



# A FAIR SHOT

ENSURING UNIVERSAL ACCESS TO COVID-19 DIAGNOSTICS,  
TREATMENTS AND VACCINES

AMNESTY  
INTERNATIONAL



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*Cover photo: A health worker prepares for COVID-19 vaccine candidate trials.*  
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# 1. EXECUTIVE SUMMARY

In an unprecedented global health crisis, COVID-19 has already led to the deaths of 1.5 million people by December 2020. It has highlighted and magnified inequalities, and disproportionately affected marginalized populations. It has led to government measures that pose threats to a range of human rights, and as it continues to spread, it is threatening to leave half of the world's workforce without jobs and push up to 150 million more people into extreme poverty. Against this background, it is essential that the extraordinary global efforts to develop, manufacture and distribute tests, treatments and vaccines for COVID-19 are conducted in ways that respect human rights.

This Amnesty International policy briefing outlines state obligations and business responsibilities in relation to COVID-19 diagnostics, treatments and vaccines. It highlights that key human rights obligations for states apply to their own populations as well as people in other countries, particularly the right to the highest attainable standard of physical and mental health and the right to enjoy the benefits of scientific progress and its applications. States are obliged to ensure that COVID-19 vaccines are available, accessible, affordable and of good quality for everyone without discrimination. Businesses also have a responsibility to respect human rights, as outlined in the UN Guiding Principles on Business and Human Rights, while the UN Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines spells out the "human rights responsibility to extend access to medicines for all."

The policy briefing then examines the key human rights concerns that have emerged on issues linked to the development and distribution of COVID-19 vaccines. These issues include:

- **Global availability and affordability**, particularly concerns about "vaccine nationalism," the potentially unfair distribution of the vaccine globally, and intellectual property rights.
- **National availability and accessibility**, with a focus on accessibility and availability within countries as well as the challenges facing national health systems.
- **National affordability and pricing**, and the negative impacts of not providing COVID-19 vaccines free at the point of care.
- **Quality and acceptability**, including concerns related to clinical trials, mandatory vaccination programmes and the reluctance of some people to be vaccinated.

This policy briefing outlines Amnesty International's position on COVID-19 diagnostics, treatments and preventive medical technologies (often using the general term "COVID-19 health products"), followed by recommendations to states and business enterprises. While some policy arguments and recommendations are relevant to all issues, the overall focus is on vaccines, given the current salience of this issue. A total of 34 detailed recommendations are contained in this paper, and summarized versions of these include:

- States must, and businesses should, develop and implement policies to ensure availability, accessibility, affordability, acceptability and quality of COVID-19 health products for all people. This should be done according to the principles of transparency, participation, accountability, equality and non-discrimination.
- States must cooperate globally and remove any potential barriers to ensure that vaccines are developed, manufactured in sufficient supply, and then distributed in a timely and inclusive manner around the globe. This obligation includes providing technical and financial assistance to other states, as well as refraining from behaviours including bilateral deals that could compromise the ability of other states to do so, which includes "hoarding" of vaccines beyond what is needed for priority, at-risk populations.
- States must ensure that intellectual property rights do not prevent any countries from upholding the right to health. This includes agreeing a 'waiver' on certain aspects of the TRIPS agreement for the production of COVID-19 health products, supporting the WHO's COVID-19 Technology Access Pool (C-TAP), and placing conditions on public funding to ensure pharmaceutical companies share their innovations, technology and data with other manufacturers.

- Businesses should develop and implement policies concerning access to COVID-19 health products, including on pricing, transparency and intellectual property, that respect the right to health and aim to make these products available, accessible and affordable to all.
- Businesses also should refrain from any action that unduly impacts on states' ability to ensure availability, accessibility and affordability of COVID-19 health products. This should include any action that may discourage states to use TRIPS flexibilities or support the proposed WTO TRIPS waiver.
- Businesses should issue non-exclusive licenses for COVID-19 health products, including technology transfer, and participate in global mechanisms to share innovations, such as C-TAP, in order to scale up supply via other manufacturers.
- States must devise national COVID-19 vaccine distribution plans to be accessible, inclusive and non-discriminatory. States should consider factors that may heighten an individual's or a community's risk to COVID-19 and pay particular attention to marginalized groups and those with intersecting identities and legal statuses. Processes should be transparent and include participation of civil society and marginalized groups. States must invest to strengthen health systems, including to ensure transportation, storage, administration and monitoring of COVID-19 health products.
- States must ensure that cost is never a barrier to accessing COVID-19 health products. Given the huge public health and economic impacts of COVID-19, states should provide vaccines free at the point of care, using their maximum available resources and tapping into international cooperation and assistance, if needed.
- Businesses must consider all the arrangements at their disposal, including policies on pricing and intellectual property, to ensure that the pricing of their products is never a barrier to accessing COVID-19 health products and does not unduly impact a state's ability to provide COVID-19 vaccines free at the point of care.
- States must ensure that any vaccines distributed are deemed safe and effective through rigorous trials and objective regulatory agencies, making this information available in a timely, transparent and accessible fashion to allow for public scrutiny.
- States must not impose blanket mandatory vaccine policies and should seek to ensure that vaccination is voluntary wherever and whenever possible. If a state seeks to introduce a vaccine requirement for specific circumstances, it must be consistent with international human rights law and standards. Amnesty International strongly opposes the use of the criminal law and, in particular, the imprisonment of people who refuse vaccination.
- States must ensure everyone has free, unhindered and easy access to credible, reliable, objective and evidence-based information about COVID-19 health products. To this end, states must lift all undue restrictions on the right to seek, receive and impart information about COVID-19 health products; adopt adequate frameworks, in line with their human rights obligations, to address the pernicious effects of false or misleading information that could compromise the right to health; and ensure that they disseminate credible, reliable, accessible, objective and evidence-based information.
- States must ensure that people whose rights to health and privacy has been violated can exercise their right to an effective remedy through judicial mechanisms, national ombudsmen, human rights commissions, consumer forums, patients' rights associations or similar institutions. These mechanisms must be accessible, transparent and effective.



People wait for food items during a government-imposed shut-down as a preventive measure against the COVID-19 in Dhaka, Bangladesh on April 17, 2020. ©Mamunur Rashid/NurPhoto via Getty Images



A doctor performs a coronavirus swab test on a patient at the Aga Khan University Hospital in Nairobi, Kenya on April 24, 2020. © YASUYOSHI CHIBA via Getty Images

## 2. BACKGROUND

In less than a year, COVID-19 has touched nearly every country around the globe. As of December 2020, more than 65 million people across 191 countries and territories had contracted the virus and 1.5 million people have died as a result.<sup>1</sup> Government attempts to curb the pandemic have led to restrictions on freedom of movement and crackdowns on critical voices.<sup>2</sup> Meanwhile, the socio-economic impacts have increased and magnified existing inequalities, disproportionately affecting historically marginalized populations.<sup>3</sup> Several UN agencies have warned that nearly half of the world's workforce is at risk of losing its livelihood,<sup>4</sup> whilst the World Bank has noted that 88-115 million people may be pushed into extreme poverty in 2021, possibly rising to as many as 150 million people.<sup>5</sup>

States, pharmaceutical companies, intergovernmental organizations and research institutes around the world have taken steps to develop medical products that can prevent, diagnose and treat COVID-19, including an unprecedented race to produce vaccines in record time. Estimates suggest that governments have invested nearly US\$20bn to fast-track the research, manufacture and distribution of vaccines.<sup>6</sup>

In May 2020, in response to this exceptional public investment, the World Health Assembly recognized “the role of extensive immunization against COVID-19 as a global a global public good.”<sup>7</sup> The UN Secretary-General publicly added that it should be “accessible to all.” Since then, 140 global public figures and experts – including heads of government in Costa Rica, Ghana, Nigeria, Pakistan, Senegal and South Africa – have joined a global call for a People's Vaccine “for all people, in all countries, free of charge.”<sup>8</sup> In November 2020, several UN Human Rights Experts stated that access to vaccines was an essential tool to prevent and contain COVID-19 around the world.<sup>9</sup>

The development, manufacture and distribution of COVID-19 vaccines may be the largest immunization effort in history. As of December 2020, more than 200 vaccine candidates were under development and nearly one quarter of these were in the third and final phase of clinical trials.<sup>10</sup> While this could be a watershed moment, these efforts present unique global, regional and national human rights challenges, especially around how vaccines will be produced and distributed, as well as when they will become available, to whom and at what cost.

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1 Johns Hopkins University, “Dashboard by the Center for Systems Science and Engineering”, <https://www.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6>

2 Amnesty International, *Daring to stand up for human rights in a pandemic* (ACT 30/2765/2020), <https://www.amnesty.org/en/documents/act30/2765/2020/en/>

3 “COVID-19 to Add as Many as 150 Million Extreme Poor by 2021”, The World Bank, 7 October 2020, <https://www.worldbank.org/en/news/press-release/2020/10/07/covid-19-to-add-as-many-as-150-million-extreme-poor-by-2021>

4 “Time for global solidarity to overcome COVID's health, social and economic challenges”, UN News, 13 October 2020, <https://news.un.org/en/story/2020/10/1075322>

5 “COVID-19 to Add as Many as 150 Million Extreme Poor by 2021”, The World Bank, 7 October 2020, <https://www.worldbank.org/en/news/press-release/2020/10/07/covid-19-to-add-as-many-as-150-million-extreme-poor-by-2021>

6 HRW, “Whoever Finds the Vaccine Must Share It: Strengthening Human Rights and Transparency around COVID-19 Vaccines”, 29 October 2020, <https://www.hrw.org/report/2020/10/29/whoever-finds-vaccine-must-share-it/strengthening-human-rights-and-transparency>

7 “International Operation to Ensure Global Access to Medicines, Vaccines and Medical Equipment to Face COVID-19”, UN General Assembly, 15 April 2020, <https://www.un.org/pga/74/2020/04/15/international-cooperation-to-ensure-global-access-to-medicines-vaccines-and-medical-equipment-to-face-covid-19/>

8 UNAIDS, “World Leaders Unite in Call for a People's Vaccine against COVID-19”, 14 May 2020, [https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/may/20200514\\_covid19-vaccine](https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/may/20200514_covid19-vaccine)

9 OHCHR, “Statement by UN Human Rights Experts Universal Access to Vaccines is Essential for Prevention and Containment of COVID-19 around the World”, 9 November 2020, <https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26484&LangID=E>

10 WHO, “Draft Landscape of COVID-19 Candidate Vaccines”, 2 December 2020, <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>

### 3. INTERNATIONAL HUMAN RIGHTS LAWS, PRINCIPLES, STANDARDS

While the development, manufacture and distribution of COVID-19 diagnostics, treatments and vaccines directly affect a range of human rights, this policy guidance is mainly framed around the **right to health and the right to enjoy the benefits of scientific progress and its applications**. However, it is important to note that other rights are affected, including the rights to life and a life with dignity,<sup>11</sup> information, privacy, participation, development and an adequate standard living for all.<sup>12</sup> Beyond this, given the impact of COVID-19, the ability of all people to access vaccines will indirectly have a wide range of human rights implications, from the rights to education and decent work to the rights to freedom of peaceful assembly and movement.

#### RIGHT TO THE HIGHEST ATTAINABLE STANDARD OF PHYSICAL AND MENTAL HEALTH

The right to the highest attainable standard of physical and mental health (the right to health) is enshrined in several international human rights treaties, and almost all countries are legally bound to at least one treaty that covers this right. All UN member states are bound to the Universal Declaration on Human Rights (UDHR), which states: “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care...”<sup>13</sup> Moreover, 171 states are party to the International Covenant on Economic, Social and Cultural Rights (ICESCR), which reiterates “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”<sup>14</sup>

The body that provides authoritative interpretation of the Covenant’s articles, the Committee on Economic, Social and Cultural Rights (CESCR), has spelled out the duties and responsibilities of states and non-state actors around these rights, respectively, concerning the right to health.<sup>15</sup> The few states that have signed but not yet ratified the ICESCR<sup>16</sup> are still bound by these principles through the Vienna Convention on the Law of Treaties, which establishes that these states must not “defeat the object and purpose of a treaty prior to its entry into force.”<sup>17</sup>

International law and standards establish that everyone has the right to health, including preventative, curative and palliative health care. The ICESCR establishes that states must undertake “to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources with a view to achieving progressively the full realization of the rights recognized in the Covenant.”<sup>18</sup> General Comment 14 establishes that this means that states must work towards ensuring that all health facilities, goods and services (including information) must be available, accessible (physically and financially), acceptable and of good quality.

Moreover, the right to health framework emphasizes that different groups of people – for example, women, children, older persons and people living with disabilities – have specific needs and face different circumstances that may affect their ability to exercise this right. As a result, states must adequately prioritize these groups when designing and implementing health policies.<sup>19</sup>

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<sup>11</sup> Human Rights Committee, General Comment 36 on Article 6 of the International Covenant on Civil and Political Rights on the right to life, CCPR/C/GC/36, 30 October 2018, paras 3 and 18

<sup>12</sup> ICESCR, Article 11 and UDHR, Article 25

<sup>13</sup> UDHR, Article 25.1

<sup>14</sup> ICESCR, Article 12.2

<sup>15</sup> CESCR, General Comment 14: The Right to the Highest Attainable Standard of Health, E/C.12/2000/4, 11 August 2000

<sup>16</sup> OHCHR, “Status of Ratification, Interactive Dashboard”, <https://indicators.ohchr.org/> As December 2020, these were Comoros, Cuba, Palau and the United States.

