

# Can Negotiations at the World Health Organization Lead to a Just Framework for the Prevention, Preparedness and Response to Pandemics as Global Public Goods?

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 **SOUTH  
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## **RESEARCH PAPER**

**147**

# **CAN NEGOTIATIONS AT THE WORLD HEALTH ORGANIZATION LEAD TO A JUST FRAMEWORK FOR THE PREVENTION, PREPAREDNESS AND RESPONSE TO PANDEMICS AS GLOBAL PUBLIC GOODS?**

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**28 FEBRUARY 2022**

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## ABSTRACT

This paper advances that WHO Member States, having agreed to the objectives of advancing equity and solidarity for future pandemic prevention, preparedness and response, now must operationalize these. The paper offers suggestions for the ongoing WHO processes of: 1) review of recommendations under examination by the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies, 2) consideration of potential amendments to the International Health Regulations (IHR) 2005, and 3) elaboration of a draft text for an international instrument on pandemic preparedness and response.

*Este documento avanza que los Estados miembros de la OMS, tras haber acordado los objetivos de avanzar equidad y solidaridad para la futura prevención, preparación y respuesta a la pandemia, ahora deben ponerlos en práctica. El documento avanza sugerencias para las discusiones en los procesos en curso de la OMS de 1) el examen de las recomendaciones que está revisando el Grupo de Trabajo sobre el Fortalecimiento de la Preparación y la Respuesta de la OMS a las Emergencias Sanitarias, 2) la consideración de posibles enmiendas al Reglamento Sanitario Internacional (RSI) de 2005, y 3) la elaboración de un proyecto de texto para un instrumento internacional sobre la preparación y la respuesta ante una pandemia.*

*Ce document avance que les États membres de l'OMS, ayant accepté de promouvoir des objectifs d'équité et de solidarité pour la prévention, la préparation et la riposte futures aux pandémies, doivent maintenant les mettre en œuvre. Le document propose des suggestions pour les processus en cours à l'OMS concernant : 1) l'examen des recommandations en cours de révision par le Groupe de travail sur le renforcement de la préparation et de la riposte de l'OMS aux urgences sanitaires, 2) l'examen des amendements potentiels au Règlement sanitaire international (RSI) 2005, et 3) l'élaboration d'un projet de texte pour un instrument international sur la préparation et la riposte aux pandémies.*

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# 1. INTRODUCTION

Globally, new cases and deaths from COVID-19 continued to grow with the highly transmissibility of the Omicron variant and lagging vaccine roll-out and uptake.<sup>1</sup> Given the cross-border spread of the disease and potential emergence of new variants, the policy priority should be to accelerate COVID-19 immunization coverage with focus on countries with low vaccination rates. Yet there is no global coordinated plan to do so. Vaccine access by country remains highly inequitable with coverage of over 70 per cent mainly in high-income countries and as low as 1 per cent in some low-income countries. The World Health Organization (WHO) has set a target of achieving 70 per cent of COVID-19 immunization coverage in all countries by end June 2022. At the current pace of vaccine roll-out, 109 countries will miss out on this target.<sup>2</sup> Wealthy countries are failing to do their part and are letting down their guard against the virus. In December 2021, health ministers of the Group of 7 agreed that urgent action is needed considering the new highly transmissible SARS-CoV-2 Omicron variant, yet no coordinated action was agreed to deliver on outstanding pledges or support broad production of COVID-19 tests, treatments and vaccines. Income inequality has also increased with the rise in extreme poverty as well as billionaire wealth. Prospects for the end of the pandemic and recovery for developing countries look bleak.

Against this backdrop, countries are gearing up to start negotiations at the World Health Organization (WHO) to develop a new instrument for pandemic prevention, preparedness and response. A central question is whether these negotiations can lead to a transformation of the current system of norms and governance towards a more just and equitable pandemic response. It is agreed that the new instrument should take a whole-of-government and whole-of-society approach, prioritizing the need for equity and guided by the principles of international cooperation and solidarity with all people and countries, to frame practical actions to deal with both causes and consequences of pandemics and other health emergencies.

This paper discusses how the agreed objectives of advancing equity and solidarity in pandemic prevention, preparedness and response can be **operationalized**. The paper advances recommendations for the ongoing WHO processes of: 1) review of recommendations under examination by the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies, 2) consideration of potential amendments to the International Health Regulations (IHR) 2005, and 3) elaboration of a draft text for an international instrument on pandemic preparedness and response.

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<sup>1</sup> Data gaps and data lags in tracking cases of COVID-19 infection and deaths are significant. For example, although new cases of COVID-19 appear to have decreased in some countries, it may be due to a slowdown in the virus spread or as result of reduced testing and reporting.

<sup>2</sup> COVID-19 Virtual Press conference transcript, 6 January 2022. [COVID-19 Virtual Press conference transcript - 6 January 2022 \(who.int\)](https://www.who.int/news-room/feature-stories/item/covid-19-virtual-press-conference-transcript-6-january-2022).

## 2. STATE OF PLAY AT THE WHO

The Member States of WHO in May 2020 began to review the global response to the COVID-19 pandemic. At present the COVID-19 pandemic is still ongoing and far from under control. Nonetheless, preliminary lessons are being drawn out and discussions are moving forward on how to address perceived gaps in the scope and implementation of existing international tools to support preparedness and response to events which pose significant public health risk including a pandemic,<sup>3</sup> and to strengthen the role of the WHO as a multilateral agency meant to act as the directing and coordinating authority on international health work.<sup>4</sup> Agreement has been reached to draft and negotiate a new international instrument within the framework of the WHO, yet the road to consensus on the specifics will be long and challenging.

By mid-2021, several reports were produced by internal WHO bodies and an independent body was established to carry out a comprehensive review. These reports examined the role of WHO as the lead international agency for global health cooperation and the extent to which countries were prepared to respond to the public health emergency and acted collectively to address the pandemic. The reports produced numerous recommendations. WHO Member States agreed in the World Health Assembly in May 2021 on a process to review the recommendations stemming out from various reports and to prioritize assessment of the potential benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response, for decision in a Special Session of the World Health Assembly (WHA).<sup>5</sup> The WHA Special Session, held from 29 November 2021 to 1 December 2021, decided to launch negotiations for a new WHO convention, agreement or other international instrument on pandemic preparedness, prevention and response.<sup>6</sup> An Intergovernmental Negotiation Body (INB) will be established and start its work by 1 March 2022 with an expectation to conclude the drafting and negotiation of the international instrument by 2024. The INB will hold its first meeting the 24 February 2022.<sup>7</sup> The WHA also decided to continue the process of examining the recommendations, including for the implementation and strengthening of the International Health Regulations (IHR) 2005, which will continue in the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR).<sup>8</sup> The sixth meeting of the WGPR was held on 10–12 January 2022.<sup>9</sup> The seventh meeting of the WGPR was held on 21–23 February 2022.

