

**Mandates of the Working Group on the issue of human rights and transnational corporations and other business enterprises; the Special Rapporteur on the right to development; the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health; the Independent Expert on the promotion of a democratic and equitable international order; the Independent Expert on human rights and international solidarity and the Special Rapporteur on extreme poverty and human rights**

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Excellency,

We have the honour to address you in our capacities as Working Group on the issue of human rights and transnational corporations and other business enterprises; Special Rapporteur on the right to development; Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health; Independent Expert on the promotion of a democratic and equitable international order; Independent Expert on human rights and international solidarity and Special Rapporteur on extreme poverty and human rights, pursuant to Human Rights Council resolutions 44/15, 42/23, 42/16, 36/4, 44/11 and 44/13.

We are independent human rights experts appointed and mandated by the United Nations Human Rights Council to report and advise on human rights issues from a thematic or country-specific perspective. We are part of the special procedures system of the United Nations, which has 56 thematic and country mandates on a broad range of human rights issues. We are sending this letter under the communications procedure of the Special Procedures of the United Nations Human Rights Council to seek clarification on information we have received. Special Procedures mechanisms can intervene directly with Governments and other stakeholders (including companies) on allegations of abuses of human rights that come within their mandates by means of letters, which include urgent appeals, allegation letters, and other communications. The intervention may relate to a human rights violation that has already occurred, is ongoing, or which has a high risk of occurring. The process involves sending a letter to the concerned actors identifying the facts of the allegation, applicable international human rights norms and standards, the concerns and questions of the mandate-holder(s), and a request for follow-up action. Communications may deal with individual cases, general patterns and trends of human rights abuses, cases affecting a particular group or community, or the content of draft or existing legislation, policy or practice considered not to be fully compatible with international human rights standards.

In this connection, we would like to bring to the attention of the European Commission our concerns about the unequal access to COVID-19 vaccines, medicines, health technologies, diagnostics and health therapies within and between countries, affecting negatively several human rights, particularly of individuals and people living in low- and middle-income countries, exacerbating inequality and discrimination and impeding the realization of a democratic and equitable international order.

European Commission

We acknowledge the efforts so far made by the European Union in supporting States towards ensuring equitable, affordable, fair, safe, timely, and universal access to COVID-19 vaccines. We would like to assure you of our support to your work and our willingness to cooperate in finding solutions and effective alternatives together with you to the concerns raised below.

While as of 27 September 2021, 44.5 per cent of the world population has received at least one dose of a COVID-19 vaccine, only 2.2 per cent of people in low-income countries received at least one dose<sup>1</sup>, compared with almost 50 per cent of fully vaccinated in high-income countries.<sup>2</sup> The WHO recently announced that even though more than 5 billion vaccines have by now been administered worldwide, progress has been highly uneven: almost 75 per cent of those doses have been administered in just 10 countries<sup>3</sup>. According to a recent estimate by researchers, most people in the poorest countries will need to wait another two years before they are vaccinated against COVID-19.<sup>4</sup>

A proposal was made by the Governments of India and South Africa on 2 October 2020 **for a temporary waiver of certain Trade-Related Intellectual Property Rights (TRIPS) Agreement protections** “in relation to prevention, containment or treatment of COVID-19”. The text of the proposal was revised in May 2021. The revised proposal refers to “[r]ecognising the global need for unimpeded, timely and secure access to quality, safe, efficacious and affordable health products and technologies for all, for a rapid and effective response to the COVID-19 pandemic and consequently the urgent need to diversify and scale-up production to meet global needs and promote economic recovery”.<sup>5</sup> The aim of the proposal is to scale up production of treatments and vaccinations against COVID-19 and accordingly to open up more opportunities for dissemination to a larger segment of the world’s population and at a lower cost. The proposal also recognizes that “the COVID-19 global pandemic requires a global response based on unity, solidarity and multilateral cooperation”.<sup>6</sup> While the large majority of States either co-sponsored the proposal or expressed support to it, some States opposed it, and others still have abstained from taking a position.

Although some steps have been taken to marshal resources for global vaccine procurement and distribution, such as through the development of the **COVAX facility**, significantly **greater international assistance and cooperation will need to take place for vaccinations to take place equitably and in a timely manner on a global scale**. This would require not only procuring a sufficient number of vaccines, but also ensuring that the national health systems in low- and middle-income countries have the capacity to distribute those vaccines in an equitable manner. Without **broader international cooperation and solidarity measures** that allow for the mobilization of adequate financing or technology and know-how, many national health systems in low- and middle-income countries will not be able to ensure that adequate health facilities, goods and services are available and accessible for all without discrimination.