<sup>17</sup> See Vienna Convention on the law of treaties (with annex). Concluded at Vienna on 23 May 1969, Article 18, <https://treaties.un.org/doc/publication/unts/volume%201155/volume-1155-i-18232-english.pdf>

<sup>18</sup> ICESCR, Article 2.1

<sup>19</sup> OHCHR/WHO, *Factsheet No. 31: The Right to Health*, <https://www.ohchr.org/documents/publications/factsheet31.pdf>; CESCR, General Comment 14, para 40

## RIGHT TO THE BENEFITS OF SCIENTIFIC PROGRESS AND ITS APPLICATIONS

*“Everyone, including vulnerable or marginalised individuals and groups, is entitled to enjoy the benefits of scientific progress – and when the benefits of science are managed as a purely commercial product reserved for the wealthy, everyone is harmed.”*

Michelle Bachelet, UN High Commissioner for Human Rights<sup>20</sup>

Both Article 27 of the UDHR and Article 15 of the ICESCR establish the right to enjoy the benefits of scientific progress and its applications.<sup>21</sup> The CESCR General Comment 25 (2020) on Science and Economic, Social and Cultural Rights specifies that these benefits include medical technologies such as vaccinations.<sup>22</sup> In April 2020, the CESCR also highlighted that “pandemics are a crucial example of the need for scientific international cooperation to face transnational threats. Viruses and other pathogens do not respect borders...”<sup>23</sup>

The CESCR states that scientific progress must be available, accessible, acceptable and of good quality to all individuals and communities. To this end, states must take steps to invest in science<sup>24</sup> and all people should have equal access to the applications of scientific progress, without discrimination.<sup>25</sup> Scientific progress and its applications also must be accessible for everyone, which includes being affordable.<sup>26</sup> To this end, the CESCR clarifies that “states should use the maximum of their available resources to overcome hurdles that any person may face to benefit from new technologies or other forms of applications of scientific advancements. This is particularly relevant for disadvantaged and marginalized groups.”<sup>27</sup>

Additionally, the CESCR spells out that good quality scientific creation and its applications should rely on the most advanced, up-to-date, accepted and verifiable science available at the time.<sup>28</sup> States should also make efforts to ensure that scientific progress and its applications are explained in a way that facilitates acceptance in different cultural and social contexts. Ethical standards that respect the autonomy – including free, prior and informed consent – and privacy are key, especially when pertaining to marginalized groups.<sup>29</sup>

### KEY HUMAN RIGHTS PRINCIPLES

States must consider several key human rights principles that are critical components of the right to health.

- **Non-Discrimination and equality.** Addressing and remedying discrimination in access to health care and the underlying, social determinants of health is an immediate obligation, irrespective of the resources available. The Office of the High Commissioner for Human Rights (OHCHR) has explained that “states must recognize and provide for the differences and specific needs of groups that generally face particular health challenges, such as higher mortality rates or vulnerability to specific diseases... Positive measures of protection are particularly necessary when certain groups of persons have continuously been discriminated against in the practice of states parties or by private actors.”<sup>30</sup>

<sup>20</sup> UN Human Rights Council, “A Joint Appeal for Open Science by CERN, OHCHR, UNESCO and WHO”, 27 October 2020, <https://www.ohchr.org/EN/HRBodies/HRC/Pages/NewsDetail.aspx?NewsID=26433&LangID=E>

<sup>21</sup> CESCR, General Comment 25 on Science and Economic, Social and Cultural Rights (article 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights, E/C.12/GC/25, 30 April 2020, para 45

<sup>22</sup> CESCR, General Comment 25, para 8

<sup>23</sup> CESCR, “Statement on the Coronavirus Disease (COVID-19) Pandemic and Economic, Social and Cultural Rights”, E/C.12/2020/1, 17 April 2020, <http://docstore.ohchr.org/SelfServices/FilesHandler.ashx?enc=4slQ6QSmIBEDzFEovLCuW1AVC1nkPsgUedPIF1vfPMKXidSV%2FGyVFSAvr6nizxSIX6zd%2Bu5KD26NraabiJKaWmNkFhhMb4MahybE5i%2FuU5sQSh6PCbcepqzIOICyklyq>

<sup>24</sup> CESCR, General Comment 25, para 16

<sup>25</sup> CESCR, General Comment 25, para 17

<sup>26</sup> CESCR, General Comment 25, para 17

<sup>27</sup> CESCR, General Comment 25, para 47

<sup>28</sup> CESCR, General Comment 25, para 18

<sup>29</sup> CESCR, General Comment 25, para 19

<sup>30</sup> OHCHR/WHO, *Factsheet No. 31: The Right to Health*, <https://www.ohchr.org/documents/publications/factsheet31.pdf>

- **Participation.** States are obliged to ensure the right to active, informed and effective participation in decision-making that affects them.<sup>31</sup> To this end, health laws, policies and practices should be designed and implemented with the meaningful oversight and participation of civil society, especially by people mostly affected by these measures, at the community, national and international levels.<sup>32</sup> Moreover, states must ensure people’s participation to guarantee effective provision of health services.<sup>33</sup>
- **Transparency and accountability.** Transparency enhances the legitimacy of states’ decisions in relation to health and fosters ownership over these decisions and their implications across all members of society.<sup>34</sup> States must include a robust framework for accountability concerning violations of the right to health. This should include access to effective judicial or other appropriate remedies for bodies such as national ombudspersons, human rights commissions, consumer forums, patients’ rights associations or similar institutions to enable them to address such violations.<sup>35</sup> All accountability mechanisms must be accessible, transparent and effective.<sup>36</sup>
- **International cooperation and assistance.** States must provide financial and technical support to uphold the right to health, especially in the face of the international spread of disease.<sup>37</sup> This may include the sharing of research, knowledge, medical equipment and supplies, as well as coordinated action to reduce the negative economic and social impacts of the crisis and promote economic recovery endeavours by all states.<sup>38</sup>

## STATE OBLIGATIONS AROUND COVID-19 DIAGNOSTICS, TREATMENTS AND VACCINES

*“Immunization is the foundation of the primary health care system and an indisputable human right. It’s also one of the best health investments money can buy.”*

World Health Organization<sup>39</sup>

The CESCR has clarified that states have a core obligation to ensure minimal levels of economic, social and cultural rights. In the case of the right to health, this includes essential primary health care<sup>40</sup> and essential medicines, without delay.<sup>41</sup> These measures include prevention, treatment and control of epidemics and other diseases by making relevant technologies available and implementing and/or enhancing relevant immunization programmes and other strategies.<sup>42</sup> The CESCR has further established that these measures are “obligations of comparable priority” to core obligations of the right to health so states cannot justify non-compliance.<sup>43</sup>

Within the context of COVID-19, the CESCR has established that states must combat the pandemic in a manner consistent with human rights, which includes extraterritorial obligations to support other states

<sup>31</sup> CESCR, General Comment 14, paras 11, 17 and 54

<sup>32</sup> CESCR, General Comment 14, paras 11 and 17

<sup>33</sup> CESCR, General Comment 14, para 54

<sup>34</sup> OHCHR, Guidelines for States on the Effective Implementation of the Right to Participate in Public Affairs, [www.ohchr.org/EN/Issues/Pages/DraftGuidelinesRighttoParticipationPublicAffairs.aspx](http://www.ohchr.org/EN/Issues/Pages/DraftGuidelinesRighttoParticipationPublicAffairs.aspx)

<sup>35</sup> CESCR, General Comment 14, *supra* note 113, para 59

<sup>36</sup> OHCHR/WHO, *Factsheet No. 31: The Right to Health*, <https://www.ohchr.org/documents/publications/factsheet31.pdf>

<sup>37</sup> WHO, *International Health Regulations (2005) Third Edition*, 1 January 2016, <https://www.who.int/publications/i/item/9789241580496>

<sup>38</sup> CESCR, “Statement on the Coronavirus Disease (COVID-19) Pandemic and Economic, Social and Cultural Rights”, para 19, The duty of international assistance and cooperation is also highlighted in articles 2.1 and 11.1 of the ICESCR.

<sup>39</sup> World Health Organization (WHO), *Immunization Agenda 2030: A Global Strategy to Leave No One Behind*, 1 April 2020, <https://www.who.int/teams/immunization-vaccines-and-biologicals/strategies/ia2030>

<sup>40</sup> CESCR, General Comment 3: The Nature of States Parties’ Obligations (art. 2, para. 1, of the Covenant), E/1991/23, 1990, para 10

<sup>41</sup> CESCR, General Comment 14, para 43

<sup>42</sup> CESCR, General Comment 14, article 12.2(c), paras 16, 44

<sup>43</sup> CESCR, General Comment 14, paras 43, 44, 47. Paragraph 47 states that the “core obligations” in paragraph 43 are non-derogable.

fulfil their duties. As examples, the CESCR has said that states should ensure that no decision or unilateral measure obstructs access to essential goods, such as health equipment. Any restriction based on the goal of securing national supply must be proportionate and take into consideration the urgent needs of other countries.<sup>44</sup>

Diagnostics, treatments and vaccines fall squarely within the state's comparable core obligations as goods that play an essential role in curbing communicable diseases. As a surveillance tool, diagnostics detect outbreaks of infectious diseases and offer insight into the effectiveness of immunization programmes.<sup>45</sup> Treatments reduce morbidity and mortality, easing the strain on health systems and contributing to the overall realization of the right to health. Likewise, vaccines prevent infection and transmission.

Indeed, mass vaccination is the only safe way to achieve herd immunity, whereby enough people have developed protection from transmission and infection that all people benefit, including those who have not been immunized, and the disease ceases to exist across a population. For this to be achieved, 70% of the population must become immune so a high uptake is key to the vaccine's effectiveness.<sup>46</sup>

In addition to their legal human rights obligations, states have agreed to prioritize health and control communicable diseases through key global political agreements, such as the Sustainable Development Goals (SDGs). While 13 of the 17 SDGs address health-related issues, SDG 3 specifically calls upon states to end the epidemics of communicable diseases<sup>47</sup> and "reduce by one third premature mortality from non-communicable diseases through prevention and treatment"<sup>48</sup> by 2030. In line with a right to health framework, SDG 3 also highlights the importance of "access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all."<sup>49</sup>

## **BUSINESS RESPONSIBILITY AROUND COVID-19 DIAGNOSTICS, TREATMENTS AND VACCINES**

Under the ICESCR, states must ensure that private actors comply with human rights standards and do not impair the availability, accessibility, acceptability and quality of health facilities, goods and services.<sup>50</sup> Equally, as articulated in the UN Guiding Principles on Business and Human Rights (UN Guiding Principles), all business enterprises have a responsibility to respect human rights wherever they operate in the world.<sup>51</sup> Among other things, they must avoid causing or contributing to human rights harm through their activities and, if harm occurs, cease the activities and remedy the harm. If directly linked to a human rights risk through their business relationships, companies must prevent or mitigate adverse human rights impacts through their leverage.<sup>52</sup> To this end, business enterprises are expected to carry out human rights due diligence "to identify, prevent, mitigate and account for how they address their impacts on human rights."<sup>53</sup>

Pharmaceutical companies and research institutes play a crucial role in facilitating access to the right to health.<sup>54</sup> Their responsibility to respect human rights requires them to consider potential and actual human rights impacts of their business decisions, including those related to research, development, manufacturing, pricing and distribution processes – all of which are often protected by intellectual property rights. To this end, in November 2020, a group of UN human rights experts stated that businesses "should refrain from

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44 CESCR, "Statement on the Coronavirus Disease (COVID-19) Pandemic and Economic, Social and Cultural Rights", para 20

45 WHO, "Vaccination Greatly Reduces Disease, Disability, Death and Inequity Worldwide", <https://www.who.int/bulletin/volumes/86/2/07-040089/en/>

46 WHO, *Immunization Agenda 2030: A Global Strategy to Leave No One Behind*, 1 April 2020, <https://www.who.int/teams/immunization-vaccines-and-biologicals/strategies/ia2030>; and OHCHR, *Human Rights Indicators: A Guide to Measurement We should never forget that behind every piece of statistical and Implementation*, 2012, [https://www.ohchr.org/Documents/Publications/Human\\_rights\\_indicators\\_en.pdf](https://www.ohchr.org/Documents/Publications/Human_rights_indicators_en.pdf)

47 WHO, SDG 3.3, [https://www.who.int/health-topics/sustainable-development-goals#tab=tab\\_2](https://www.who.int/health-topics/sustainable-development-goals#tab=tab_2)

48 SDG 3.4, [https://www.who.int/health-topics/sustainable-development-goals#tab=tab\\_2](https://www.who.int/health-topics/sustainable-development-goals#tab=tab_2)

49 WHO, SDG 3.8, [https://www.who.int/health-topics/sustainable-development-goals#tab=tab\\_2](https://www.who.int/health-topics/sustainable-development-goals#tab=tab_2)

50 OHCHR/WHO, *Factsheet No. 31: The Right to Health*, p 26

51 This responsibility was expressly recognized by the UN Human Rights Council on 16 June 2011, when it endorsed the UN Guiding Principles, and on 25 May 2011, when the 42 governments that had then adhered to the Declaration on International Investment and Multinational Enterprises of the OECD unanimously endorsed a revised version of the OECD Guidelines for Multinational Enterprises (OECD Guidelines). See Human Rights Council, *Human Rights and Transnational Corporations and other Business Enterprises*, Resolution 17/4, UN Doc A/HRC/RES/17/4, 6 July 2011; OECD Guidelines for Multinational Enterprises, 2011, OECD Publishing, [www.oecd.org/corporate/mne/](http://www.oecd.org/corporate/mne/)