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<sup>3</sup> The term “pandemic” is not defined in any WHO instrument. A well-accepted definition of pandemic is “an epidemic occurring worldwide, or over a very wide area, crossing international boundaries and usually affecting a large number of people.”, Porta M., (ed.), *A Dictionary of Epidemiology*, Fifth Edition, Oxford University Press, NY, 2008. According to the same source, an epidemic refers to “the occurrence in a community or region of cases of an illness, specific health-related behavior, or other health-related events clearly in excess of normal expectancy”. The International Health Regulations (2005) require Member Parties to assess and notify events detected by the national surveillance system that may constitute a public health emergency of international concern, that includes any event of potential international public health concern, including those of unknown causes or sources and those involving other events or diseases, as well as cases of certain diseases or events involving certain diseases using the decision instrument set out in Annex 2 as guidance. See *International Health Regulations, 2005*, pp. 43–46, available from [International Health Regulations \(2005\) Third Edition \(who.int\)](https://apps.who.int/gb/ebwha/pdf_files/WHASSA2/SSA2(5)-en.pdf).

<sup>4</sup> WHO Constitution, article 2(a), available from [https://www.who.int/governance/eb/who\\_constitution\\_en.pdf](https://www.who.int/governance/eb/who_constitution_en.pdf), accessed 8 December 2021.

<sup>5</sup> WHA Resolution 74.4, available from [https://apps.who.int/gb/ebwha/pdf\\_files/WHA74/A74\\_R7-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_R7-en.pdf) and Decision WHA74(16), available from [https://apps.who.int/gb/ebwha/pdf\\_files/WHA74/A74\(16\)-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74(16)-en.pdf).

<sup>6</sup> Decision SSA2(5), available from [https://apps.who.int/gb/ebwha/pdf\\_files/WHASSA2/SSA2\(5\)-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHASSA2/SSA2(5)-en.pdf).

<sup>7</sup> Intergovernmental Negotiating Body, INB/1, <https://apps.who.int/gb/inb/>.

<sup>8</sup> Workplan for the WGPR, document A/WGPR/5/3, 8 December 2021, [Member States Working Group on Strengthening WHO Preparedness for and Response to Health Emergencies](https://apps.who.int/gb/ebwha/pdf_files/WHASSA2/SSA2(5)-en.pdf).

<sup>9</sup> See [https://apps.who.int/gb/wgpr/e/e\\_wgpr-6.html](https://apps.who.int/gb/wgpr/e/e_wgpr-6.html).

One of the first tasks in the process of negotiating a new international instrument on pandemic prevention, preparedness, and response will be to define the substantive elements to be included. This process will also be informed by the parallel discussions to strengthen the implementation of the IHR (2005) including potential targeted amendments. There is a diversity of positions among countries on the urgency of a new international instrument and whether to pursue targeted amendments to the IHR (2005). Developing countries will strengthen their collective negotiating position if they can reach consensus on the substantive elements to advance as priority in both the discussions in the WGPR and in the INB and propose them in the form of draft texts. To date, the coalition of “Friends of the Pandemic Treaty”<sup>10</sup>—a mix of countries across regions— has led the assertion of priorities. Various other countries, including the United States, Russia and China, have finally agreed to enter the INB negotiations. The United States prioritizes the strengthening of the IHR (2005) through amendments. Soon after the WHA Special Session decision was adopted, the United States circulated proposed IHR amendments and held informal consultations, creating tension in the run up to the January meetings of the WGPR and the WHO Executive Board (EB). To settle matters, the WHO EB adopted a decision noting that the WGPR will discuss strengthening of the IHR (2005) including through implementation, compliance, and potential amendments, and urging Member States to consider potential amendments to the IHR (2005).<sup>11</sup>

It is a murky road ahead for building multilateral consensus, if at all possible, subject to political will to engage in transformative reforms that respond to the diverse priorities of the WHO Member States.<sup>12</sup>

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<sup>10</sup> A first public call for the pandemic treaty was made on 3 March 2020 by a group of heads of State from Albania, Chile, Costa Rica, Croatia, Fiji, France, Germany, Greece, Indonesia, Italy, Kenya, Korea, the Netherlands, Norway, Portugal, Romania, Rwanda, Serbia, Senegal, Spain, South Africa, Thailand, Trinidad and Tobago, Tunisia, Ukraine and United Kingdom – and the Director General of WHO, see <https://www.who.int/news/item/30-03-2021-global-leaders-unite-in-urgent-call-for-international-pandemic-treaty>.

<sup>11</sup> Document EB150(3), [https://apps.who.int/gb/ebwha/pdf\\_files/EB150/B150\(3\)-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/EB150/B150(3)-en.pdf).

<sup>12</sup> See Velásquez G. and Syam N., “A New WHO International Treaty on Pandemic Preparedness and Response: Can It Address the Needs of the Global South?”, [The South Centre | Policy Brief 93, May 2021](#); “The world must act now to be prepared for future health emergencies”, BMJ 2021, 375 <https://www.bmj.com/content/bmj/375/bmj.n2879.full.pdf>; Moon S., Kickbusch I., “A pandemic treaty for a fragmented global polity”, *Lancet Public Health*. 2021 Jun;6(6):e355-e356. Doi: 10.1016/S2468-2667(21)00103-1, <https://www.thelancet.com/action/showPdf?pii=S2468-2667%2821%2900103-1>.

### 3. LESSONS FROM THE RESPONSE TO THE COVID-19 PANDEMIC

The COVID-19 pandemic has brought several positive lessons. Cost-effective measures for infection prevention have been widely implemented, including hand washing, that can significantly reduce infection burden. Rapid development of COVID-19 vaccines was enabled by a mix of collaboration and competition involving multiple players from academia, private firms, public research institutions, regulatory agencies and various forms of public-private partnerships backed by substantial funding from the public sector.<sup>13</sup> The pandemic has also served as a wake-up call for governments to increase domestic investment in health systems and commitment to universal healthcare. There is increased recognition of the central role of healthcare workers, who have shown incredible commitment during the pandemic despite the challenges and risks they have faced. The pandemic has also brought to bear the importance of the WHO as the main supra-national body to help drive collective action on global health problems.

There have been, however, many deficiencies in the global response to the COVID-19 pandemic. Countries' public health systems were caught unprepared and alone could not cope with the impact. The global response has lacked timeliness, coordination and solidarity among governments and health agencies in actions and communications. The dire inequity in access to vaccines among countries to reduce the virus spread and cases of serious illness and death from the disease will be remembered as the paradigm of failed global cooperation during the COVID-19 pandemic. The biggest challenge to solve and not repeat is the two track pandemic. A **political choice** continues to be made to restrain sharing of knowledge and tools, including diagnostics, treatments and vaccines, that could save millions of lives.<sup>14</sup>

The COVID-19 pandemic has heightened entrenched social, economic and health disparities and inequities within and among countries. The most vulnerable and marginalized people and segments of the population have been hit the hardest. Health systems and front-line healthcare workforce have been severely strained by the pandemic. Citizens' increasing distrust in governments for COVID-19 information and vaccine mandates contributed to the spread of the virus. Prospects for the end of the pandemic and recovery in developing countries look bleak, with extremely slow progress on equitable vaccine distribution and the continuous threat of spread of emerging COVID-19 variants.

The Independent Panel on Pandemic Preparedness and Response (IPPR) provided a glaring assessment<sup>15</sup> and noted in its progress report that governments are yet to act on its urgent recommendations.<sup>16</sup> Global health diplomacy must not be sidelined in the battle to advance foreign policy, nationalism and domestic security and private sector interests, as has been largely the case in the COVID-19 pandemic. The global health community must work together to address the supra-national challenge by sharing resources, confronting public distrust and apathy in addressing injustice.

