes”, *Bulletin of the World Health Organization* online version, 3.

research, and many small manufacturers exit the market.²²⁹ However, compensation schemes have been established in several developed countries with different compensation criteria.²³⁰

A global approach to compensation schemes was first introduced by COVAX during the H1 N1 influenza and most recently during the COVID-19 pandemic.²³¹ During the latter, it established a no-fault compensation program that will operate until 30 June 2022 and seeks to compensate “*any person receiving a Vaccine in any of the 92 countries in the AMC Group, who suffers an unexpected SAE [serious adverse effect] found to be associated with such Vaccine will receive a no-fault, lump-sum compensation for that event in full and final settlement of any claims*”²³². The level of compensation would be established depending on the nature and severity of the harm or injury and adjusted in accordance with the GDP per capita of the country where the unexpected SAE occurs²³³. The payment of such compensation to consumers should be borne from a fund (apparently financed by vaccine manufacturers) and partly from the AMC countries. Nevertheless, the AMC countries shall indemnify manufacturers, donors, distributors, and other stakeholders against any losses they incur from the deployment and use of those vaccines²³⁴. Further, if a particular claimant brought a successful claim against a manufacturer under the local law and the country is not willing or able to pay

²²⁹ Looker, C.& Heath, K. (2011) “No-fault compensation following adverse events attributed to vaccination: a review of international programmes”, Bulletin of the World Health Organization online version, 3.

²³⁰ D'Errico, S. *et al.* (2021) “First Do No Harm”. No-Fault Compensation Program for COVID-19 Vaccines as Feasibility and Wisdom of a Policy Instrument to Mitigate Vaccine Hesitancy”, Vaccines MDPI Switzerland, 3.

²³¹ Geneva Health Files (2021) “COVAX & the question of liability: COVID-19 vaccines” [<https://genevahealthfiles.substack.com/p/covax-and-the-question-of-liability>, last accessed on 05/11/2021].

²³² COVAX (2020) “Additional information on indemnification for COVAX AMC participants”, Briefing Note, 3.

²³³ COVAX AMC (2021), “Program Protocol”, [<https://covaxclaims.com/program-protocol/>, last accessed on 22/11/2021].

²³⁴ COVAX (2020) “Additional information on indemnification for COVAX AMC participants”, Briefing Note, 3.

such award, it could be paid by a third party (apparently the Multilateral Investment Guarantee Agency) on behalf such country.²³⁵

iii. What are the problems it entails?

Vaccine manufacturers tend to limit their liability by seeking indemnity from the vaccine's recipient countries through the subscription of bilateral purchase agreements. Such limitation of liability is partly explained by the existence of different legal systems addressing liability throughout the world and the potential risks of the deployment of a novel vaccine in the worldwide market.²³⁶

During the COVID-19 pandemic pharmaceutical companies have gained enormous negotiation power towards States. The EU Commission experienced negotiation problems regarding liability limitation with the pharmaceutical companies, while apparently the US had accepted the exemptions demanded from such companies.²³⁷ As reported,²³⁸ Pfizer not only has obliged several Latin American countries to indemnify vaccines manufacturers from any claim brought against them, but also to non-disclosure obligations, and to waive jurisdiction and penalties for late vaccine deliveries. As a consequence of the tensions during the negotiations with some vaccines manufacturers, for instance, Argentina had to adapt its legislation and authorize the subscription of vaccine purchase agreements which include the obligation to indemnify vaccine manufacturers from -almost- any claim brought against them²³⁹

²³⁵ Geneva Health Files (2021), "COVAX & the question of liability: COVID-19 vaccines" [<https://genevahealthfiles.substack.com/p/covax-and-the-question-of-liability>, last accessed on 05/11/2021]; COVAX (2020), "Additional information on indemnification for COVAX AMC participants", Briefing Note, 3.

²³⁶ Lobo, F. (2021) "Restructuring the Global Vaccine Industry", South Centre, Research Paper 134, 53.

²³⁷ Lobo, F. (2021) "Restructuring the Global Vaccine Industry", South Centre, Research Paper 134, 53.