52 UN Office of the High Commissioner for Human Rights, *Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework* (2011), UN Doc HR/PUB/11/04, Principles 11 and 13 including Commentary, [www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR\\_EN.pdf](http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf)

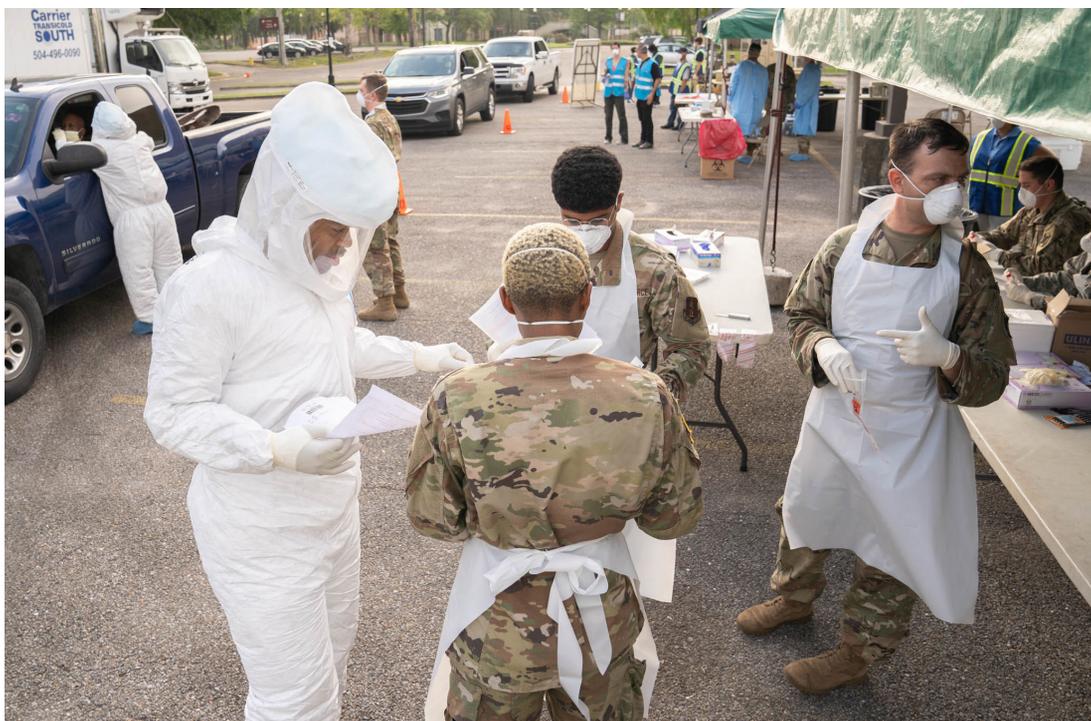
53 UN Guiding Principles on Business and Human Rights, Principle 15

54 CESCR, General Comment 14, para 33

causing or contributing to adverse impacts on the rights to life and health by invoking their intellectual property rights and prioritizing economic gains.”<sup>55</sup> Likewise, SDG 3 reiterates that the intellectual property regime should not be an obstacle to affordable medicines and vaccines in developing countries.<sup>56</sup>

The UN Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines (Guidelines for Pharmaceutical Companies) state that businesses have a “human rights responsibility to extend access to medicines for all,” and should develop and implement policy on access to medicines, considering all arrangements at their disposal to ensure that these are affordable to as many people as possible. To do so, the Guidelines for Pharmaceutical Companies specifies that businesses should take into account: (i) a country’s stage of economic development; (ii) the differential purchasing power of populations within a country; and (iii) the rights, needs and challenges of populations that may be at heightened risk of vulnerability and marginalization.<sup>57</sup>

In line with these considerations, the Guidelines for Pharmaceutical Companies recommends “as part of its access to medicines policy, the company should issue open and non-exclusive voluntary licences with a view to increasing access, in low-income and middle-income countries, to all medicines... They should also include any necessary transfer of technology. The terms of the licences should be disclosed.”<sup>58</sup>



*Louisiana National Guard Soldiers and Airmen test first responders for COVID-19 infections on March 20, 2020 at Louis Armstrong Park in New Orleans, United States. © Louisiana National Guard*

<sup>55</sup> OCHCR, “Statement by UN Human Rights Experts Universal Access to Vaccines is Essential for Prevention and Containment of COVID-19 around the World”, 9 November 2020, <https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26484&LangID=E>

<sup>56</sup> SDG Target 3B, [https://www.who.int/health-topics/sustainable-development-goals#tab=tab\\_2](https://www.who.int/health-topics/sustainable-development-goals#tab=tab_2)

<sup>57</sup> Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, A/63/263, 11 August 2008, Guidelines 5, 30 and 33

<sup>58</sup> Guidelines for Pharmaceutical Companies, Guideline 33

## 4. GLOBAL AVAILABILITY AND AFFORDABILITY

*“The great beauty of science is that it has no borders – and that, working together, every scientist and student of science can contribute to the shared knowledge and benefit of all.”*

Michelle Bachelet, UN High Commissioner for Human Rights<sup>59</sup>

### AVAILABILITY AND ALLOCATION ACROSS COUNTRIES

*“The race for a COVID-19 vaccine must be, above all, a race to prevent more deaths and to protect the humankind, without discrimination on any ground and without consideration for national origin. This race... should be anchored in the essentiality of international cooperation and assistance and in the conviction that sharing the benefits of scientific progress is a human right as central as the rights to health and to life.”*

UN Human Rights Experts<sup>60</sup>

To respect human rights, it is crucial that countries cooperate globally to ensure that safe and effective vaccines are developed in a timely manner, produced in sufficient doses at affordable prices, and distributed fairly across countries to achieve broad, non-discriminatory immunization coverage around the globe. However, at least two barriers have emerged: “vaccine nationalism” and the intellectual property rights regime.

### ‘VACCINE NATIONALISM’

Many high-income countries have made advance purchases of billions of doses of future vaccines for their populations, leaving limited potential supplies for others. This undermines efforts to ensure sufficient availability and inclusive distribution around the world.<sup>61</sup> In August 2020, the UK was the world’s highest per capita buyer, with an average of five doses per citizen.<sup>62</sup> The USA led the total number of purchases worldwide, securing 800 million doses of at least six vaccine candidates, with an option to purchase around 1 billion more. The European Union, Japan, Canada and Australia followed suit, securing millions of additional potential doses from several companies.<sup>63</sup> By September 2020, Oxfam concluded that governments representing 13% of the global population had already secured over half of the promised doses of COVID-19 vaccine candidates.<sup>64</sup>

The scale of these bilateral agreements contravenes states’ human rights obligations. While the obligation to protect the right to health requires states to purchase vaccines for their populations, these purchases must

<sup>59</sup> UN Human Rights Council, “A Joint Appeal for Open Science by CERN, OHCHR, UNESCO and WHO”, 27 October 2020, <https://www.ohchr.org/EN/HRBodies/HRC/Pages/NewsDetail.aspx?NewsID=26433&LangID=E>

<sup>60</sup> OHCHR, “Statement by UN Human Rights Experts Universal Access to Vaccines is Essential for Prevention and Containment of COVID-19 around the World”. Please note that the authors of this statement include Tlaleng Mofokeng, Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health; Olivier De Schutter, Special Rapporteur on extreme poverty and human rights; Anita Ramasastry (Chair), Dante Pesce (Vice-Chair), Surya Deva, Elzbieta Karska, and Gilithu Muigai, Working Group on the issue of human rights and transnational corporations and other business enterprises; Obiora C. Okafor, Independent Expert on human rights and international solidarity, and Saad Alfarargi, Special Rapporteur on the right to development.

<sup>61</sup> L Phelan et al, “Legal agreements: barriers and enablers to global equitable COVID-19 vaccine access”, *The Lancet*, Vol 396, Issue 10254, 7 September 2020, [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31873-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31873-0/fulltext)

<sup>62</sup> “The unequal scramble for coronavirus vaccines — by the numbers”, *Nature*, 24 August 2020, updated 27 August 2020, <https://www.nature.com/articles/d41586-020-02450-x>

<sup>63</sup> “The unequal scramble for coronavirus vaccines — by the numbers”, *Nature*, 24 August 2020, updated 27 August 2020, <https://www.nature.com/articles/d41586-020-02450-x>

<sup>64</sup> Oxfam International, “Small Group of Rich Nations Have Bought up More than Half the Future Supply of Leading COVID-19 Vaccine Contenders”, 17 September 2020, <https://www.oxfam.org/en/press-releases/small-group-rich-nations-have-bought-more-half-future-supply-leading-covid-19>

be proportionate and take into consideration the urgent needs of other countries.<sup>65</sup> Likewise, in order to meet their independent responsibility to respect human rights, businesses must ensure that they do not contribute to or are otherwise involved in a state's failure to comply with its international obligations.

Moreover, while states should use the maximum of their available resources to secure the right to health,<sup>66</sup> those that are unable to do so must request international cooperation. States in a position to provide technical or financial assistance must collaborate as a means of fulfilling their duty to the right to health.<sup>67</sup> This is especially true within the context of diseases that are transmissible beyond the frontiers of a state, such as COVID-19. In this regard the CESR makes clear that “the international community has a collective responsibility to address this problem. The economically developed states parties have a special responsibility and interest to assist the poorer developing states in this regard.”<sup>68</sup> Several global initiatives to fulfil this collective responsibility are described below.

Finally, the economic cost-benefit is clear. The WHO has recently estimated that an investment of \$38 billion to fully fund one of these collective initiatives to support global access to COVID-19 health products would be paid back “in less than 36 hours once global mobility and trade alone are restored.”<sup>69</sup>

## RECOMMENDATIONS

- States must, and businesses should, develop and implement policies to ensure availability, access, affordability, acceptability and quality of COVID-19 health products for all people. This should be done according to the principles of transparency, participation, accountability, equality and non-discrimination.
- States must and businesses should refrain from making bilateral agreements that negatively affect the global supply of a vaccine and jeopardize availability across countries, which includes “hoarding” of vaccines beyond what is needed for priority, at-risk populations.

## THE COVAX PILLAR

In April 2020, the World Health Organization (WHO) and other actors launched the “Access to COVID-19 Tools Accelerator” (ACT-A) to facilitate access to COVID-19 health products around the world. One of its pillars, COVAX, seeks to pool global demand around COVID-19 vaccines and distribute two billion doses by the end of 2021.<sup>70</sup> Three organizations – the WHO, the Coalition for Epidemic Preparedness Innovations (CEPI), and Gavi, the Vaccines Alliance – came together to form the COVAX Pillar. CEPI coordinates on development and manufacturing, the WHO coordinates on policy and allocation, and Gavi is responsible for procurement and delivery at scale.

Functioning as a global procurement mechanism whereby countries can advance-order doses from a portfolio of vaccine candidates, the COVAX Facility within the COVAX Pillar seeks to use its collective purchasing power to negotiate pricing and speed up production of COVID-19 vaccines. As of November 2020, 178 countries had signed commitment agreements, submitted non-binding confirmations of intent to participate, or are eligible to participate in the COVAX Facility.<sup>71</sup>

There are two ways in which countries purchase vaccines through the COVAX Facility: Upper-income and upper-middle-income economies have been pooled together as “self-financing” countries that would pay for these vaccines directly, while lower-middle- and lower-income economies will make purchases through the Advanced Market Commitment (AMC), a financing plan that brings together contributions from governments, the private sector and philanthropic organizations. According to the COVAX Facility, the latter is only likely to begin vaccine delivery in March 2020.<sup>72</sup>

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<sup>65</sup> CESCR, “Statement on the Coronavirus Disease (COVID-19) Pandemic and Economic, Social and Cultural Rights”, para 20

<sup>66</sup> CESCR, General Comment 25, para 47

<sup>67</sup> CESCR, General Comment 14, paras 38 and 45; ICESCR, Article 2.1

<sup>68</sup> CESCR General Comment 14, para 40

<sup>69</sup> WHO, “UN Welcomes nearly \$1 Billion in Recent Pledges – to Bolster Access to Lifesaving Tests, Treatments and Vaccines to End COVID-19”, 30 September 2020, <https://www.who.int/news/item/30-09-2020-un-welcomes-nearly-1-billion-in-recent-pledges-to-bolster-access-to-lifesaving-tests-treatments-and-vaccines-to-end-covid-19>

<sup>70</sup> Gavi, The COVAX Facility Commitment Agreements, 19 October 2020, [https://www.gavi.org/sites/default/files/covid/pr/COVAX\\_CA\\_COIP\\_List\\_COVAX\\_PR\\_19-10.pdf](https://www.gavi.org/sites/default/files/covid/pr/COVAX_CA_COIP_List_COVAX_PR_19-10.pdf)

<sup>71</sup> Gavi, The COVAX Facility Commitment Agreements, 19 October 2020, [https://www.gavi.org/sites/default/files/covid/pr/COVAX\\_CA\\_COIP\\_List\\_COVAX\\_PR\\_19-10.pdf](https://www.gavi.org/sites/default/files/covid/pr/COVAX_CA_COIP_List_COVAX_PR_19-10.pdf)

<sup>72</sup> Gavi, The COVAX Facility Commitment Agreements, 19 October 2020, [https://www.gavi.org/sites/default/files/covid/pr/COVAX\\_CA\\_COIP\\_List\\_COVAX\\_PR\\_19-10.pdf](https://www.gavi.org/sites/default/files/covid/pr/COVAX_CA_COIP_List_COVAX_PR_19-10.pdf)

## THE WHO FAIR ALLOCATION FRAMEWORK

The WHO Fair Allocation Framework will guide the allocation of vaccines between countries through COVAX Facility.<sup>73</sup> In its first phase, the WHO Framework focuses on reducing mortality and protecting health systems,<sup>74</sup> allocating to each participating country doses equal to 3% of its population to cover frontline health and care workers.<sup>75</sup> The COVAX Facility will then disperse doses for up to 20% of each country's population to immunize high-risk adults – older people and people with underlying health conditions or others depending on locally relevant risk factors.<sup>76</sup> During the second phase, each country will receive doses for additional priority populations, which is further described in Chapter 4.<sup>77</sup>

Once vaccines start receiving approval, the WHO will further detail how the framework will be operationalized.<sup>78</sup> For example, some vaccines may prove to be safe and effective for only some populations or may have particular storage and distribution requirements, rendering them more suitable in some countries than others. This could mean that lower-income economies may need more resources in preparing to develop the vaccine or may end up with unequal availability and accessibility to vaccines. The WHO is developing guidance for countries on programme preparedness, implementation and country-level decision-making.<sup>79</sup>

## THE COVAX FACILITY

Multilateral approaches to vaccine procurement and distribution have the potential to be a fairer than the current approach of 'vaccine nationalism' practiced by many countries through huge bilateral deals, which may reduce access for others. States should join and support these initiatives, but also work to ensure they make COVID-19 health products available and accessible to the maximum number of people at a global level.