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<sup>13</sup> For an elaboration of public funding invested in COVID-19 vaccine R&D, see Wouters O.J., Kenneth C. Shadlen, Maximilian Salcher-Konrad, et al., "Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment", *Lancet* 2021; published online 12 February 2021, DOI: [https://doi.org/10.1016/S0140-6736\(21\)00306-8](https://doi.org/10.1016/S0140-6736(21)00306-8).

<sup>14</sup> The waiver of intellectual property protection related to COVID-19 vaccines, drugs, treatments and other technologies for the duration of the pandemic has not been adopted sixteen months after the proposal was tabled by India and South Africa at the World Trade Organization.

<sup>15</sup> [Main Report & accompanying work - The Independent Panel for Pandemic Preparedness and Response.](#)

<sup>16</sup> [Losing time: End this pandemic and secure the future \(theindependentpanel.org\).](#)

All countries bear the risk of pandemics and benefit from preventing them. As noted by the WHO Director General Tedros Adhanom Ghebreyesus, “no one is safe until everyone is safe”. To date insufficient attention has been given to the need to deliver global public goods (GPG) for pandemic prevention, preparedness and response. A clear example is equitable access to vaccines. Broad immunization produces positive externalities: it reduces spread and risk of serious disease. Critical elements for building an effective global system to prevent and respond to pandemics are cooperation, shared responsibilities, and solidarity among States.<sup>17</sup> Advancing the right to health and equity including in access to life-saving tools must be a primary goal. Countries with greater resources and capacities must bear a greater share of responsibility for the provision of global public goods, including through policies and resources to support prevention and response efforts of other countries; an appeal that is more often made from the standpoint of morals/ethics, aid,<sup>18</sup> charity<sup>19</sup> or self-interest diplomacy. As part of the negotiations to kick off in the WHO, these responsibilities can be defined and legal obligations established to ensure these are delivered upon.

Notwithstanding the efforts of the WHO Secretariat, the WHO has proven to be unprepared to foster global cooperation during COVID-19 pandemic and yet it is the most optimal platform to build a new global framework for pandemic prevention, preparedness and response. Despite the challenges of the fragmentation of global health governance with a growing number of fora and influential actors, the complex geopolitical environment and the limited powers of WHO to influence States’ behavior, the WHO remains the main global institution to advance consensus on norms, enhance coordination and provide technical support in particular for developing countries. Hence, emphasis on strengthening the role of WHO is well founded. This requires, among other actions, augmenting its core financing and greater compliance with the guidance issued by WHO during pandemics.

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<sup>17</sup> The concepts of shared responsibilities and solidarity can be seen as mirroring elements of the principle of “common but differentiated responsibilities” in the context of environmental law in the sense that States have general responsibilities but those with greater resources and capacities must carry greater share of responsibilities as part of collective action, including to improve equity considerations.

<sup>18</sup> At present OECD countries are discussing whether to include donated vaccines (surplus) as part of Overseas Development Assistance (ODA) which would decrease overall ODA expenditures. See Ritchie E., McDonnell A., Dissanayake R., “The vaccine mark-up: counting more in ODA than we paid for vaccines is illogical, immoral, and unpopular”, 7 February 2022, <https://cgdev.org/blog/vaccine-mark-counting-more-oda-we-paid-vaccines-illogical-immoral-and-unpopular>.

<sup>19</sup> The aid-charity model for global health has been questioned long before the COVID-19 pandemic, see for example Gostin L.O., Friedman E.A., Ooms G., Gebauer T., Gupta N., Sridhar D., et al., “The joint action and learning initiative: Towards a global agreement on national and global responsibilities for health”, *PLoS Med* 8(5) (2011): e1001031. <https://doi.org/10.1371/journal.pmed.1001031>.

#### 4. THE PROMISE TO DELIVER ON EQUITY, GUIDED BY SOLIDARITY

The December 2021 WHA decision provides an important foundation for the negotiations for a new instrument for pandemic prevention, preparedness and response to build upon. The next step is to define and advance concrete mandates in the form of a draft text. Member States of WHO agreed that the new instrument should “prioritize the need for equity” and agree to “guide their efforts [...] by the principle of solidarity with all people and countries, that should frame practical actions to deal with both causes and consequences of pandemics and other health emergencies.”<sup>20</sup> They also agree on the need “to address gaps in the current system for the development and distribution of, and unhindered, timely and equitable access to, medical countermeasures such as vaccines, therapeutics and diagnostics” as well as “strengthening health systems and their resilience with a view to achieving universal health coverage (UHC)”.

The discussions in the WGPR on the potential benefits of negotiating a new instrument helped to build consensus for the WHA decision that stresses on the need to deliver on equity as part of the international instrument negotiations. Among the potential benefits of a new instrument that the WGPR noted was that of “addressing equitable access to countermeasures such as vaccines, therapeutics and diagnostics. A framework could facilitate concrete measures and long-term mechanisms to develop, manufacture and scale up countermeasures through increasing local production, sharing of technology and know-how for broadening manufacturing capacity, and strengthening regulatory systems.”<sup>21</sup>

The interim report submitted by the WGPR to the WHO EB in January 2022 states:<sup>22</sup>

“Member States agree that equity is critically important for global health both as a principle and as an outcome and will remain an issue of focus for the WGPR. Member States 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 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.”<sup>23</sup>

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<sup>20</sup> Decision SSA2(5), paras 4–5.

<sup>21</sup> Document SSA2/3, para 9(f) [https://apps.who.int/gb/ebwha/pdf\\_files/WHASSA2/SSA2\\_3-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHASSA2/SSA2_3-en.pdf).

<sup>22</sup> Document EB150/16, [https://apps.who.int/gb/ebwha/pdf\\_files/EB150/B150\\_16-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/EB150/B150_16-en.pdf).

<sup>23</sup> A/WGPR/5/2, para 8(a).



## 5. IMMEDIATE PRIORITIES FOR THE WGPR ON EQUITY

This section reflects on the recommendations that the WGPR can advance immediately. Recommendations that the WGPR can advance for equity through the strengthening of the IHR (2005) and the INB negotiations are discussed in separate sections.

The WGPR will continue reviewing recommendations to strengthen WHO preparedness and response to health emergencies. Member States will define priorities for advancing actions. Clearly the recommendations related to equity require most urgent attention by the WGPR to agree on actions. This work will also inform the negotiations for the international instrument in the INB.