²³⁸ Pharmaceutical Technology (2021) "Pfizer accused of 'bullying' Latin American countries during vaccine negotiations" [<https://www.pharmaceutical-technology.com/news/company-news/pfizer-latin-american-vaccine/>, last accessed on 03/11/2021].

²³⁹ Republic of Argentina (2020), Law no. 27.573, Article 4, as amended by Decree no. 431/2021.

Moreover, Brazil, Chile,²⁴⁰ Colombia, the Dominican Republic, and Peru had to waive its sovereign immunities on any of their assets to enforce any arbitration award.²⁴¹ All these requirements occurred while the Global North was hoarding most of the available vaccine doses.²⁴²

The lack of transparency due to non-disclosure obligations undermines the possibility of assessing the real risks of the vaccine industry. This situation was similar during the H1N1 influenza. By that time a resolution of the Parliamentary Assembly of the Council of Europe affirmed that “[m]ember States should “ensure that the private sector does not gain undue profit from public health scares and that it is not allowed to absolve itself of liabilities with a view to privatizing profits whilst sharing the risks”.²⁴³ A multilateral solution is required to limit the financial burden on countries of the Global South regarding the liability risk.

iv. How should the treaty address this issue?

It is worth noting that a new treaty on pandemics preparedness and response would apply only to State members of the WHO and not to the vaccine manufacturers themselves. Considering this, there could be two possible options.

The first one –unlikely to happen– could be the obligation of States to adapt their domestic legal system to special liability rules regarding the vaccines manufacturers to apply during a pandemic. This solution is unlikely to be accepted among the Global South as they may not be able to limit vaccine manufacturers’ liability and bear such costs, in equal terms as countries from

²⁴⁰ Perrone, N. (2021) “El costo oculto de los contratos con Pfizer”, CIPER [<https://www.ciperchile.cl/2021/11/11/el-costo-oculto-de-los-contratos-con-pfizer/>, last accessed on 20/11/2021].

²⁴¹ Rizvi, Z. (2021) “Pfizer’s power”, Public Citizen, 10.

²⁴² Pharmaceutical Technology (2021) “Pfizer accused of ‘bullying’ Latin American countries during vaccine negotiations” [<https://www.pharmaceutical-technology.com/news/company-news/pfizer-latin-american-vaccine/>, last accessed on 03/11/2021].

²⁴³ Fairgrieve, D. *et al.* (2020) “Products in a Pandemic: Liability for Medical Products and the Fight against COVID-19”, European Journal of Risk Regulation 11, 599.

the Global North. Moreover, this solution does not guarantee that vaccine manufacturers will not require different liability and indemnity standards.

The second solution would be to establish a “No-fault compensation program”. Such program could be similar to the current program offered by COVAX to the low- and middle-low-income countries to AMC group,²⁴⁴ but including also other middle-income countries from the Global South. Such “No-fault compensation program” should establish equitable criteria to calculate the compensation sum, taking into consideration not only the GDP of the relevant country but other equitable criteria. Yet, this solution still has to address the indemnity issue since, as previously stated, the eligible countries from the AMC group would still have the obligation to indemnify vaccine manufacturers. Moreover, other countries unwilling or unable to join the “No fault compensation program” would be left with the challenge of facing the negotiation power of the vaccine industry. To solve this issue, the treaty could include guidelines similar to the “Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines”.²⁴⁵ Such guidelines could set a framework to the pharmaceutical companies and vaccine manufacturers in general for their expected behaviour during a pandemic, suggesting reasonable limits on their liability, its scope and duration, exemptions to low-income countries, among others.

5. Conclusions

At the time of writing this paper, a decision to start negotiations for a possible new pandemic treaty at the WHA is about to be taken, while COVID-19 continues to produce deaths and socioeconomic damage on the ground and to occupy a central role in public decision-making, two years after the first case

²⁴⁴ COVAX (2020) “Speed, scale, access” [https://www.gavi.org/sites/default/files/covid/pr/COVAX_CA_COIP_List_COVAX_PR_V5.pdf, last accessed on 05/11/2021], 6.