<sup>1</sup> Source: [Coronavirus \(COVID-19\) Vaccinations - Statistics and Research - Our World in Data](#)

<sup>2</sup> WHO Director-General remarks at the press conference for the Inauguration of the WHO Hub for Pandemic and Epidemic Intelligence, 1 September 2021.

<sup>3</sup> WHO, WHO Director General’s opening remarks at G20 Health Ministers Meeting – 5 September, 2021.

<sup>4</sup> Source: COVID Vaccines Will Not Reach Poorest Countries Until 2023, by T.V. Padma, Nature magazine, 6 July, 2021

<sup>5</sup> WTO communication - Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19. Revised Decision Text. 21 May 2021, IP/C/W/669/Rev.1

<sup>6</sup> Idem.

Moreover, we are concerned by **the lack of transparency in contracts between the European Union and pharmaceutical companies, including the limited publication of contracts worldwide, and significant redactions of key information of public interest in the few contracts that were published.**<sup>7</sup> This lack of transparency makes it difficult to monitor the pricing differences and the human rights impact of indemnification clauses as well as the compliance of the concerned companies with their responsibilities to respect the right to health and to ensure everyone can enjoy the benefits of scientific progress. The partial or full built-in immunity clauses for the case of adverse side effects of the vaccines is a cause of special concern.

We express our concern that the speedy production of safe and effective vaccines against COVID-19 has not been followed by swift action to ensure equality of access within and between countries, which affects negatively several human rights, including the right to life, the right to the highest attainable standard of health, the right to enjoy the benefits of scientific progress and its applications, and the right to development particularly of individuals and people living in low- and middle-income countries. Such unequal access to COVID-19 vaccines, medicines, health technologies, diagnostics, and health therapies within and between countries exacerbates inequality and discrimination and impedes the realization of a democratic and equitable international order.

The High Commissioner has noted in its Guidance on Access to COVID-19 vaccines<sup>8</sup> that access to vaccines and medicines is disturbingly uneven in many places, with poorer health outcomes for women and girls, national, ethnic, religious, racial and linguistic minorities, indigenous populations, persons living in poverty, LGBTI people, persons with disabilities, migrants, particularly undocumented migrants, stateless persons, and others experiencing marginalisation. COVID-19 infection rates and outcomes for minorities and people in vulnerable groups have mirrored these patterns, in part due to structural inequalities and discrimination. These facts raise a substantial risk that these populations and groups will fall behind in vaccination rates relative to others. A group of experts of the Special Procedures have raised concerns over unequal access to COVID-19 vaccines by billions of people in developing countries<sup>9</sup> and how this affects in particular those in vulnerable situation, who are frequently neglected in terms of health care.<sup>10</sup>

Earlier this year, the Human Rights Council called for “equitable, affordable, timely, and universal access for all countries.”<sup>11</sup> It reaffirmed vaccine access as a protected human right and expressed “concern that the unequal distribution of vaccines delays the end of the pandemic”. The Human Rights Council urged all States, individually and collectively, to “remove unjustified obstacles restricting exports of COVID-19 vaccines” to “facilitate the trade, acquisition, access to and distribution of COVID-19 vaccines as a crucial element of their responses to the pandemic” for all and to “refrain from taking any economic, financial or trade

<sup>7</sup> WHO Collaborating Center for Governance, University of Toronto and Transparency International, May 2021, [For-Whose-Benefit-Transparency-International.pdf \(ti-health.org\)](#)

<sup>8</sup> OHCHR Guidance on Access to COVID-19 vaccines, available at: [COVID-19\\_AccessVaccines\\_Guidance.pdf \(ohchr.org\), December 2020.](#)

<sup>9</sup> [OHCHR | UN experts: G7 Governments must ensure vaccines' access in developing countries](#)

<sup>10</sup> A/HRC/47/28 para 101-104.

<sup>11</sup> A/HRC/RES/46/14 - UN Human Rights Council resolution on Ensuring equitable, affordable, timely and universal access for all countries to vaccines in response to the coronavirus disease (COVID-19) pandemic, Resolution, 23 March 2021, <https://undocs.org/A/HRC/RES/46/14>

measures that may adversely affect equitable, affordable, fair, timely and universal access to COVID-19 vaccines, in particular in developing countries.” It also called for enhanced “access to science, innovation, technologies, technical assistance and knowledge-sharing”, as well as all stakeholders to “commit to transparency in all matters related to the production, distribution and fair pricing of vaccines (...),” and urged States to immediate steps to prevent speculation and undue export controls and stockpiling that may hinder affordable, timely, equitable and universal access for all countries to COVID-19 vaccines.” The Human Rights Council equally emphasized “the central role of the State in responding to pandemics and other health emergencies, and the socioeconomic consequences thereof, and in advancing sustainable development and the realization of human rights.”