The IPPR has noted in its progress report of November 2021 that its call for immediate action remains outstanding. Table 1 below reproduces selected IPPR recommendations and next steps suggested in its six-month progress report that if acted upon would serve to advance equity.<sup>24</sup>

Table 1  
**IPPR Priority Recommendations in the Area of Equity**

Recommendation	Due from May 2021	Suggested next steps
G7 countries commit to provide 60% of the USD 19 billion required for ACT-A; with remainder from G20-HICs	Immediately	ACT-A should urgently take on recommendations of its review. Donors must urgently close ACT-A 2021 budget gap on path toward fulfilling total of USD 23.4 billion to meet global targets and deliver the tools that are needed over the next 12 months
WTO and WHO to convene major vaccine producing countries and manufacturers to agree on voluntary licensing and technology transfer for COVID-19 vaccines. If no actions within three months, a TRIPS waiver should come into force immediately	Immediately	As voluntary licensing agreements have not yet been forth-coming, WTO member States must use upcoming Ministerial Conference (30 Nov–3 Dec 2021) to align on TRIPS waiver.
Production and access to COVID-19 tests and therapeutics scaled up urgently in LMICs; and fully fund and use GFATM COVID-19 Response Mechanism II (USD 1.7 b needed; spend USD 3.7 b)	Immediately	Donors must urgently close the ACT-A budget gap through 2022. New therapies, including monoclonal antibodies, must be rapidly deployed to LMICs, if it is authorized as part of test and treat strategies for all countries.

<sup>24</sup> See Johnson Sirleaf, E., Clark H., “Losing Time: End this Pandemic and Secure the Future”, November 2021, [https://theindependentpanel.org/wp-content/uploads/2021/11/COVID-19-Losing-Time\\_Final.pdf](https://theindependentpanel.org/wp-content/uploads/2021/11/COVID-19-Losing-Time_Final.pdf).

High-income countries to commit to provide at least 1 billion doses for 92 LMICs through COVAX by 1 Sept 2021	No later than 1 Sept 2021	Transparency in availability of doses, slot swaps to ensure priority to LIC doses through COVAX or AVAT, support for country readiness planning and prioritization of HCWs and vulnerable are key to maximizing benefit of vaccination before end 2021
More than 2 billion doses by mid-2022 through COVAX and other coordinated mechanisms	Mid 2022	Government accountability for timely delivery is key
Focus WHO mandate on normative, policy and technical guidance, including supporting countries to build capacity for PP&R and resilient and equitable health systems	No later than WHA75	Member States should undertake further discussion on this during EB 149 in 2022 in response to WGPR
Establish WHO financial independence based on fully unearmarked resources; and an increase in MS fees to 2/3 of the base program budget with replenishment for remainder	No later than WHA75	Member States should support an ambitious set of recommendations from the WGSF and give unambiguous support for higher degree of financial sustainability for WHO
Transform the current ACT-A into a truly global end-to-end platform for vaccines, diagnostics, therapeutics, and essential supplies delivered as global public goods	Medium-term	MS should review ACT-A comprehensively in 2022 with a view to designing and creating an end-to-end platform that includes support for non-exclusive intellectual property licensing and technology transfer and an international legal instrument supporting sharing of R&D
Ensure technology transfer and commitment to voluntary licensing are included in all agreements where public funding invested in research and development	Medium-term	MS should provide sustainable financing for pooled technology access (including WHO C-TAP), the Medicines Patent Pool and WHO-facilitated technology transfer hubs
Establish strong financing and regional capacities for manufacturing, regulation, and procurement of tools for equitable and effective access to vaccines, therapeutics, diagnostics and essential supplies, and for clinical trials	Medium-term	MS, WHO and IFIs identify resource needs and mobilize funds for building manufacturing capacity for pandemic countermeasures in low and middle-income countries and to enhance regional self-sufficiency

The IPPR recommendations for increased financing to WHO are not included in this table, considering that financing is a topic being considered separately by the WGPR and by the Working Group on Sustainable Financing for WHO. The WGPR should prioritize advancing consensus on IPPR recommendations and actions for its report to the WHA 75th session in



May 2022. The WGPR can also consider advancing other relevant recommendations on equity from other sources.<sup>25</sup>

First and foremost, more vaccine doses need to be delivered to countries and populations in need. For this, there is need to close the funding gap to support roll-out through the COVID-19 Vaccines Global Access (COVAX), the vaccine pillar of the ACT-Accelerator initiative, and take actions to increase global vaccine production and delivery. The financial cost of reaching 70 per cent COVID-19 vaccination coverage in 133 low and middle-income countries by June 2022 is estimated at 9.1 billion USD.<sup>26</sup> Countries with excess doses should also increase vaccine donations particularly to the COVAX, following the principles for vaccine donations.<sup>27</sup> The initial goal of COVAX was to deliver 2 billion vaccine doses by end 2021. It has reached 1.1 billion in January 2022. COVAX is currently short of 5.2 billion USD, noting that it will not be able to accept more donations without new resources, as donor countries do not cover certain costs associated with donations.<sup>28</sup> It is alarming that over 421 million surplus doses in high-income countries reached their use-by dates by the end of 2021.<sup>29</sup> Donations are welcome due to the urgency of the need for vaccines. However, charitable donations will not address vaccination inequity. Coordinated efforts should have been made early in the pandemic to rapidly increase vaccine manufacturing.<sup>30</sup>

To address the undersupply problem now and start preparing for the next pandemic, there is need to open production of effective vaccines to other manufacturers. The mRNA platform vaccine producers (Moderna and Pfizer) have not been willing to license their technology in developing countries, despite limited production capacity. In the third quarter of 2021, Moderna made a revenue of 5 billion USD from its vaccine, its only commercial product. The United States Government has taken a passive stance of pledging increased donations but not compelling Moderna to share,<sup>31</sup> despite being a major funder for the development of the vaccine and the contribution from government scientists.<sup>32</sup>

Building capacity across regions requires transfer of know-how and technology, and to overcome barriers of intellectual property protection.<sup>33</sup> In South Africa, the firm Afrigen Biologics with the University of the Witwatersrand, and support from WHO has recently announced it has successfully produced a COVID-19 mRNA vaccine candidate replicating Moderna's mRNA vaccine, despite the unwillingness of Moderna to share expertise and

<sup>25</sup> WHO Dashboard of COVID-19 related recommendations, <https://app.powerbi.com/view?r=eyJrIjojODgyYjRmZjQ0N2UyNi00NGE4LTg1YzYzMtYzE2OGFhZjBiYzFjIiwidCI6ImY2MTBjMGJlZWJkMjQtNGIzOS04MTBiLTNkYzI4MGFmYjU5MCIsImMiOj9&pageName=ReportSection729b5bf5a0b579e86134>.

<sup>26</sup> UNICEF, "Costs and predicted financing gap to deliver COVID-19 vaccines in 133 low- and middle-income countries", 10 January 2022, Table 3A. <https://www.unicef.org/media/114216/file/Costs-and-Predicted-Financing-Gap-to-Deliver-COVID-19-Vaccines-in-133-Low-and-Middle-Income-Countries.pdf>.

<sup>27</sup> Principles for sharing COVID-19 vaccine doses with COVAX, 3 February 2022, [COVAX Principles COVID-19 Vaccine Doses COVAX.pdf \(gavi.org\)](https://www.gavi.org/covax-principles).

<sup>28</sup> Cash shortages mean COVAX cannot accept new doses, says executive Financial Times, 25 January 2022, <https://www.ft.com/content/d8506581-81a3-4cd2-bf3c-073eca9a0ae4>.

<sup>29</sup> Feinmann, J., "How the world is (not) handling surplus doses and expiring vaccines", *BMJ* 2021; 374 Doi: <https://doi.org/10.1136/bmj.n2062>.

<sup>30</sup> See Correa C., "Vaccination inequalities and the role of the multilateral system", *South Views* No. 224, July 2021, <https://www.southcentre.int/southviews-no-224-19-july-2021/#more-16709>.