While the COVAX Facility's goal is to "guarantee fair and equitable access" for every country in the world, much remains unclear around how this will be done. For instance, many of the higher-income economies already have been purchasing additional batches of vaccine doses via bilateral agreements with companies. This has created a parallel procurement structure that allows rich countries to tap into global availability via multiple sources, compromising the effectiveness of COVAX as a mechanism to foster global access to COVID-19 vaccines.

Within the COVAX Facility, lower income countries who rely on the AMC (see box above) have different opportunities to access vaccines than higher-income countries who are self-financing. For example, self-financing countries can request vaccines for up to 50% of their population once all countries in this group are offered equal amounts of the additional request.<sup>80</sup> However, it is unclear how this may affect the access of AMC countries to any additional doses beyond their initial allocation to cover up to 20% of their population. The Facility also offers self-financing countries "committed or optional purchases."<sup>81</sup>

73 WHO, "Fair Allocation Mechanism for COVID-19 Vaccines through the COVAX Facility", 9 September 2020, <https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility>

74 WHO, "Fair Allocation Mechanism for COVID-19 Vaccines through the COVAX Facility", 9 September 2020, page 5, <https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility>

75 WHO, "Fair Allocation Mechanism for COVID-19 Vaccines through the COVAX Facility", 9 September 2020, p 24 and 26, <https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility>. This includes physicians, nurses and technicians and other workers in these settings, as they are essential to treat and protect the population and come in close contact with infected individuals and provide care for high-mortality risk groups.

76 WHO, "Fair Allocation Mechanism for COVID-19 Vaccines through the COVAX Facility", 9 September 2020, <https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility>

77 WHO, "Fair Allocation Mechanism for COVID-19 Vaccines through the COVAX Facility", 9 September 2020. If expected supply constraints persist at this point, the timing of this second rollout may rely on a weighted allocation approach, taking account of a country's COVID-19 threat (spread of the virus) and vulnerability (health systems and population factors).

78 WHO, "Fair Allocation Mechanism for COVID-19 Vaccines through the COVAX Facility", 9 September 2020, <https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility>

79 WHO, "Fair Allocation Mechanism for COVID-19 Vaccines through the COVAX Facility", 9 September 2020, <https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility>

80 Gavi, the Vaccine Alliance, "COVAX explained", 3 September 2020, <https://www.gavi.org/vaccineswork/covax-explained>

81 Gavi, the Vaccine Alliance, "COVAX explained", 3 September 2020, <https://www.gavi.org/vaccineswork/covax-explained>

The latter allows these countries to pay upfront a higher price for doses so they can select their vaccines, which may compromise the goal of the COVAX Facility as a vehicle to ensure fair access for every country around the world.

Finally, the composition of the self-financing countries group to include upper-income and most upper-middle income countries assumes that the latter have the equal ability to pay as richer countries. While loans from international financial institutions are becoming increasingly available for this purpose, this clearly poses risks for countries already making significant debt repayments. The UN Guiding Principles on foreign debt and human rights emphasises that external debt repayment should not interfere with a state's efforts to realise core rights obligations with respect to the right to health.<sup>82</sup>

Transparency and accountability also have been of concern. While the COVAX Facility has announced agreements with several companies,<sup>83</sup> as of December 2020, the Facility did not have a policy of publicly disclosing the terms and conditions of contracts with states or companies. This raises questions about how the COVAX Facility, states and other actors are maximizing availability, accessibility and affordability of COVID-19 vaccines for all. In October 2020, following pressure by civil society, the COVAX Pillar appointed a civil society organization representative to each of their 10 working groups.<sup>84</sup> While this is a positive development, it is unclear whether civil society will be included in the COVAX Facility architecture itself, and questions remain about how transparency, participation and accountability will be fully operationalized across COVAX's policies and practices.

There also are outstanding questions around how the COVAX Facility plans to align strategies to collaborate with the COVID-19 Technology Access Pool (C-TAP), which is discussed below.

## RECOMMENDATIONS

- States must fulfil their obligation to international cooperation not only by joining global mechanisms such as COVAX, but also by other forms global cooperation to ensure that COVID-19 health products are accessible to the maximum number of people. States in a position to do so must provide technical and financial assistance to those countries in need of assistance.
- States and businesses engaging in COVAX must push for the mechanism to foster meaningful participation of civil society and developing countries in decision-making, as well as follow principles of transparency, participation, accountability, equality, and non-discrimination in its work. All contracts and negotiations concerning COVID-19 health products should be negotiated transparently and be publicly available.

## INTELLECTUAL PROPERTY RIGHTS

*“The emerging intellectual property disputes over patents as well as the possibility of having oligopolistic manufacturers could also hinder the development and production of COVID-19 vaccines as well as the availability, accessibility and affordability of the vaccine at national and international levels.”*

UN Human Rights Experts<sup>85</sup>

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<sup>82</sup> UN Human Rights Council, Report of the Independent Expert on the effects of foreign debt and other related international financial obligations of States on the full enjoyment of all human rights, particularly economic, social and cultural rights, Addendum : Missions to Norway and Ecuador, A/HRC/14/21/Add.1, 21 April 2010

<sup>83</sup> Gavi, the Vaccine Alliance, “172 countries & multiple candidate vaccines engaged in COVID-19 Vaccine Global Access Facility”, 4 September 2020, <https://www.gavi.org/news/media-room/172-countries-multiple-candidate-vaccines-engaged-covid-19-vaccine-global-access>

<sup>84</sup> Gavi, the Vaccine Alliance, “COVAX welcomes appointment of civil society representatives”, 30 October 2020, <https://www.gavi.org/news/media-room/covax-welcomes-appointment-civil-society-representatives>

<sup>85</sup> OCHCR, “Statement by UN Human Rights Experts Universal Access to Vaccines is Essential for prevention and containment of COVID-19 around the World”, 9 November 2020

Intellectual property rights such as patents and trade secrets (including complex manufacturing know-how and other biological resources) play a key role in the debate around COVID-19 health products. While intellectual property regimes set out to enhance the development of medical products through economic incentives, this system of exclusive rights often adversely impacts availability, accessibility and affordability in two key ways. First, intellectual property rules often restrict the sharing of data around research, development and manufacturing of new products, thereby affecting the innovation process and affecting adequate availability for those who need these products. Second, intellectual property, especially patents, allows patent holders exclusive rights and the ability to set the prices for a period of time, which negatively affects affordability.<sup>86</sup>

Given these challenges, the CESCR established that states must align their intellectual property laws with their human rights obligations to ensure that a balance is “reached between intellectual property and the open access and sharing of scientific knowledge and its applications, especially those linked to the realization of other ESCR, such as the rights to health.”<sup>87</sup>

The CESCR has further stated that “states parties should ensure that the right to health is given due attention in international agreements and, to that end, should consider the development of further legal instruments. In relation to the conclusion of other international agreements, states parties should take steps to ensure that these instruments do not adversely impact upon the right to health.”<sup>88</sup>

The Maastricht Principles on Extraterritorial Obligations of States in the Area of Economic, Social and Cultural Rights (the Maastricht Principles) further clarified these obligations.<sup>89</sup> They establish that “states must elaborate, interpret and apply relevant international agreements and standards in a manner consistent with their human rights obligations.”<sup>90</sup> This includes in relation to states’ international trade. The commentary to this principle cites the jurisprudence of the CESCR, as well as decisions by the European Court of Human Rights and the Inter-American Court of Human Rights, which affirm the principle that states cannot ignore their human rights treaty obligations by concluding treaties that contradict those obligations.<sup>91</sup>

Some business enterprises have engaged in or have stated that they may consider granting voluntary licences for COVID-19 health products.<sup>92</sup> While any such agreements may contribute to access and availability, they are unlikely to meet the scale and scope of the challenge posed by COVID-19 and should always be accompanied by adequate technology transfer and other measures as needed. This has led to discussions about how to overcome the obstacles surrounding intellectual property rights and undisclosed technical know-how in order to ensure availability, accessibility and affordability of COVID-19 health products. As explained below, these discussions have centred on the current intellectual property regime established by the World Trade Organization (WTO) and the new COVID-19 Technology Access Pool (C-TAP), a proposed voluntary sharing platform created to foster greater collaboration around intellectual property rights.

## WORLD TRADE ORGANIZATION

The WTO’s Trade Related Aspects of Intellectual Property Rights (TRIPS) sets out minimum standards for many forms of intellectual property that are pertinent to pharmaceutical companies, such as copyrights, trademarks, patents, undisclosed information (including trade secrets and test data) and anti-competitive practices.<sup>93</sup>

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<sup>86</sup> CESCR, General Comment 25, para 61

<sup>87</sup> CESCR, General Comment 25, para 62

<sup>88</sup> CESCR, General Comment 14, para 39

<sup>89</sup> The Maastricht Principles constitute an international expert opinion, clarifying human rights law on extraterritorial obligations. The Maastricht Principles were issued on 28 September 2011 by 40 international law experts from all regions of the world, including current and former members of international human rights treaty bodies, regional human rights bodies, as well as former and current Special Rapporteurs of the UN Human Rights Council. The Maastricht Principles do not purport to establish new elements of human rights law. Rather, they clarify extraterritorial obligations of States on the basis of standing international law. The Principles and their commentary, which sets out the legal authority for each principle, are available at: <http://eprints.lse.ac.uk/47404/>

<sup>90</sup> Maastricht Principles, Principle 17

<sup>91</sup> Maastricht Principles, Principle 14.3

<sup>92</sup> Gates Foundation, “Life Science Companies and the Bill & Melinda Gates Foundation: Commitments to Expanded Global Access for COVID-19 Diagnostics, Therapeutics, and Vaccines”, 30 September 2020, <https://www.gatesfoundation.org/Media-Center/Press-Releases/2020/09/Commitments-to-Expanded-Global-Access-for-COVID-19-Diagnostics-Therapeutics-and-Vaccines>

<sup>93</sup> Médecins Sans Frontières, *India and South Africa Proposal for WTO Waiver from Intellectual Property Protections for COVID-19-related Medical Technologies*, 8 October 2020, [https://msfaccess.org/sites/default/files/2020-10/COVID\\_Brief\\_ProposalWTOWaiver\\_ENG\\_2020.pdf](https://msfaccess.org/sites/default/files/2020-10/COVID_Brief_ProposalWTOWaiver_ENG_2020.pdf)

As intellectual property rights can create barriers to timely access to lifesaving health products, the TRIPS includes safeguards known as “flexibilities”. These allow states can amend their laws to better fulfil their public health obligations and provide medicines for all. The flexibilities also allow states to determine patentability criteria, issue compulsory licences, and place limitations on or make exceptions to exclusive rights, among other measures. The SDG 3 notes the importance of these flexibilities to provide access to affordable essential medicines and vaccines for all, emphasizing the right of developing countries to tap into these flexibilities for these purposes.<sup>94</sup> These flexibilities often require domestic legal and policy changes.<sup>95</sup>

The COVID-19 pandemic has also raised questions about whether the flexibilities are sufficient to address the world’s urgent needs, given that they usually apply on a country-by-country, case-by-case, and drug-by-drug basis.<sup>96</sup> For example, while the flexibilities allow for compulsory licences, whereby a government must authorize a third party to manufacture a patented product without the patentee’s permission, the process is not straightforward. A government body must grant the licence, which may require remuneration.<sup>97</sup> There also are concerns that this can lead to scrutiny by other governments.<sup>98</sup> Moreover, compulsory licences on patents alone are not sufficient for adequate technology transfer or the creation of local manufacturing capacity. This often renders these licences irrelevant for low- or middle-income countries.<sup>99</sup>