²⁴⁵ UN General Assembly (2008) Report to the General Assembly of the UN Special Rapporteur on the right to the highest attainable standard of health, A/63/263, 15.

was reported. For instance, although it has the highest vaccination rates in the world, Europe is currently facing a new wave of cases, which has led to new restrictive measures and triggered strong protests and criticism.²⁴⁶ At the same time, on the African continent only 9 out of 54 countries have reached the (very low) target of having 10% of their population vaccinated,²⁴⁷ and Latin American countries have reached their highest extreme poverty rates in the last two decades, due to the COVID-19 crisis and despite the emergency social protection measures adopted to curb it.²⁴⁸

These ongoing circumstances have demonstrated that the international policy challenges on this matter are still great and that there is no silver bullet that, on its own, can guarantee success against a global health threat such as a pandemic. Also, the recent experiences have exposed the fragility of the international health governance system and its asymmetric and unequal character, which has impacted more pronouncedly on countries of the Global South.

As seen along this paper, there are ways to improve international health law to address the present and future pandemics and to provide more equitable solutions. The paradigmatic case is the forthcoming negotiation of a new treaty on pandemic preparedness and response, while any other agreement or the

²⁴⁶ BBC-News (2021) 'Covid:WHO says it is very worried about Europe surge', [<https://www.bbc.com/news/world-europe-59358074>, last accessed: 22/11/2021], France24 (2021) 'Covid-19 en Europe : l'Autriche reconfinée, la colère gronde aux Pays-Bas et en Belgique' [<https://www.france24.com/fr/europe/20211122-covid-19-reconfinement-en-autriche-troubles-aux-pays-bas-la-col%C3%A8re-gronde-en-europe>, last accessed: 22/11/2021], CNN (2021) 'Europe is learning a crucial lesson -- vaccines work, but they alone won't stop Covid now' [<https://edition.cnn.com/2021/11/19/europe/europe-covid-vaccination-rates-fourth-wave-cmd-intl/index.html>, last accessed: 22/11/2021].

²⁴⁷ New York Times (2021), 'Most African countries missed a target to vaccinate 10 percent of their people.' [<https://www.nytimes.com/2021/09/30/world/africa/africa-covid-vaccine.html> last accessed on 22/11/2021].

²⁴⁸ The Guardian (2021) 'A tale of two pandemics: the true cost of Covid in the global south' [<https://www.theguardian.com/world/2021/nov/23/a-tale-of-two-pandemics-the-true-cost-of-covid-in-the-global-south>, last accessed 23/11/2021], CEPAL (2021) 'Pandemic Prompts Rise in Poverty to Levels Unprecedented in Recent Decades and Sharply Affects Inequality and Employment' [<https://www.cepal.org/en/pressreleases/pandemic-prompts-rise-poverty-levels-unprecedented-recent-decades-and-sharply-affects>, last accessed: 22/11/2021].

reform of existing instruments in this regard would be welcomed. In any case, notwithstanding the manner in which they are to be implemented, if the changes to the regulatory *status quo* do not address its fundamental flaws, the challenges posed by the current pandemic will continue to deepen.

In this paper it has been argued that, in view of both the difficulty that negotiations on a possible new treaty will present and the special needs of the Global South, the best way to frame the required improvements on international health law is a binding convention or agreement in accordance with article 19 of the WHO Constitution, with a framework convention-protocol approach. The Global South's negotiators of this hypothetical new instrument (or of any other kind of agreement on the matter) should pay special attention to the six key issues identified in this paper, for which both the main problems and possible solutions have been indicated. As noted, however, the issues considered in this study does not exhaust those that require careful analysis.

Accordingly, Global South countries should seek that such possible new framework convention or any other agreement on the matter addresses, among others, the following six key issues:

(i) The WHO should be granted real authority to govern global health emergencies, such as a pandemic.

(ii) Both a strong compliance mechanism and a functioning dispute settlement system are crucial.

(iii) An international treaty on pandemics should address the access and benefit sharing of pathogens and genetic sequence data to foresee measures for the detection and response, as well as for the development of countermeasures.

(iv) A pandemic treaty needs to foresee and achieve an equitable distribution of medical supplies.

(v) The equitable distribution of vaccines should be ensured through multilateral governance.

(vi) Lastly, any new agreement on the matter should establish equitable standards to address the liability limitations imposed by the vaccine manufacturers.

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