<sup>31</sup> The contract Moderna entered into with the Biomedical Advanced Research and Development Authority (BARDA) may give the federal government legal authority to access and share the ingredient list and manufacturing instructions for Moderna's COVID-19 vaccine, see <https://www.warren.senate.gov/imo/media/doc/2021.10.12%20Letter%20to%20WH%20and%20BARDA%20on%20Moderna%20Contract.pdf>.

<sup>32</sup> Moderna filed patents for the genetic sequence that prompts an immune response and did not include the names of the government-funded scientists from the National Institute of Health (NIH).

<sup>33</sup> Forms of intellectual property rights include patents, copyright and trade secrets. Patent law creates an exclusive right to make, use, or sell the invention claimed by the patent for a limited period of time (minimum 20 years).

resources.<sup>34</sup> Without Moderna's support, the project will need to run its own lengthy and costly clinical trials. Moreover, while the risk of potential intellectual property infringement is currently low, there is uncertainty for the future as the mRNA platform moves forward towards or commercialization which may take up to two years, and for the potential application to other diseases. The WHO quietly initiated this mRNA hub with little support opting on this new technology for its high effectiveness and potential for other disease areas.

The WGPR can agree to enhance vaccine manufacturing capacity for new platform technology and others. Immediate actions governments can take now is to exercise legal powers to mandate sharing of know-how and limit the exclusionary impact of intellectual property protection.<sup>35</sup> As recommended by the IPPR, an immediate action is to support the temporary suspension—waiver—of intellectual property rights under the rules of the World Trade Organization (WTO)<sup>36</sup> for tools to support the COVID-19 pandemic response, including vaccines, treatments, and diagnostic tests. This process has already missed its deadline for decision of December 2021.<sup>37</sup> Health ministries and attachés can influence the speed and outcome of the decision to be made in the WTO.

Priority should also be given to increasing the roll out of low-cost, effective testing and treatments for COVID-19. Of the more than 3.5 billion tests reported globally as of October 2021, only 0.4 per cent were performed in low-income countries. Currently there are few proven treatments for COVID-19 and effective new therapeutics are still under development and regulatory review or not widely available. Access is also constrained by limited production and high prices, driven by high demand and intellectual property protection. The WGPR should agree on action for increased investment for procurement and delivery of diagnostic tests and treatments in countries in most need, through the ACT-Accelerator.<sup>38</sup>

Immediate action is also needed to accelerate production of generics and local manufacturing in developing countries to support low-cost production and sustainable supply. Case by case voluntary licensing is not a viable solution to ensure access during pandemics. Voluntary licenses are based mainly on business partnerships established with a commercial (for profit) purpose, which also leads licensees to prioritize sales in developed countries, rather than to prioritize access. The right holder can refuse to license. Most licenses being granted for COVID-19 vaccines, treatments and diagnostics give the licensee exclusive rights to manufacture and commercialize the product in specific countries on commercial terms (i.e., subject to royalty payments, confidentiality, limited know-how transfer and data). The terms and conditions of the deals are often not disclosed. There are important ongoing efforts on voluntary licensing patented new COVID-19 treatments (i.e., molnupiravir, paxlovid) to enable production of low-cost generic supply through the Medicines Patent Pool (MPP). However, these voluntary licenses are restricted to certain generic producers and include numerous conditions such as limited geographical scope—many developing countries are excluded as “high-middle income economies”. MPP to date

<sup>34</sup> “South Africa’s scientists copy Moderna’s vaccine”, *Nature* 602, 3 February 2022, pp. 372–373. Doi: <https://doi.org/10.1038/d41586-022-00293-2>.

<sup>35</sup> See Gurgula O., “Accelerating COVID-19 vaccine production via involuntary technology transfer”, Policy Brief 102, South Centre, September 2021, *The South Centre | Policy Brief 102, September 2021*.

<sup>36</sup> The Agreement on Trade Related Aspects on Intellectual Property Rights (TRIPS).

<sup>37</sup> See Ismail F., “The WTO TRIPS Waiver should help build vaccine manufacturing capacity in Africa”, Policy Brief 97, South Centre, July 2021 <https://www.southcentre.int/policy-brief-97-july-2021/#more-16784>; Vawda Y., “The TRIPS COVID-19 Waiver, Challenges for Africa and Decolonizing Intellectual Property”, Policy Brief 99, South Centre, August 2021 <https://www.southcentre.int/policy-brief-99-august-2021/#more-16840>; Correa C., Syam N., Uribe, D., *Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims Under Free Trade and Investment Agreements*, Research Paper No. 135, (Geneva, South Centre, September 2021). <https://www.southcentre.int/research-paper-135-september-2021/#more-17099>.

<sup>38</sup> The estimated funding need for diagnostics is 7 billion, for treatments 3.5 billion, up to September 2022. See ACT-Accelerator Strategic Plan & Budget: October 2021 to September 2022, [ACT-Accelerator Strategic Plan & Budget: October 2021 to September 2022 \(who.int\)](https://www.who.int/publications-detail/act-accelerator-strategic-plan-and-budget-october-2021-to-september-2022).

has no voluntary licenses to enhance access to new COVID-19 monoclonal antibody treatments. There has also been limited voluntary sharing of intellectual property, know-how and data through the WHO COVID-19 Technology Access Pool (C-TAP). The WGPR should recommend more support for MPP and for C-TAP. The potential of C-TAP is clear: it has a first license from the Spanish National Research Council (CSIC) that will allow sharing of a COVID-19 serological antibody technology (test) available to any manufacturer (license is non-exclusive) to sell in any territory and royalty free.

The WGPR can support consensus building on the multilateral temporary waiver of intellectual property rights that should extend to diagnostics and treatments in addition to vaccines, and recommend broader support for technology transfer to generic producers in developing countries via the WHO and ACT-Accelerator. The WGPR can also immediately recommend WHO to increase its work to support developing countries in making use of provisions of the TRIPS Agreement “TRIPS flexibilities” to promote access to effective and affordable medicines and other tools and increase local production.<sup>39</sup>

The WGPR can also recommend that the INB takes up the IPPR recommendations it classified as “medium-term”, including to “transform the current ACT-A into a truly global end-to-end platform for vaccines, diagnostics, therapeutics, and essential supplies delivered as global public goods”. The ACT-A in its design has had serious shortcomings including in its governance and accountability.<sup>40</sup>

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<sup>39</sup> See Velásquez G., *Re-thinking Global and Local Manufacturing of Medical Products After COVID-19*, Research Paper No. 118, (Geneva, South Centre, September 2020). <https://www.southcentre.int/research-paper-118-september-2020/>; Ismail Faizel, “The WTO TRIPS Waiver Should Help Build Vaccine Manufacturing Capacity in Africa,” Policy Brief 97, South Centre, July 2021. <https://www.southcentre.int/policy-brief-97-july-2021/>.