In October 2020, India and South Africa requested a waiver that would allow countries to neither grant nor enforce patents and other specific intellectual property rights related to COVID-19 products until global herd immunity is achieved.<sup>100</sup> A significant number of lower- and middle-income countries supported this proposal. Most high-income countries opposed it. Several other states requested additional information and the decision was postponed to enable consultation.<sup>101</sup> The TRIPS Council further discussed the waiver on 20 November 2020 and is set to do so again on 10 December 2020. The WTO General Council will also discuss the waiver on 17 December 2020. The waiver proposal has also been supported by a group of UN Human Rights Experts.<sup>102</sup>

## COVID-19 TECHNOLOGY ACCESS POOL (C-TAP)

In May 2020, Costa Rica and the WHO launched the COVID-19 Technology Access Pool (C-TAP) as a voluntary sharing platform to pool all data, know-how, biological material and intellectual property, and then licence production and technology transfer to other potential producers. This would be done under non-exclusive licences, maximizing supply and lowering costs, thereby increasing availability and affordability of COVID-19 diagnostics, treatments and vaccines. To carry this out, participating companies and research institutions can license products through the Medicines Patent Pool (MPP),<sup>103</sup> a UN-backed body for sharing licences and patents. From 2010 to 2019, the MPP licences produced 9.59 billion doses of generic drugs to treat HIV/AIDS, hepatitis C and tuberculosis, saving the international community US\$1.23 billion.<sup>104</sup>

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<sup>94</sup> WHO, “SDGs”, [https://www.who.int/health-topics/sustainable-development-goals#tab=tab\\_2](https://www.who.int/health-topics/sustainable-development-goals#tab=tab_2)

<sup>95</sup> Médecins Sans Frontières, *India and South Africa Proposal for WTO Waiver from Intellectual Property Protections for COVID-19-related Medical Technologies*, 8 October 2020

<sup>96</sup> Médecins Sans Frontières, *India and South Africa Proposal for WTO Waiver from Intellectual Property Protections for COVID-19-related Medical Technologies*, 8 October 2020; WHO, *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade*, 5 February 2013, <https://www.who.int/publications/i/item/9789241504874>

<sup>97</sup> WTO, Article 31 of the TRIPS Agreement, [https://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm02\\_e.htm#art31](https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#art31)

<sup>98</sup> Office of the United States Trade Representative, “USTR Releases Annual Special 301 Report on Intellectual Property Protection and Review of Notorious Markets for Counterfeiting and Piracy”, 29 April 2020, <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2020/april/ustr-releases-annual-special-301-report-intellectual-property-protection-and-review-notorious>

<sup>99</sup> E Urias and S V Ramani, “Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A review of the existing evidence”, US National Library of Medicine, 3 September 2020, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7468182/#CR59>

<sup>100</sup> WTO, “Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Communication from India and South Africa, 2 October 2020”, <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:IP/C/W669.pdf&Open=True>. The waiver request was co-sponsored by Kenya and Eswatini. See also briefing by Médecins Sans Frontières, *India and South Africa proposal for WTO waiver from intellectual property protections for COVID-19-related medical technologies*.

<sup>101</sup> WTO, “Members Discuss Intellectual Property Response to the COVID-19 Pandemic”, 20 October 2020, [https://www.wto.org/english/news\\_e/news20\\_e/trip\\_20oct20\\_e.htm](https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm)

<sup>102</sup> OHCHR, “Statement by UN Human Rights Experts Universal Access to Vaccines is Essential for Prevention and Containment of COVID-19 around the World”, 9 November 2020, <https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26484&LangID=E>

<sup>103</sup> MPP partners with civil society, governments, international organizations, industry, patient groups and other stakeholders, to prioritize and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations. MPP was founded by Unitaid, which continues to be MPP’s main funder. See <https://medicinespatentpool.org/>

<sup>104</sup> K Peruhudoff and J Sellin, “COVID-19 Technology Access Pool (C-TAP): A Promising Human Rights Approach”, *Medicines Law & Policy*, 18 June 2020, <https://medicineslawandpolicy.org/2020/06/covid-19-technology-access-pool-c-tap-a-promising-human-rights-approach/>

As of December 2020, no company had joined C-TAP. While nearly 40 states had expressed support for C-TAP, countries with strong pharmaceutical industries remained silent, including France, Germany, Switzerland, the UK and the USA. Some states have argued that voluntary licences would suffice to ensure patents are not an obstacle to access.<sup>105</sup> However, voluntary licences tend to be exclusive, bilateral agreements that lack transparency and do not adequately contribute to maximizing availability, accessibility and affordability for all.

## RECOMMENDATIONS

### To States

- States must assess and make any necessary adjustments to their intellectual property laws, policies and practices to ensure that these do not form a barrier to COVID-19 health products for all people globally.
- States must respect the spirit of the Doha Declaration on the TRIPS Agreement and Public Health (2001) by supporting initiatives that increase access to COVID-19 health products, such as the proposed WTO TRIPS waiver.<sup>106</sup>
- States should support C-TAP and promote open and non-exclusive licences that include technology transfer to ensure that the product is available, accessible and affordable to the maximum number of people. All terms and conditions should be publicly disclosed.<sup>107</sup>
- States should make public funding to companies conditional on them joining global mechanisms, such as C-TAP, and publicly disclosing disaggregated costs of research, development, production, marketing distribution and all other relevant data in a timely and accessible fashion.

### To businesses

- Businesses must refrain from any action that unduly impacts on the state's ability to ensure availability, accessibility and affordability of COVID-19 health products. Instead, companies should issue open and non-exclusive licences that include technology transfer; all terms and conditions should be publicly disclosed.<sup>108</sup>
- Businesses should respect the spirit of the Doha Declaration on TRIPS Agreement and Public Health (2001) by supporting initiatives that increase access to COVID-19 health products and refraining from any action that may discourage the use of TRIPS flexibilities and the approval of the proposed WTO TRIPS waiver.
- Businesses should join global mechanisms such as C-TAP and publicly disclose disaggregated costs and data related to research, development, production, marketing, distribution, study designs and protocols, data sets, test results, and anonymity-protected patient data around clinical trials in a timely and accessible fashion.

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<sup>105</sup> Argentina, Bangladesh, Barbados, Belgium, Belize, Bhutan, Brazil, Chile, Dominican Republic, Ecuador, Egypt, El Salvador, Honduras, Indonesia, Lebanon, Luxembourg, Malaysia, Maldives, Mexico, Mongolia, Mozambique, Norway, Oman, Pakistan, Palau, Panama, Paraguay, Peru, Portugal, Saint Vincent and Grenadines, South Africa, Sri Lanka, Sudan, The Netherlands, Timor-Leste, Uruguay and Zimbabwe.

<sup>106</sup> Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, Principles 26 and 27, [https://www.who.int/medicines/areas/human\\_rights/A63\\_263.pdf?ua=1](https://www.who.int/medicines/areas/human_rights/A63_263.pdf?ua=1)

<sup>107</sup> Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, Principle 30.

<sup>108</sup> Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, Principle 30.



Volunteers serve over a 100 hot meals per day to families whose household income has been cut off due to the COVID-19 lockdown period on May 5, 2020 in Chitungwizaon, Zimbabwe. © Jekesai NJIKIZANA / AFP via Getty Images



Women gather to collect support for families in need during a government-imposed nationwide lockdown as a preventive measure against the COVID-19 coronavirus on April 14, 2020 in Rawalpindi, Pakistan. © FAROOQ NAEEM/AFP via Getty Images

# 5. NATIONAL AVAILABILITY AND ACCESSIBILITY

## AVAILABILITY AND ALLOCATION WITHIN COUNTRIES

It will take time to manufacture COVID-19 health products, especially vaccines, in sufficient quantities and then globally distribute them on a significant scale. For vaccines, even in the best-case scenario, supplies will be limited throughout 2021 and probably 2022. Distribution will necessarily be phased. International organizations and states are devising allocation programmes to decide who receives these vaccines first at the global, regional, national and then local levels. States must also take measures to ensure adequate infrastructure is in place to facilitate access to COVID-19 vaccines, including transportation, storage and distribution.

## WHO ROADMAP FOR PRIORITIZING USES OF COVID-19 VACCINES

In October 2020, WHO SAGE issued its Roadmap for Prioritizing Uses of COVID-19 Vaccines (Roadmap),<sup>109</sup> which lays out **three stages of prioritization** and explains how each country's **epidemiologic setting** will determine when these vaccines should be distributed, and to which **priority groups**. WHO SAGE recommends a matrix of these three stages to make up a country's allocation plan.

In terms of **stages of prioritization**, the Roadmap's stages 1 and 2 correspond to the Phase 1 of the WHO's Fair Allocation Framework (See Chapter 3):

- Stage 1: very limited vaccine availability (1-10% of country population)
- Stage 2: limited availability (11-20% of country population)
- Stage 3: moderate availability (21-50% of country population)

The WHO SAGE Roadmap recommends that **priority groups** or subsets based on risk – very high, high, moderate, low – be placed in different stages (see box below).<sup>110</sup> To determine where priority groups should be placed, states must then consider its **epidemiologic setting** and its immunisation goals. The WHO SAGE Roadmap lays out three broad settings:

- *Community transmission*: During large outbreaks, the goal is to reduce morbidity and mortality, and maintain the critical essential services, while considering groups “placed at disproportionate risks to mitigate the consequences of the pandemic”, such as health workers.
- *Sporadic cases/clusters of cases*: When there is one or more sporadic cases, or clusters in time, location and/or by common exposure, the goal is the same as the community transmission setting; however, the intervention is limited to focused areas that have high transmission rates.
- *No cases setting*: When transmission in a country has stopped through non-pharmaceutical interventions, the initial focus would be to prevent transmission over border crossings. Health workers, essential travellers and border protection staff would be prioritized, and an emergency reserve kept for possible outbreaks. Older adults, the highest risk group for severe disease, are only covered under Stage 3, in case epidemic conditions shift suddenly.

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<sup>109</sup> WHO, “WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination”, 13 September 2020, <https://www.who.int/publications/i/item/who-sage-values-framework-for-the-allocation-and-prioritization-of-covid-19-vaccination>

<sup>110</sup> WHO, “WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination”, 13 September 2020, <https://www.who.int/publications/i/item/who-sage-values-framework-for-the-allocation-and-prioritization-of-covid-19-vaccination>

## THE WHO SAGE ROADMAP INCLUDES THE FOLLOWING PRIORITY GROUPS:

**Health workers** are included according to risk, per the interim guidance from WHO/ILO, and includes those engaged in routine and COVID-19 immunization delivery.

**Essential workers** include police officers, municipal services, child-care providers, agriculture and food workers, transportation workers, and government workers essential to critical functioning of the state.

**Older adults** are defined by age-based risk and may vary by country/region. This includes older adults in high risk living situations, such as those in long-term care facilities or unable to physically distance.

**Groups with comorbidities or health states** such as diabetes or pregnancy that carry higher risk; WHO recommends countries pay attention to disadvantaged groups and the under-diagnosis of comorbidities.

**Groups under socioeconomic disadvantage** include ethnic, racial, gender, and religious groups and sexual minorities; people living with disabilities; people living in extreme poverty, homeless and those living in informal settlements; low-income migrant workers; refugees, internally displaced persons, asylum seekers, people in conflict /humanitarian emergencies, migrants in irregular situations; nomadic populations; populations in rural/remote areas.

**Groups unable to physically distance** include people living/working in detention facilities, dormitories, informal settlements, low-income dense areas; people in occupations such as mining/meat processing.

**Travellers** include those at risk of bringing infection on return (students, business travellers, migrant/aid workers); WHO states the economically/politically powerful should not unduly benefit from this group.

**Border personnel** includes border protection staff and those for outbreak management such as isolation, quarantine and immunization staff.

**Teachers and school staff** depend on the country context and specific needs. For example, preschool teachers may be included due to the critical developmental stage and challenges of distance learning.

## VACCINE PRIORITIZATION AND HUMAN RIGHTS STANDARDS

Although the WHO will advise countries on allocation criteria, ultimately states have the duty to develop their national plans<sup>111</sup> and ensure they fully abide by their human rights obligations to ensure non-discrimination and a specific focus on marginalized, at-risk groups. A human rights perspective is particularly important to consider how systemic discrimination has affected the access to health services of marginalized and at-risk groups. These include Indigenous peoples, ethnic, religious and linguistic minorities, groups experiencing racial discrimination, refugees, migrants and internally displaced people, communities discriminated on the basis of work and descent, people living in prisons and detention centres, people with disabilities and people living in informal settlements, among others. Moreover, states must pay special attention to the fact that, when identities and statuses intersect, discrimination and inequality can be compounded.<sup>112</sup> It is worth noting that the WHO will reserve 5% of doses out of each COVAX batch for UN agencies and other organizations to deploy to humanitarian and emergency settings. However, the access, timing and financing of this mechanism is under discussion as of December 2020.

<sup>111</sup> WHO, "Fair Allocation Mechanism for COVID-19 Vaccines through the COVAX Facility", p 11. See <https://www.gavi.org/sites/default/files/covid/covax/who-covid19-vaccine-allocation-final-working-version-9sept.pdf>

<sup>112</sup> CESCR, General Comment 35



A press conference of the World Health Organization (WHO) organised by the Geneva Association of United Nations Correspondents (ACANU) amid the COVID-19 outbreak on July 3, 2020 at the WHO headquarters in Geneva.  
© Fabrice COFFRINI / POOL / AFP via Getty Images

The WHO SAGE Roadmap does not use gender as criteria for vaccine prioritization, noting that “while there is evidence that the risk of severe disease and death is higher in males than in females, particularly in older age groups, this difference in risk is diminished when comorbidities and other factors are taken into account.” It also notes, however, that “in some contexts, women are disadvantaged in terms of access to health care, political and social status, and decision-making authority due to social structural features in some communities.” Previous public health emergencies also have shown that women and girls, especially in care-giving roles, often face disproportionate impacts and unequal access to health care.<sup>113</sup> Therefore, states must ensure that these women do not face barriers in accessing COVID-19 health products, including vaccines.