<sup>40</sup> See Moon S., Armstrong J., Hutler B., Upshur R., Katz R., Atuire C., Bhan A., Emanuel E., Faden R., Ghimire P., Greco D., Ho C.W., Kochhar S., Schaefer G.O., Shamsi-Gooshki E., Singh J.A., Smith M.J., Wolff J. “Governing the Access to COVID-19 Tools Accelerator: towards greater participation, transparency, and accountability”, *Lancet*. 2022 Jan 29;399(10323):487–494. Doi: 10.1016/S0140-6736(21)02344-8. Epub 2021 Dec 11. PMID: 34902308; PMCID: PMC8797025. A Strategic Review of the ACT-Accelerator also pointed to the tradeoffs in its operational model between speed and responsiveness versus ease of accountability and broad inclusion of stakeholders in governance. See ACT-Accelerator Strategic Review, Dalberg Advisors, 8 October 2021, [https://www.who.int/docs/default-source/coronaviruse/act-accelerator/act-a-strategic-review-report-8oct2021-final.pdf?sfvrsn=152da120\\_1&download=true](https://www.who.int/docs/default-source/coronaviruse/act-accelerator/act-a-strategic-review-report-8oct2021-final.pdf?sfvrsn=152da120_1&download=true).

## 6. EQUITY CONSIDERATIONS AS PART OF STRENGTHENING OF THE IHR (2005)

The WGPR will be reviewing the implementation of the IHR (2005) by WHO Member States and the WHO, and it may suggest as part of its report to the WHA any recommendations for improving implementation. This can include proposals for amendments to the IHR (2005) with the understanding that it will not lead to a renegotiation of the IHR. The IHR review process is complementary to the INB negotiations for an international instrument on pandemics. The scope of IHR (2005) is broad, it includes not only infectious diseases but any event that may constitute a potential public health emergency of international concern (IPHEIC).

The IHR (2005) is a binding agreement of international law among 194 States that entered into force in 2007.<sup>41</sup> Not much attention has been given in the current WHO discussions to how the IHR (2005) can be strengthened to promote equity in pandemic prevention, preparedness and response. The discussions have focused on the legal nature of the provisions in the regulations, the role of WHO in the IHR implementation and limited State compliance with certain provisions. In fact, the report of the Review Committee on the Functioning of the IHR during the COVID-19 response presented to the WHA in May 2022 does not provide recommendations for improving the functioning of the IHR (2005) that directly relate to advancing equity.<sup>42</sup>

Certainly, increasing compliance with obligations in the IHR (2005) is necessary. Reflection on the reasons for limited compliance with certain obligations will also serve to fill the gaps. The main purpose of the regulations is to foster global cooperation among States and through the WHO, which requires trust and solidarity. An emphasis on achieving compliance mainly by suggesting revisions to tighten existing obligations and create new ones, may be counterproductive. These proposals must be carefully assessed. Current obligations in the IHR (2005) to support for countries need to also be the focus of the discussion on increasing compliance, in particular in respect of developing countries with less resources and weak health systems that limit their ability to fully implement the IHR (2005), and bearing in mind existing inequities. For example, the Ebola Interim Assessment Panel noted that there are “clear disincentives for countries to report outbreaks quickly and transparently as they are often penalized by other countries as a result” and recommended the IHR review committee to “consider incentives for encouraging countries to notify public health risks to WHO, including innovative financing mechanisms such as insurance triggered to mitigate adverse economic effects.”<sup>43</sup> With the respect to the obligation of establishing and maintaining core capacities listed in the IHR (2005), a progressive approach to meet the obligations is more appropriate for developing countries than proposals to set specific deadlines. The improvement of the self-assessment and monitoring mechanisms and commitment by countries to participate, for example through Universal Peer Reviews that also take into account the efforts at broader health system strengthening and advance human rights, would serve to increase accountability. Solidarity and equity considerations should also be embedded into the design and functioning of the mechanism, rather than to serve solely as a mechanism for increased compliance.

<sup>41</sup> The WHA has the authority to adopt regulations on certain issues as set out in Article 21 of the WHO Constitution, [who constitution en.pdf](https://www.who.int/publications/m/item/a74-9-who-s-work-in-health-emergencies).

<sup>42</sup> Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response, Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response, <https://www.who.int/publications/m/item/a74-9-who-s-work-in-health-emergencies>.

<sup>43</sup> Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response, document A69/21, para 61., [EB Document Format \(who.int\)](https://www.who.int/publications/m/item/a74-9-who-s-work-in-health-emergencies).

Previous reports of the IHR review committee have advanced recommendations that can advance greater equity to support IHR implementation which remain outstanding. An important area is to advance on strengthening health systems together with IHR core capacities as key elements to achieving the Sustainable Development Goals (SDGs). Priority should also be placed on greater predictable and sustainable funding for full implementation of IHR (2005) and increasing technical resources to support capacity building. Previous review committees have noted that “full implementation of the IHR... cannot be achieved without significantly greater funding and, despite the urgency of the task, cannot be achieved in a very short timeframe because of the systemic improvement required in many States Parties.”<sup>44</sup> Many countries cannot meet these costs solely with domestic funding and require external financing. More effort needs to be put into costing the strengthening of core capabilities in the context of overall health system strengthening and to mobilize financing and technical resource support. The WHO alone is not able to do such costing. As noted, the topic of financing is being addressed separately by the WGPR and by the Working Group on Sustainable Financing for WHO, but there has been no discussion to date on financing of IHR (2005) implementation.

The lack of preparation and failures in the global response to COVID-19 call for greater collaboration among countries and by the WHO with countries. The WGPR should consider recommending bolstering and clarify what these obligations are with respect to the IHR (2005). In particular, the obligations in Article 44 “collaboration and assistance” could be strengthened.<sup>45</sup>

Box 1.

**IHR (2005) Article 44: Collaboration and assistance**

1. State Parties shall undertake to collaborate with each other, to the extent possible, in:
  - a) the detection and assessment of and response to events as provided under these Regulations;
  - b) the provision or facilitation in the development, strengthening and maintenance of the public health capacities required under these Regulations;
  - c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and
  - d) the formulation of the proposed laws and other legal administrative provisions for the implementation of these Regulations.
2. WHO shall collaborate with State Parties, upon request, to the extent possible, in:
  - a) the evaluation an assessment of their public health capacities in order to facilitate the effective implementation of these Regulations;
  - b) the provision or facilitation of technical cooperation and logistical support to States Parties; and
  - c) the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1.

In article 44.1, after “collaborate” the wording “and assist” could be added to clarify that the obligation refers not only to collaboration (shared) but also assistance (from one country to

<sup>44</sup> Ibid., para.4.

<sup>45</sup> A legal interpretation of Article 44 is elaborated in Cinà M., Hoffman S., et al., “The Stellenbosch Consensus on the International Legal Obligation to Collaborate and Assist in Addressing Pandemics”, *International Organizations Law Review*, 2020, <https://doi.org/10.1163/15723747-2020024>. It is noted that “there was...no consensus among the authors on whether Article 44 mandates how countries should implement their individual obligations pursuant the common and shared responsibility. Article 44.1 indicates that duties of collaboration will not necessarily be fulfilled in the same manner by each country but does not provide information on how exactly a specific state party will determine its individual duty”.



another), adding that this should be in particular towards developing countries. In Art 44.1 a new point e) can be added to include “the development and distribution of, and unhindered, timely and equitable access to, medical countermeasures such as vaccines, therapeutics and diagnostics, as well as strengthening health systems.”<sup>46</sup> The wording in Article 44.1 “to the extent possible” could be deleted. The WHO can also be requested to provide guidance on the implementation of Article 44.1 and to provide a detailed catalogue of the support that it can provide all countries and developing countries, under Article 44.2.