Finally, the only commonality across the WHO SAGE Roadmap is that high-risk health workers are prioritized at Stage 1 across all three epidemiologic settings. While there may be different levels of risks for health workers, and they may be accorded different levels or prioritization, it is crucial for all states to recognize the definition of “health worker” as everyone working in the health sector and involved in the delivery of health care in any capacity. This includes, but is not limited to, doctors, nurses, hospital cleaners, ambulance drivers, administrative staff at hospitals, and health and social care workers working in the community or other settings.

Likewise, states must ensure that other frontline essential workers at heightened risk of infection are protected according to their level of risk, including anyone providing essential public services such as emergency response, public transport workers, refuse collectors, agricultural workers, as well those working in businesses that have generally been allowed to function during lockdowns, such as people working in grocery stores and delivery services. In short, states must consider the categories broadly and ensure that risk across these professional categories is what determines access to COVID-19 vaccines.

<sup>113</sup> According to research by the WHO, women form 70% of workers in the health and social sector. See, WHO, *Gender equity in the health workforce: Analysis of 104 countries, Health Workforce Working Paper 1*, [https://www.who.int/hrh/resources/gender\\_equity-health\\_workforce\\_analysis/en/](https://www.who.int/hrh/resources/gender_equity-health_workforce_analysis/en/)

## RECOMMENDATIONS

- States must devise national COVID-19 vaccine distribution plans to be accessible, equitable, inclusive and non-discriminatory, in line with human rights laws and standards. In addition to criteria identified by WHO SAGE, states should consider factors that may heighten an individual's or a community's risk to COVID-19, and pay particular attention to marginalized groups and those with intersecting identities and legal statuses. Factors may include social, environmental and occupational risks, and the impact of systemic discrimination.<sup>114</sup>
- States must ensure that the design and implementation of allocation plans are informed by collection and analysis of data around the impact of COVID-19 on specific groups. All data must be disaggregated<sup>115</sup> and available in a transparent and accessible manner.
- States must ensure that any decision-making processes around national allocation are rooted in transparency and the right to information, involving meaningful and effective participation of representatives of civil society, especially with representation from at-risk populations that could be most impacted by these decisions.<sup>116</sup>

## ACCESSIBILITY AND NATIONAL HEALTH SYSTEMS

Strong national health systems with adequate infrastructure are needed to safely transport, store, distribute and administer COVID-19 health products, including vaccines. Challenges identified around transportation, storage, administration and monitoring of COVID-19 vaccines are of particular concern in low- to lower-middle-income countries, which may have weaker health systems. In addition to strengthening existing health systems, states will likely need to adopt new systems or create infrastructure to accommodate COVID-19 vaccine distribution, and retrain or recruit additional health workers. Moreover, the diversion of resources to respond to COVID-19 has disrupted health services in many countries, and these must also be restored without further retrogression due to COVID-19 vaccine distribution.<sup>117</sup> While numerous challenges arise, this is an opportunity for states to invest in national health systems to strengthen their infrastructure, boost access to services, recruit and train more health workers, and secure new ways to expand access essential medicines, among other measures.

In October 2020, the fifth meeting of the Emergency Committee convened by the WHO Director-General under the International Health Regulations (IHR/2005) stressed the importance of enhancing countries' readiness in critical areas around the COVID-19 vaccine, including supply and logistics with a focus on cold storage chains.<sup>118</sup> The WHO recommended that states establish a national multi-disciplinary taskforce and develop a national deployment and vaccination plan<sup>119</sup> as an operational blueprint to roll out COVID-19 vaccines in-country. The WHO also provided countries with the COVID-19 Vaccine Introduction Readiness Assessment Tool (VIRAT) to periodically assess their progress.<sup>120</sup>

## TRANSPORTATION AND STORAGE

Experts have warned that countries need to adapt and scale up infrastructure to ensure ample vaccines can be delivered without losing their safety and effectiveness. Several COVID-19 vaccines under development

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<sup>114</sup> These identities and statuses include sex, gender, age, sexual orientation, gender identity, Indigenous status, ethnicity, work and descent, disability, and migrant or refugee status.

<sup>115</sup> Data should be disaggregated by sex, gender, age, sexual orientation, gender identity, Indigenous status, ethnicity, work and descent, disability, migrant or refugee status, among other identities and statuses.

<sup>116</sup> CESCR, General Comment 16: The Equal Right of Men and Women to the Enjoyment of All Economic, Social and Cultural Rights (Article 3 of the International Covenant on Economic, Social and Cultural Rights), E/C.12/2005/4, 11 August 2005; General Comment 25

<sup>117</sup> "COVID-19 Disrupting Services to Treat Non-Communicable Diseases, WHO survey finds", UN News, 1 June 2020, <https://news.un.org/en/story/2020/06/1065172>

<sup>118</sup> WHO, "Statement on the Fifth Meeting of the International Health Regulations (2005) Emergency Committee regarding the Coronavirus Disease (COVID-19) Pandemic", 30 October 2020, [https://www.who.int/news/item/30-10-2020-statement-on-the-fifth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/30-10-2020-statement-on-the-fifth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic)

<sup>119</sup> WHO, "Guidance on Developing a National Deployment and Vaccination Planning for COVID-19 vaccines", 16 November 2020, [https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine\\_deployment-2020.1](https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine_deployment-2020.1)

<sup>120</sup> WHO, COVID-19 Vaccine Introduction Readiness Assessment Tool, 21 September 2020, [https://apps.who.int/iris/bitstream/handle/10665/336188/WHO-2019-nCoV-Vaccine\\_introduction-RA\\_Tool-2020.1-eng.xlsx](https://apps.who.int/iris/bitstream/handle/10665/336188/WHO-2019-nCoV-Vaccine_introduction-RA_Tool-2020.1-eng.xlsx)

require specialized storage during transportation and distribution. For example, the Pfizer-BioNTech vaccines require ultra-cold storage at -70°C (-94°F) that is largely unavailable in low- and middle-income countries. Moderna's and Johnson & Johnson's vaccine candidates need to be shipped frozen, but they can then be stored at refrigeration temperatures for at least a month. AstraZeneca's vaccine does not require an ultra-cold storage and transport system and can last at least six months in refrigerator temperatures, likely making it easier and cheaper to distribute globally. These varying requirements raise concerns that higher income countries with a less robust infrastructure could have less access to particular vaccines, undermining the importance of universal access across countries. In some places, ensuring access to COVID-19 vaccines also may require states to invest in mobile health units to reach remote locations, expand the health workforce and provide tailored training administer COVID-19 vaccines across a range of settings.

## HEALTH WORKERS

A health worker refers to everyone working in the health care sector and involved in the delivery of health care in any capacity, which includes but is not limited to doctors, nurses, hospital cleaners, ambulance drivers, administrative staff at hospitals, and any health and social care workers working in the community or other settings. Health workers play a critical role in the response to COVID-19 and are the backbone of well-functioning health systems. As the main interlocutors between states and their populations, health workers will be central to mass COVID-19 immunisation drives, whether addressing misconceptions so people can make informed decisions around vaccinations, or managing equipment needed to administer vaccines. Indeed, studies have shown that a higher density of health workers is correlated to higher vaccination coverage rates, and the lack of health workers can limit vaccination uptake.<sup>121</sup> Given this key role in guaranteeing the right to health, health workers also may be exposed to reprisals or harassment. This may come from those who mistrust new vaccines and their government's response to COVID-19, due to misinformation. Therefore, states must strengthen their health systems by investing in their health workforce, per recommendations below.

## VACCINE ADMINISTRATION

States may have some experience with the challenges of routine immunization plans, but the breadth of COVID-19 vaccines under development will likely require a range of administration techniques and timelines.<sup>122</sup> For example, Johnson & Johnson's vaccine candidate requires one dose, while the Moderna and Pfizer-BioNTech vaccines require a second dose three and four weeks apart, respectively. AstraZeneca's vaccine candidate is most effective as two doses, the first in half the amount as the first dose. Multiple doses with such varying administration requirements will need careful planning and procurement to ensure that sufficient stock is available to administer in a timely manner, as well as informational campaigns so that people return for a second dose within the designated period. These logistical challenges may become more complex if states use more than one COVID-19 vaccine.

## IMMUNIZATION REGISTRY

Given the challenges of a mass vaccination effort, discussion has resurfaced for digital vaccination cards or a biometric immunization registry, whereby biometric data and/or other identifying information are used to record and store a person's vaccination history. This possibility raises concerns around the right to privacy and that governments could use this information for mass surveillance systems, including for the purpose of law enforcement and immigration, or that companies could access the data for other purposes.<sup>123</sup> Furthermore, digital vaccination certificates could also become de facto "immunity passports" that could be used to restrict the right to freedom of movement in certain spaces or block access to services such

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<sup>121</sup> S Anand and T Bärnighausen, "Health Workers and Vaccination Coverage in Developing Countries: an Econometric", *The Lancet*, Vol 369, 14 April 2007, <https://www.thelancet.com/pdfs/journals/lancet/PIIS0140673607605996.pdf>

<sup>122</sup> WHO, "Guidance on Developing a National Deployment and Vaccination Planning for COVID-19 Vaccines", 16 November 2020, [https://www.who.int/publications-detail-redirect/WHO-2019-nCoV-Vaccine\\_deployment-2020.1](https://www.who.int/publications-detail-redirect/WHO-2019-nCoV-Vaccine_deployment-2020.1)

<sup>123</sup> Access Now, *The Impact of COVID-19 Digital Health Certificates*, July 2020 <https://www.accessnow.org/cms/assets/uploads/2020/07/Impact-COVID-19-digital-health-certificates.pdf>

as education, housing and employment.<sup>124</sup> Likewise, suggestions that national identification numbers be required for COVID-19 vaccines may exclude undocumented populations or socio-economically disadvantaged groups who do not have this documentation.

## RECOMMENDATIONS

- States must ensure that health systems have sufficient health workers across geographic areas. These workers must be adequately trained to work with individuals and communities, particularly those identified as priority populations for COVID-19 health efforts. This is especially important in situations when historical marginalisation and discrimination against particular groups have led to mistrust in health systems and workers.
- States must ensure that health workers receive fair wages and work under acceptable conditions needed to protect their health and safety, as well as provide a safe and enabling environment to exercise their work free from reprisals, intimidation or threats.
- Any attacks or acts of violence against health workers must be promptly investigated in a thorough, independent and impartial manner by state authorities, and perpetrators must be brought to account. In doing so, states should acknowledge that some health workers may be at additional or specific risk due to their multiple and intersecting identities, especially women which often make up the majority of a health workforce.
- To ensure preparedness for COVID-19 vaccines and continue ongoing services, states must invest the maximum available resources to strengthen their health systems. In addition to prioritising health workers, investments should be made to address transportation, storage, and vaccine administration. These investments should be made with an eye towards building a more robust national health system that can sustainably increase the availability, accessibility, affordability and quality of health facilities, goods and services for all people.
- Ensure that digital tools respect the highest human rights and data protection law and standards, including the Toronto Declaration,<sup>125</sup> and ensure that these tools do not to discriminatory outcomes or other human rights harms, including those which may be caused by private companies involved in pandemic response, and that data are not used for any purposes beyond the specific circumstances for which their use is justified.
- Medical data should be generally protected as confidential and private in order to ensure that people can seek medical support and care without any fear of negative repercussions. Therefore, law enforcement and immigration officials should not be provided with individualized medical data collected as part of exceptional public health measures.
- States must ensure that people whose rights to health and privacy has been violated can exercise their right to an effective remedy through judicial mechanisms, national ombudsmen, human rights commissions, consumer forums, patients' rights associations or similar institutions.

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<sup>124</sup> "COVID-19 Immunity Passports and Vaccination Certificates: Scientific, Equitable, and Legal Challenges", *The Lancet*, 4 May 2020, [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31034-5/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31034-5/fulltext)

<sup>125</sup> Amnesty International, *The Toronto Declaration: Protecting the Rights to Equality and Non-Discrimination in Machine Learning Systems* (Index: POL 30/8447/2018), 17 May 2018, <https://www.amnesty.org/en/documents/poi30/8447/2018/en/>

## 6. NATIONAL AFFORDABILITY AND PRICING

*“With AIDS we saw that when treatments were found the wealthier people in wealthier countries got back to health, while millions of people in developing countries were left to die. We must not repeat the same mistake when a vaccine for COVID-19 is found. The right to health is a human right – it should not depend on the money in your pocket or the color of your skin to be vaccinated against this deadly virus. A vaccine should be a global public good and free of charge for all.”*

Winnie Byanyima, Executive Director of the Joint United Nations Programme on HIV and AIDS (UNAIDS)<sup>126</sup>

As part of their human rights obligations, states must take measures to eliminate any cost barrier that people may face in accessing the right to health, including those related to pricing of goods and services. A call for affordable COVID-19 diagnostics, treatments and vaccines reflects the CESCR’s General Comments 14 and 25, which make clear that: “states should use the maximum of their available resources to overcome hurdles that any person may face to benefit from new technologies or other forms of applications of scientific advancements” and that health authorities should be provided with a clear mandate to overcome policies that are not inclusive.<sup>127</sup> States unable to progressively realize the right to health must request international cooperation, and states in a position to provide technical or financial assistance must do so.<sup>128</sup>

The CESCR also has explained that states should adopt regulatory measures to prevent profiteering from essential medicines and supplies, which would include COVID-19 diagnostics, treatments and vaccines,<sup>129</sup> and that states have a duty to prevent unreasonably high costs for essential medicines from undermining the rights of large segments of the population to health.<sup>130</sup> In line with their responsibility to respect human rights, companies must also ensure that their pricing does not prevent states from eliminating cost as a barrier to accessing health goods and services.

According to the Guidelines for Pharmaceutical Companies, businesses should “consider all the arrangements at their disposal with a view of ensuring that medicines and other medical products are affordable to as many people as possible.”<sup>131</sup> This is particularly important as a company’s pricing to states can impact the amount of resources that governments have at their disposal to make COVID-19 diagnostics, treatments and vaccines affordable to its population.

### FREE COVID-19 VACCINES AT THE POINT OF CARE

While there is a clear human rights obligation on states to ensure that all health products are affordable, in the case of immunisations for highly infectious diseases such as COVID-19 there are cogent arguments in favour of making access free at the point of care. These arguments include the overwhelming socio-economic and human rights costs of low uptake rates can have on immunised and non-immunised people alike<sup>132</sup>, and the negative impact that financial and administrative barriers can have on vaccine uptake.

<sup>126</sup> Oxfam, “As Pandemic Deaths Pass 1 Million, COVID-19 Survivors from 37 Countries Write to Pharmaceutical Bosses to Demand a People’s Vaccine”, 29 September 2020, <https://www.oxfamamerica.org/press/pandemic-deaths-pass-1-million-covid-19-survivors-37-countries-write-pharmaceutical-bosses-demand-peoples-vaccine/>

<sup>127</sup> CESCR, General Comment 25, para 47

<sup>128</sup> CESCR, General Comment 14, paras 38 and 45; ICESCR, Article 2.1

<sup>129</sup> CESCR, “Statement on the Coronavirus Disease (COVID-19) Pandemic and Economic, Social and Cultural Rights”, 17 April 2020, <http://docstore.ohchr.org/SelfServices/File.sHandlerashx?enc=4slQ6QSmIBEDzFEovLCuW1AVC1NkPsgUedPIF1vFPMKXidSV%2FGyVFSAvr6nizxSIX6zd%2Bu5KD26NraabiJKaWMnkFhhMb4MahybE51%2FoU5sQSh6PCbc epqzI0iCYklyq>

<sup>130</sup> CESCR, General Comment 17, para 35

<sup>131</sup> Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, Principle 33, [https://www.who.int/medicines/areas/human\\_rights/A63\\_263.pdf?ua=1](https://www.who.int/medicines/areas/human_rights/A63_263.pdf?ua=1)

<sup>132</sup> The WHO estimates that the pandemic will shrink the global economy by US\$7 billion in 2020. WHO, “ACT Accelerator: An Economic Investment Case & Financing Requirements”, September 2020 – December 2021, 24 September 2020, <https://www.who.int/publications/i/item/an-economic-investment-case-financing-requirements>

States have committed to progressively guarantee universal health care, whereby all people can use the health services they need without risk of financial hardship.<sup>133</sup> Livelihoods have been hit hard by the pandemic, and in an effort to ensure that cost is not a barrier to health, the WHO recommended in June 2020 that states “fund public health by suspending payments or user fees at the point of care for essential health services for all patients.”<sup>134</sup> To ensure that all people are free of COVID-19 and its devastating impacts, states should ensure this position includes COVID-19 vaccines.

As one of the most cost-effective public health interventions to avoid disease,<sup>135</sup> vaccines can break the chain of transmission between people early in the disease cycle and avoid any further health and socio-economic impacts. Furthermore, immunization programs are the only safe way to achieve herd immunity, and the WHO that this will only be possible if 70% of the population becomes immune.<sup>136</sup>

Cost can prevent access to immunizations, especially for marginalized people, and the elimination of fees can improve vaccine uptake and decreases disparities across populations.<sup>137</sup> In 1994, the USA introduced a free vaccine programme for children without insurance, which increased uptake across races, ethnicities and income groups.<sup>138</sup> In 1993, Uganda introduced universal fees into its health system, which raised less than 5% of its expenditure and led to a sharp decline in users, especially among lower-income populations. When Uganda removed user fees in 2011, the use of health services dramatically increased, and immunization coverage nearly doubled from 41% to 80% within two years.<sup>139</sup>

Fees can also introduce administrative barriers, for example if people have to demonstrate that they do not have the means to pay by presenting identification, proof of residency or other documents that the most disadvantaged people often cannot readily present due to cost, inaccessible language, or other issues. In addition to the bureaucratic obstacle, these processes also often expand opportunities for corruption and stigmatisation.<sup>140</sup>

## RECOMMENDATIONS

- States must ensure that cost is never a barrier to access COVID-19 health products, and use their maximum available resources and international assistance, if needed, to provide COVID-19 vaccines free at the point of care. States and international financial institutions should work together to ensure cost is not a barrier anywhere for anyone.
- Global mechanisms, such as ACT-A/COVAX and C-TAP, should promote pricing that allows States to ensure that cost is not a barrier to COVID-19 vaccines, and make every effort to ensure that COVID-19 vaccines are free at the point of care.
- Businesses must consider all the arrangements at their disposal, including policies on pricing and intellectual property, to ensure that the pricing of their products is never a barrier to accessing COVID-19 health products and does not unduly impact a state's ability to provide COVID-19 vaccines free at the point of care.
- Businesses should publicly disclose as much information as possible about its pricing arrangements, including public funding received for the research and development of the vaccine, to contribute to a transparent pricing of COVID-19 health products.

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<sup>133</sup> WHO, *Universal Health Coverage (UHC) Factsheet*, 24 January 2019, [https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-\(uhc\)](https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-(uhc))

<sup>134</sup> WHO, “Maintaining Essential Health Services: New Operational Guidance for the COVID-19 Context”, 1 June 2020, <https://www.who.int/news-room/detail/01-06-2020-maintaining-essential-health-services-new-operational-guidance-for-the-covid-19-context>

<sup>135</sup> WHO, “Ten Threats to Global Health in 2019”, <https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019>

<sup>136</sup> S Vanderslott et al, “Vaccination”, *Our World in Data*, December 2019. <https://ourworldindata.org/vaccination#vaccines-save-lives>

<sup>137</sup> WHO, “Immunization Agenda 2030: A Global Strategy to Leave No One Behind”, 2 April 2020, p 12, <https://www.who.int/teams/immunization-vaccines-and-biologicals/strategies/ia2030>

<sup>138</sup> B Walsh et al, “Since the Start Of The Vaccines For Children Program, Uptake Has Increased, And Most Disparities Have Decreased”, *Health Affairs*, Vol 35, No 2, February 2016, <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2015.1019>

<sup>139</sup> Commission on Social Determinants of Health, *Closing the Gap in a Generation Health Equity through Action on the Social Determinants of Health*, Final Report, World Health Organization, 2008, p 103, [https://apps.who.int/iris/bitstream/handle/10665/43943/9789241563703\\_eng.pdf?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/43943/9789241563703_eng.pdf?sequence=1)

<sup>140</sup> M Sepúlveda Carmona et al, *The Human Rights Approach to Social Protection*, Ministry of Foreign Affairs of Finland, 1 June 2012, <https://ssrn.com/abstract=2114384>

## 7. QUALITY AND ACCEPTABILITY

Vaccines are deemed of **quality** if they comply with the scientific community's most recent standards concerning safety and effectiveness.<sup>141</sup> To ensure this standard, these products must go through approval processes under an objective, independent regulatory agency tasked with ensuring its safety and efficacy. This due diligence must be done by states producing and selling products, as well as states receiving products for distribution. It is also worth noting that not all vaccines will be safe and effective for all populations. To ensure universal access and non-discrimination, states must ensure that key populations are included in research and development.

In line with the CESCR's General Comment 25, **acceptable** vaccines are those that respect medical ethics and informed consent, and are designed to respect privacy and confidentiality, while being culturally appropriate by being sensitive to age, gender, religion or other characteristics.<sup>142</sup>

To be deemed acceptable, the scientific benefits of these products must be explained and disseminated in a manner that is understandable in a range of social and cultural contexts.<sup>143</sup> This is a crucial component to the right to health because individuals and communities can only make informed decisions about their health when they are given accurate, timely and accessible information, available in all local languages and in accessible formats for all people.<sup>144</sup>

Within the context of COVID-19, questions surrounding the quality and acceptability of diagnostics, treatments and vaccines have led to debates on the human rights implications of clinical trials, mandatory vaccines and "vaccine hesitancy". The principles of transparency and participation are particularly key to these issues. The CESCR also emphasizes the importance of participation and transparency to ensure that risks and advances of science can be made public "in order to enable society, through informed, transparent and participatory public deliberation, to decide whether or not the risks are acceptable."<sup>145</sup>

This engagement allows states to build more informed and sustainable policies, given that "the participation of various sectors of society allows the authorities to deepen their understanding of specific issues; helps to identify gaps, as well as available policy and legislative options and their impact on specific individuals and groups; and balances conflicting interests."<sup>146</sup>

### CLINICAL TRIALS

As of December 2020, 13 COVID-19 vaccine candidate trials were in the final phase three (involving humans)<sup>147</sup> and plans were under way to carry out clinical trials by both home and host companies involving roughly 280,000 people in 34 countries around the world. These countries include Australia, Brazil, China, Japan, Russia, South Africa, the United Arab Emirates (UAE), the UK and the USA. Additional trials are planned in Mexico, Venezuela and elsewhere in 2020 and 2021.<sup>148</sup> Clinical trials will likely continue for some time, as dozens of other vaccine candidates are at earlier stages of development.

The right to not be subjected to non-consensual medical treatment and experimentation is reflected in Article 7 of the International Covenant on Civil and Political Rights (ICCPR), stated throughout the Universal Declaration on Bioethics and Human Rights, and discussed in the CESCR's General Comment 25 on the

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<sup>141</sup> CESCR, General Comment 25, para 18

<sup>142</sup> CESCR, General Comment 25, paras 18 and 19

<sup>143</sup> CESCR, General Comment 25, para 44

<sup>144</sup> WHO/OHCHR, Fact Sheet No. 31, *The Right to Health*, <https://www.ohchr.org/documents/publications/factsheet31.pdf>

<sup>145</sup> CESCR, General Comment 25, para 57

<sup>146</sup> OHCHR, "Guidelines for States on the Effective Implementation of the Right to Participate in Public Affairs", [www.ohchr.org/EN/Issues/Pages/DraftGuidelinesRighttoParticipationPublicAffairs.aspx](http://www.ohchr.org/EN/Issues/Pages/DraftGuidelinesRighttoParticipationPublicAffairs.aspx)

<sup>147</sup> WHO, "Draft Landscape of COVID-19 Candidate Vaccines", 2 December 2020, <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>

<sup>148</sup> CEPI, "321 Vaccine Candidates against COVID-19 Now in Development", 4 September 2020, [https://cepi.net/news\\_cepi/321-vaccine-candidates-against-covid-19-now-in-development/](https://cepi.net/news_cepi/321-vaccine-candidates-against-covid-19-now-in-development/)



A worker holds a tray containing unlabeled ampoules of COVID-19 vaccine candidates under development on Friday, Aug. 7, 2020.  
© Andrey Rudakov/Bloomberg via Getty Images

right to the benefits of scientific progress and its applications.<sup>149</sup> In scientific research situations, such as clinical trials, the CESCR enumerates obligations on states to ensure that all entities, including non-state actors, refrain from discriminatory criteria, follow ethical standards, and obtain free, prior and informed consent from participants.<sup>150</sup> The UN Universal Declaration on Bioethics and Human Rights further outlines how this consent should be carried out, stating that participants must be given adequate information in a comprehensible form, which should include ways to withdraw consent at “at any time and for any reason without any disadvantage or prejudice.”<sup>151</sup>

With regards to the safety and effectiveness of scientific research, the CESCR notes that states should prevent or mitigate any potential risks by applying the precautionary principle, thereby ensuring that all risks involved have been adequately mitigated and communicated as part of an adequate informed consent process.”<sup>152</sup> Moreover, the benefits of the medical research to participants and other affected individuals should be maximized and any possible harm minimized. In this sense, individuals or groups partaking in clinical studies should be able to secure the vaccines under trial once these are approved.