Equity should also be an observed principle in the discussion of the recommendation by the IHR review committee on COVID-19 to improve timely sharing of public health information with the WHO and subsequently by the WHO with other countries. The review committee recommended that “WHO should develop a mechanism for States Parties to automatically share real-time emergency information, including genomic sequencing, needed by WHO for risk assessment, that builds on relevant regional and global digital systems.” Currently there is no explicit obligation in the IHR (2005) to automatically share genomic sequencing data with WHO. Rightly so, as many countries lack capacity for genomic sequencing and detection capacities, and there is lack of consensus on the manner in which such information can be accessed, used and shared. More emphasis is needed on building these capacities domestically, increasing local expertise and infrastructure.

The IHR review committee in the Ebola outbreak and response took a different approach from the IHR review committee on COVID-19 response, crafting its recommendation as follows: “WHO and States Parties should ensure that sharing of samples and sequence data is balanced with benefit-sharing on an equal footing.”<sup>47</sup> This recommendation serves to balance country obligations under the IHR (2005) with other potential obligations and goals under the Nagoya Protocol of the Convention on Biological Diversity (CBD). This approach is better suited for building a consensus solution in the WPGR, together with emphasis on supporting capacity building. This recommendation does not discard that access may be facilitated while providing assurance that the objective of benefit sharing will be advanced. This balance was adequately achieved in the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (PIP).<sup>48</sup> A proposal to amend the IHR (2005) in Article 6.2 to explicitly create an obligation to share genomic sequence data is not in line with the principle of equity and would undermine advancement of the objectives of the CBD, of which most countries are party. A recommendation WGPR can advance is to increase support for WHO to provide technical assistance to countries to build genomic sequencing and detection capacities, supporting IHR (2005) implementation and consistent with other legal obligations stemming from other agreements (i.e., CBD Nagoya Protocol), as well as specific actions to advance access to vaccines and other medical countermeasures.<sup>49</sup> Discussions on a potential specialized agreement on access and benefit sharing for human pathogens and genome sequences can continue in the context of the INB.

Another important equity consideration in the review of IHR (2005) is how to ensure that the national measures adopted by governments (i.e., trade restrictions, travel restrictions, regulation of travel-entry vaccine certificates) are not disproportionate and discriminatory. The WHO should develop more detailed guidance that countries commit to follow, including

<sup>46</sup> This wording is adapted from the WHA Decision SSA2(5), *Ibid* at 6.

<sup>47</sup> *Ibid* at 40, para 174.

<sup>48</sup> The PIP Framework applies to the sharing of H5N1 and other influenza viruses with human pandemic potential and the sharing of benefits. See <https://www.who.int/publications/i/item/9789240024854>.

<sup>49</sup> In this respect, the African Group has noted that “mobilizing political support for expedited access depends on being able to demonstrate to decision makers that adequate benefit sharing measures are in place to make vaccines and treatments available and affordable to African countries”. See Submission by the African Union Continental Coordinating Committee on Matters Related to Biodiversity, Biosafety and ABS, Comments on WHO Secretariat reports on Decision WHA72(12), [africanunion\\_comments\\_wha7212reports.pdf \(who.int\)](#).

on vaccine passports. For example, all travelers that are vaccinated with vaccines that have completed the WHO emergency listing process should receive equal treatment for proof of immunization.<sup>50</sup>

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<sup>50</sup> An example of a discriminatory policy applied, but which IHR (2005) currently does not directly regulate, was the refusal by some European Union (EU) Member States to accept the WHO-approved for emergency use AstraZeneca vaccine manufactured in India (Covishield) as proof of immunity for travel purposes because the European Medicines Agency (EMA) had not yet approved Covishield, while the AstraZeneca vaccine manufactured in sites in the EU and United Kingdom (UK) was accepted.

## 7. A NEW INTERNATIONAL INSTRUMENT: TOWARDS A JUST FRAMEWORK

The negotiation of a new convention or other international instrument on pandemics in the WHO offers an opportunity to fill longstanding gaps in necessary cooperation and coordination to address common global health problems. The WHA Decision of December 2021 to start negotiations provides for a clear initial mandate to deliver greater global solidarity and equity in prevention, preparedness and response to pandemics.

The WGPR has rightly suggested that the new instrument “should be anchored in all the principles found in the WHO Constitution (Preamble), including the principle of non-discrimination and the right to the enjoyment of the highest attainable standard of health. These are important in advancing equity and universal health coverage, ensuring equitable access to medical countermeasures and health services, both now and in the future.”<sup>51</sup>

The WHA Decision establishing the INB and the WGPR have also highlighted that equitable access to countermeasures such as vaccines, therapeutics and diagnostics must be a key objective of the new instrument. The WGPR has agreed that a potential benefit of an instrument could be to establish “a framework [to] facilitate concrete measures and long-term mechanisms to develop, manufacture and scale up countermeasures through increasing local production, sharing of technology and know-how for broadening manufacturing capacity, and strengthening regulatory systems”.<sup>52</sup>

Accordingly, the necessary normative elements for such framework need to be defined and mechanisms steer and coordinate research and development efforts to deliver tools to advance health for all as global public goods. The market-led model of research and development has shown during the COVID-19 pandemic—as in many disease areas including those that disproportionately affect developing countries (i.e., neglected tropical diseases)—that it is not fit to deliver global public health. In the context of the WHO, countries have long recognized the gaps, having discussed the merits of negotiating and concluding a treaty for coordination and funding of medical research and development<sup>53</sup>, but have failed to collectively act. There is growing evidence of the viability of alternative models of innovation to deliver timely, appropriate and affordable medical technologies,<sup>54</sup> including for development and scale up of effective and low-cost COVID-19 vaccines.<sup>55</sup> COVID-19 has reinvigorated attention to the need to reorient research and development in the global public interest.<sup>56</sup> What is mostly needed is political will to build and sustain the appropriate ecosystem and mobilize all relevant players to cooperate.

Research and development for COVID-19 vaccines has advanced rapidly, through a combination of market-based incentives (profit motivation driving private firms), government incentives (grants and subsidies, intellectual property), partnerships (biotech firms both public and private, research institutes, universities), financing (public, private, investors, donors) and pathways for emergency regulatory approvals. However, these efforts have been disjointed, there has been insufficient coordination. The WHO has played an important

<sup>51</sup> Document SSA2/3, para. 11(e), *Ibid* at 19.

<sup>52</sup> Document SSA2/3, para. 11(f), *Ibid* at 19.

<sup>53</sup> See Velásquez G., “Rethinking The R&D Model for Pharmaceutical Products: A Binding Global Convention”, Policy Brief 8, South Centre, April 2012. [The South Centre | Policy Brief 8, April 2012.](#)

<sup>54</sup> See Munoz, V., et al. “Can medical products be developed on a non-profit basis? Exploring product development partnerships for neglected diseases”, *Science and Public Policy* 42.3 (2015): 315–338.

<sup>55</sup> The Corbevax vaccine, now authorized for emergency use in India, is an example of a viable open-science approach, with no intellectual property protection.

<sup>56</sup> See Swaminathan S., Pecoul B. et al, “Reboot Biomedical R&D in the global public interest”, *Nature* 602, 10 February 2022, pp. 207–210. <https://www.nature.com/articles/d41586-022-00324-y>



albeit limited role through the WHO R&D Blueprint and participation in the COVAX pillar of the ACT-Accelerator initiative. Most significantly, efforts have not pursued a collective goal of advancing science to deliver global access to vaccines as a global public good.

Despite the significant amount of public tax payer financing that went into vaccine research and development, —including basic research, clinical trials and manufacturing— and the guaranteed market conditions for scale-up through advance purchases, governments have not leveraged their power adequately as lead financiers and purchasers to obtain a fair deal from developers. Governments have also fared poorly in information sharing and coordination to collectively leverage their bargaining power with vaccine manufacturers to obtain better terms in purchasing contracts, including on price, and indemnity clauses, and allow for disclosure of contractual terms. Governments and other funders (donors, development banks, CEPI) missed the opportunity to include conditions on equitable access when funding research and development (R&D) and negotiating purchase agreements for vaccines. Lack of transparency in contracts has been a major stumbling block for governments to provide vaccine access to their populations and for the adequate operation of the multilateral mechanism for promoting access.

Vaccine procurement has operated in two tracks—the bilateral or regional track whereby governments directly purchase from vaccine manufacturers, and the COVAX mechanism track. In the first track, the distribution of existing vaccine doses has been largely left to market forces, which allocate disproportionately towards wealthy countries. Countries did not adhere to the equitable global allocation mechanism developed by WHO to advance universal access to vaccination. The over-demand for vaccine doses, assured through pre-purchase agreements by a few wealthy countries, reduced the doses available for purchase under the second, multilateral track. Moreover, its functioning is further hindered by lack of normative capacity of WHO to steer and coordinate government and private sector actions such as in fair vaccine dose allocations and delivery on contracts, inappropriate governance, —as a loose coalition of entities joined under the initiative under a temporal, voluntary initiative— and underfunding.

Research and development to deliver new diagnostics and treatments for COVID-19 has been disappointing, due to similar gaps in the ecosystem.

### **7.1 Advancing Draft Text for Negotiation**

Regardless of the legal nature that the international instrument takes, the instrument will need to create new specific legal mandates if the instrument is to be transformative.<sup>57</sup> Some of the mandates that could be included in the draft text to be negotiated by the INB that would serve to support equity, and in particular the objective of building a multilateral coordinated system for production, procurement and distribution of vaccines, diagnostics, medicines and other tools during pandemics are the following:

1. Strengthen role of the WHO for effective coordination, norm-setting and technical guidance, requiring countries to commit to compliance. This should include, for example, commitment by countries to restrain advance purchase commitments during global supply shortages in order to allow for equitable allocation across countries in accordance with WHO guidance.

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<sup>57</sup> For discussion of other topics that may be included in a new WHO convention, see Velásquez G., Syam N., Ibid. at 11; Bustamante T., del Rosario J., Magliolo M., Segal L., “A New Treaty on Pandemics: Some Key Issues from a Global South Perspective”, Working Paper, November 2021, South Centre [The South Centre | Working Paper on Pandemic Treaty, 23 November 2021](https://www.southcentre.int/working-paper-on-pandemic-treaty-23-november-2021/1) <https://www.southcentre.int/working-paper-on-pandemic-treaty-23-november-2021/1>.

2. Define responsibilities of parties involved in the multilateral system to support global research and development, procurement and delivery of medical countermeasures
3. Equitable governance and inclusive decision-making.
4. Minimum financial allocation by developed countries for pooled procurement and equitable distribution of countermeasures for pandemic response, through a multilateral system that builds on the lessons from the ACT-Accelerator.
5. Sharing with WHO information regarding purchase agreements (e.g., quantities, prices, delivery timetables) in a timely manner.
6. Commitments to enhance public investment in research and development by all countries and share results of publicly financed research.
7. Commitments to introduce access conditions in grants and contracts (bilateral or multilateral) and other direct public or multilateral funding for private sector (multilateral initiatives, banks, donors). WHO can be tasked to provide guidance on model provisions for contracts.
8. Pool financing through a global research and development fund to support research and sharing of results, including support for open science, prioritizing involvement of developing country institutions and researchers.
9. Incentives as part of the global research and development fund to stimulate collaborative R&D with developing country public and private sector labs, universities and firms.
10. Waiving of pre-existing intellectual property held by parties supported by the global R&D fund and no assertion of intellectual property rights thereafter.
11. Commitment to sustained investment in regional infrastructure and expertise for diagnostic, medicine and vaccine production.
12. Financial and technical support for regional procurement mechanisms, regional supply chains and regional transfer of technology hubs
13. Encourage governments to make use of TRIPS flexibilities to promote access to medical countermeasures.
14. Multilateral and-or regional mechanisms to facilitate transfer of technology and know-how, backed by government commitments to encourage private sector to share.
15. Mandates to disclose information, including:
  - Transparency in clinical trial design, raw data and results
  - Transparency in government contracts for research and development and contracts for procurement, including advanced purchasing agreements
  - Transparency of private R&D investments broken down by specific costs
  - Transparency in prices, including pre-purchase agreements
  - Transparency of public financing provided to stimulate research and development in the form of grants, direct payments, subsidies, tax exemptions, and other incentive mechanisms, and the eligibility for such incentives
  - Transparency in national regulatory frameworks to facilitate collaborative approaches
16. Promote regulation of access to and sharing of pathogen samples, genome sequencing and other information in accordance with other international instruments to promote sharing of benefits through a defined multilateral system that supports building and sustaining capacities and infrastructure in developing countries.
17. Commitment to support a one health approach through enhanced collaboration of WHO with relevant international organizations (i.e., World Organisation for Animal Health (OIE), the Food and Agriculture Organization of the United Nations (FAO), the United Nations Environment Programme (UNEP) to support developing countries to enhance capacities, including to establish effective cross-sectoral surveillance, including on antimicrobial resistance.

In addition, the international instrument must contain a framework for enhancing overall capacity building and financing for the WHO, in collaboration with other international

organizations and the broader United Nations system, and to support in particular developing countries, beyond the scope of the IHR (2005).

## 8. CONCLUSIONS

The WHO Member States have agreed that in order to prevent, prepare and respond better to future pandemics, lessons must be drawn from the gaps in the context of the current COVID-19 pandemic to devise a new collective path towards a safer future for all.

A collective road map must be advanced to transform the current system of norms and governance towards a more just and equitable pandemic response and ensure all countries are better prepared to deal with health emergencies. The work of the WHO bodies must have this high level of ambition.

The biggest risk in the negotiations is lack of agreement on concrete mandates that transform current normative frameworks, re-structure public-private cooperation and governance structures to deliver global public goods effectively and equitably. The outcomes must not pay lip service to the principles of equity and solidarity. A **political choice** continues to be made to restrain sharing of knowledge and tools, including diagnostics, treatments and vaccines, that could save millions of lives. A political choice is to be made now to rectify and change the course of the future.

As part of the negotiations to kick off in the WHO, it is time to define these responsibilities and establish legal obligations to ensure these are delivered upon.

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ISSN 1819-6926