Specific groups or people in marginalized situations due to sex, gender, age, sexual orientation, gender identity, Indigenous status, ethnicity, disability, socio-economic conditions, or migrant or refugee status, among other identities and statuses, may warrant additional safeguards and “should be especially protected in order to avoid any discrimination; and cultural diversity and pluralism should be given due regard.”<sup>153</sup>

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<sup>149</sup> CESCR, General Comment No. 14

<sup>150</sup> CESCR, General Comments 25, 19

<sup>151</sup> UN Universal Declaration on Bioethics and Human Rights, 19 October 2005, Article 6.1

<sup>152</sup> CESCR, General Comments 25, para 71

<sup>153</sup> CESCR, General Comment 25, para 19

The CESCR also notes that, “when research is done in countries or among populations different to those of the researchers, the state of origin must guarantee the rights and obligations of all parties involved.”<sup>154</sup> Furthermore, the CESCR highlights that additional safeguards are necessary when a state or non-state actor seeks to “conduct research, take decisions or create policies relating to science that have an impact on indigenous peoples.”<sup>155</sup> For these populations, states must ensure the collective right to free, prior and informed consent regarding decisions that affect them, which goes beyond every individual’s right to free, prior and informed consent as outlined above.<sup>156</sup>

## RECOMMENDATIONS

- States must ensure that vaccines are researched and developed for a range of populations, so all groups have access to a product that is safe and effective without discrimination with respect to age, gender, ethnic/racial descent, medical conditions, socio-economic status or any other grounds of discrimination. Individuals or groups partaking in clinical studies should be able to secure the vaccines under trial once these are approved.
- States have a duty to protect people from participating in research or trials that contravene the ethical standards for responsible research and hold any offending actors to account. This is especially true for people from historically marginalized communities or at-risk populations that may face undue pressure to participate in clinical trials or to take an approved vaccine without free, prior and informed consent.
- States must ensure that trials and national immunization programmes can detect and respond to any concern about vaccine safety and effectiveness through continuous monitoring and coordination among relevant stakeholders, especially civil society representatives, including those from communities or populations at risk. States must adopt a robust accountability framework for any violations of the right to health. This mechanism must be accessible, transparent and effective.
- States and businesses have a responsibility to ensure that public and private investment in scientific institutions is not used to unduly influence the orientation of research, restrict the scientific freedom of the research entity, or accelerate the regulatory process of approvals.<sup>157</sup>

## VACCINATION MANDATES AND REQUIREMENTS

COVID-19 immunization plans must be carried out in a way that is consistent with the protection of human rights. Research has also shown that compliance with COVID-19 restrictions, “requires public acceptability and trust in government, which may be eroded if restrictions are harshly enforced or maintained for long durations.”<sup>158</sup> With these in mind, states should promote and facilitate the take up of COVID-19 vaccines and ensure that they are voluntary to the fullest extent wherever and whenever possible. In this respect, states must always guarantee individuals with the right to prior, free and informed consent. This requires unhindered access to objective, credible and evidence-based information. The Universal Declaration on Bioethics and Human Rights further explains that, “consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.”<sup>159</sup>

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<sup>154</sup> CESCR, General Comment 25, para 22

<sup>155</sup> CESCR, General Comment 25, para 40

<sup>156</sup> Article 19 of the UN Declaration on the Rights of Indigenous Peoples (A/RES/61/295): “States shall consult and cooperate in good faith with the indigenous peoples concerned through their own representative institutions in order to obtain their free, prior and informed consent before adopting and implementing legislative or administrative measures that may affect them.” See also the UN Committee on the Elimination of Racial Discrimination’s General Recommendation XXIII on the Rights of Indigenous Peoples, para 4(d).

<sup>157</sup> CESCR, General Comment 25, para 43

<sup>158</sup> L F Wiley , “Public health law and science in the community mitigation strategy for Covid-19”, *Journal of Law and the Biosciences*, Vol 7, Issue 1, January-June 2020, p 6, <https://doi.org/10.1093/jlb/lisaa019>

<sup>159</sup> Universal Declaration on Bioethics and Human Rights, Article 6.1

The WHO has named lack of confidence in immunisations as one of the main reasons why people chose to not be vaccinated.<sup>160</sup> Known as “vaccine hesitancy,” this reluctance towards or refusal of vaccines has become a global trend that stems from wavering trust in the importance, safety and effectiveness of vaccines.<sup>161</sup> Disinformation campaigns on social media, often based on non-scientific evidence, have further fuelled vaccine hesitancy.<sup>162</sup> In this respect, the CESCR has recommended that states “establish protective measures in relation to messages from pseudoscience, which create ignorance and false expectations among the most vulnerable sectors of the population.”<sup>163</sup> Within the context of COVID-19, the politicization of the race towards a vaccine has also led to questioning whether national regulatory agencies are taking all necessary steps to ensure that these vaccines undergo proper scrutiny to be deemed safe and effective.<sup>164</sup> Given these concerns, the CESCR calls on states to take measures to avoid risks associated with conflicts of interest, which should always be disclosed and regulated to foster trust in these processes.<sup>165</sup>

While blanket mandates on vaccination infringe human rights, it is plausible that states could justify certain vaccine requirements, as a specific measure to prevent the spread of COVID-19, especially in situations of heightened risk. These requirements could include situations where people are not forced per se to be vaccinated, but their employment, schooling or freedom of movement may be contingent upon an immunization requirement. In these cases, additional human rights, such as the right to education and to livelihood and decent work, also are at stake and need to be taken into account accordingly.

Several international instruments allow for limitations on rights for the sake of public health, provided these include safeguards. The Universal Declaration on Bioethics and Human Rights stipulates that these principles could be limited by law “for the protection of public health or for the protection of the rights and freedoms of others. Any such law needs to be consistent with international human rights law.”<sup>166</sup> The CESCR’s General Comment 14 provides further guidance on limitations on rights on the grounds of public health, stating that these “must be in accordance with the law, including international human rights standards, compatible with the nature of the rights protected by the Covenant, in the interest of legitimate aims pursued, and strictly necessary for the promotion of the general welfare in a democratic society”.<sup>167</sup> Furthermore, the CESCR specifies that any restriction on these rights should be of limited duration, subject to review, and the least restrictive alternative must be adopted where several types of limitation are available.<sup>168</sup>

Similarly, the ICCPR allows for restrictions to be imposed on human rights, if they are provided by law, and necessary to protect certain specified legitimate aims, one of which is public health, and “are consistent with the other rights recognized in the [ICCPR].”<sup>169</sup> The Siracusa Principles on the Limitation and Derogation of Provisions in the ICCPR (Siracusa Principles), an expert interpretation of the ICCPR, provide specific guidance on when and how restrictions to human rights may be implemented<sup>170</sup> In relation to public health, they note that these “measures must be specifically aimed at preventing disease or injury or providing care for the sick and injured”. A recommendation below outlines how states must justify a vaccine requirement, according to their human rights obligations.

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<sup>160</sup> WHO, “Ten threats to global health in 2019”, <https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019>

<sup>161</sup> A de Figueiredo et al, “Mapping Global Trends in Vaccine Confidence and Investigating Barriers to Vaccine Uptake: A Large-scale Retrospective Temporal Modelling Study”, *The Lancet*, Vol 396, Issue 10255, 26 September 2020, [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31558-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31558-0/fulltext)

<sup>162</sup> “[The] analysis of social media activity for up to 190 countries, researchers found that each 1-point increase in efforts by foreign vaccine disinformation campaigns on social media was associated with a 15% annual increase in the number of negative tweets about vaccination.” See S L. Wilson, C Wiysonge, “Social Media and Vaccine Hesitancy”, *BMJ Global Health*, Vol 5, Issue 10, <https://gh.bmj.com/content/5/10/e004206>

<sup>163</sup> CESCR, General Comment 25, para 44

<sup>164</sup> A de Figueiredo et al, “Mapping Global trends in Vaccine Confidence and Investigating Barriers to Vaccine Uptake: A Large-Scale Retrospective Temporal Modelling Study”, *The Lancet*, 10 September 2020, [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31558-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31558-0/fulltext); and J V Lazarus et al, “A global Survey of Potential Acceptance of a COVID-19 Vaccine”, *Nature Medicine*, 20 October 2020, <https://www.nature.com/articles/s41591-020-1124-9>

<sup>165</sup> CESCR, General Comment 25, paras 53 and 59

<sup>166</sup> Universal Declaration on Bioethics and Human Rights, Article 27

<sup>167</sup> CESCR, General Comment 14, para 28

<sup>168</sup> CESCR, General Comment 14, para 29

<sup>169</sup> ICCPR, Article 12(3)

<sup>170</sup> More specifically, the Principles state that: (i) no limitation on a right recognized by the ICCPR shall be discriminatory; (ii) any limitations must respond to a pressing public or social need, pursue a legitimate aim, and be proportional to that aim; (iii) states should use no more restrictive means than are required for the achievement of the purpose of the limitation; (iv) the burden of justifying a limitation upon a right guaranteed under the ICCPR lies with the state; and (v) every limitation imposed shall be subject to the possibility of challenge to and remedy against its abusive application.

## RECOMMENDATIONS

- States must ensure everyone has free, unhindered and easy access to credible, reliable, objective and evidence-based information about COVID-19 health products, in relevant languages and in accessible formats for all people. States must ensure that this information covers all initiatives that respond to the specific needs and concerns of particular communities, especially those most at risk. States must guarantee the free flow of information by lifting all undue restrictions on the right to seek, receive and impart information about COVID-19 health products, thus ensuring the effective exercise of the right to health.
- States should adopt adequate frameworks, in line with their human rights obligations, to address the pernicious effects of false or misleading information that could compromise the right to health. In this regard, states must ensure that they disseminate credible, reliable, accessible, objective and evidence-based information, including to address false or misleading information related to COVID-19 health products.
- Social media companies involved in facilitating and moderating online content should uphold their human rights responsibilities by engaging in human rights due diligence and taking concrete action to respond to the dissemination of false or misleading information. In doing so, social media companies should ensure greater transparency regarding, and oversight of, content moderation practices and policies to ensure that human rights are respected in practice.
- States must not impose blanket mandatory vaccine policies and should seek to ensure that vaccination is voluntary wherever and whenever possible. As states carry the burden of justifying a limitation upon a right guaranteed under international human rights law, any potential vaccine requirement must reflect the Siracusa Principles and states must demonstrate that this requirement:
  - pursues a legitimate aim to prevent disease or injury and constitutes a necessary, proportionate and reasonable measure to achieve this aim through an evidence-based rationale that explains why the goal cannot be achieved with less restrictive measures;
  - exists under a limited scope and time for the purpose of the specific, legitimate aim and does not have a discriminatory effect on groups that experience historical and structural discrimination, in line with international human rights laws and standards;
  - includes regulations that are consistent with human rights, in line with the CESCR's General Comment 25, and undergoes periodic monitoring and review, with channels to challenge and remedy against its possible abusive application; and
  - contains accessible and sufficient precision to enable individuals and communities to regulate their conduct accordingly and allows for reasonable exceptions to avoid negative impacts on other human rights, without involving punitive measures such as fines for non-compliance. Amnesty International strongly opposes the use of the criminal law and, in particular, the imprisonment of people who refuse vaccination.

## 8. CONCLUSION

The COVID-19 pandemic has caused a global public health and socio-economic crisis. But the rapid development of vaccines could strongly mitigate its impact and perhaps even bring much of this crisis to a close. However, pending questions around how these vaccines will be distributed, to whom they will become available and at what cost, still pose challenging human rights concerns. Drawing upon a range of international human rights laws and standards, this Amnesty International briefing lays out guidance for states and businesses to address these questions while fulfilling their human rights obligations and responsibilities.

Within this context, it is crucial for states and businesses to develop and implement, in line with human rights standards, policies to ensure availability, accessibility, affordability, acceptability and quality of vaccines for all people. These should be done by fostering international cooperation and breaking down barriers to global availability and affordability across countries. They should make every effort to ensure that COVID-19 vaccines are free at the point of care. Human rights also must be at the heart of any national allocation plan, taking into consideration how systemic discrimination has historically affected the access to health services of marginalized and at-risk groups. To this end, states must ensure everyone has free, unhindered and easy access to credible, reliable, objective and evidence-based information about COVID-19 vaccines, in relevant languages and in accessible formats for all people. In so doing, states must not impose blanket mandatory vaccine policies and should seek to ensure that vaccination is voluntary; any potential vaccine requirement must be justified according to international human rights law.

Although COVID-19 is new, many of the human rights concerns the pandemic has exposed are systemic. For years these have affected people's access to life-saving health products and services. Now is the time to safeguard the right to health and ensure we level out the playing field so that the fruits of science represent a truly global solution to the COVID-19 pandemic. While each country is in a very different stage in the path towards securing COVID-19 vaccines for its population, this Amnesty International policy briefing contains recommendations that are salient for all governments and businesses engaged in this task. Moreover, as immunisation plans are operationalised, undoubtedly, new questions will emerge and need to be addressed. Amnesty International will monitor these developments and continue to issue recommendations to states and businesses alike to ensure that human rights are at the forefront of any efforts to tackle COVID-19.

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# A FAIR SHOT

## ENSURING UNIVERSAL ACCESS TO COVID-19 DIAGNOSTICS, TREATMENTS AND VACCINES

In an unprecedented global health crisis, nearly 65 million people across 191 countries and territories had contracted coronavirus and 1.5 million people died as a result, as of December 2020. Against this background, the extraordinary global efforts to develop, manufacture and distribute tests, treatments and vaccines for COVID-19 are coming under increasing scrutiny.

Vaccines, specifically, could strongly mitigate the human rights impacts of COVID-19 and bring much of this crisis to a close. However, questions as to when and how these vaccines will be distributed, to whom they will become available and at what cost, pose challenging human rights concerns. Drawing upon international laws and standards, this Amnesty International briefing lays out guidance for states and businesses to address these questions while meeting their human rights obligations and responsibilities.

Amnesty International calls upon states and businesses to ensure availability, accessibility, affordability, acceptability and quality of vaccines for all people. International cooperation is crucial to break down barriers to global availability and affordability across countries. Nationally, governments also must make every effort to ensure that COVID-19 vaccines are free at the point of care and that human rights must be at the heart of in-country allocation plans, paying special attention to disproportionately impacted at-risk groups. Now is the time to safeguard the right to health and ensure we level out the playing field so that the fruits of science represent a truly global solution to COVID-19.