We would also like to recall that, under the International Covenant on Economic, Social and Cultural Rights (ICESCR) everyone is entitled, to have access without discrimination to a COVID-19 vaccine that is safe, effective and based on the application of scientific progress necessary to enjoy the highest attainable standard of health; the Committee on Economic, Social and Cultural Rights (CESCR) adopted a specific general comment (No 25) and public statements on this issue.<sup>12</sup> In the current context of the pandemic, the CESCR stated that “States must: [...] guarantee physical accessibility to vaccines, especially for marginalized groups and people living in remote areas, using both State-run and private channels and through strengthening the capacity of health systems to deliver vaccines; thirdly, guarantee affordability or economic accessibility for all, including by providing vaccines free of charge, at least for lower income persons and the poor [...]”<sup>13</sup> The CESCR noted that unequal access to vaccines for least developed and developing countries is discriminatory and undermines progress on achieving the Sustainable Development Goals. It reiterated the obligation for international cooperation noting, that “given the global nature of the pandemic, States have the obligation to support, to the maximum of their available resources, efforts to make vaccines available globally. Vaccine nationalism breaches the extraterritorial obligations of States to avoid taking decisions that limit the ability of other States to make vaccines available to their populations and thus to implement their human rights obligations relating to the right to health, as it results in a shortage of vaccines for those who are most in need in the least developed countries.”<sup>14</sup>

As spelled out by the Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001 at the Doha WTO Ministerial Meeting<sup>15</sup>, intellectual property rights cannot become a barrier to the effective enjoyment of the human right to health and States must be allowed to interpret intellectual property rules in a way that supports public health both in access to existing medicines and in creating of new technologies. This implies that States must first ensure that access to essential medicines and vaccines is not impeded by intellectual property rights; secondly help countries develop medicines and vaccines quickly to meet the demand.<sup>16</sup>

Furthermore, the Global Health Summit of the leaders of G20 and other states issued on 21 May 2021 the Rome Declaration. This Declaration underlined the urgent

<sup>12</sup> Committee on Economic Social and Cultural Rights (CESCR), General Comment No. 25 (2020) on science and economic, social and cultural rights (article 15 (1) (b), (2), (3) and (4) of the Covenant), para. 70. See also E/C.12/2020/2.

<sup>13</sup> CESCR, Statement on universal and equitable access to vaccines for the coronavirus disease (COVID-19), 15 December 2020, available at: [https://www.ohchr.org/Documents/HRBodies/CESCR/E\\_C\\_12\\_2020\\_2\\_AUV.docx](https://www.ohchr.org/Documents/HRBodies/CESCR/E_C_12_2020_2_AUV.docx).

<sup>14</sup> Statement on universal affordable vaccination against coronavirus disease (COVID-19), international cooperation and intellectual property, 23 April, 2021, available at: [E/C.12/2021/1 - E - E/C.12/2021/1 -Desktop \(undocs.org\)](https://undocs.org/E/C.12/2021/1-E-E/C.12/2021/1-Desktop)

<sup>15</sup> Doha WTO Ministerial Declaration: Declaration on the TRIPS agreement and public health, 14 November 2001. Idem., para 17.

need to scale up efforts, including through synergies between the public and private sectors and multilateral efforts, to enhance timely, global, and equitable access to safe, effective, and affordable COVID-19 tools (vaccines, therapeutics, diagnostics, and personal protective equipment, henceforth ‘tools’).<sup>17</sup>

In the framework of the Rome Declaration, States have committed to enable equitable, affordable, timely, global access to high-quality, safe, and effective prevention, detection and response tools, leveraging and drawing on the experience of ACT-A, as well as to non-pharmaceutical measures, clean water, sanitation, hygiene and (adequate food) nutrition and to strong, inclusive, and resilient health systems; and support robust vaccine delivery systems, vaccine confidence and health literacy. They also pledged to invest predictably, effectively, and adequately, in line with national capacities, in domestic, international and multilateral cooperation in research, development, and innovation, for health systems tools and non-pharmaceutical measures, considering issues of scalability, access, and manufacturing from an early stage.<sup>18</sup>

Under the Guiding Principles on Business and Human Rights and under the Guiding Principles on Extreme Poverty and Human Rights, endorsed by Human Rights Council resolutions 17/4 and 21/11, States have a duty to take measures to ensure that business enterprises within their territory or jurisdiction conduct effective human rights due diligence to identify, prevent, mitigate and account for how they address their impacts on human rights throughout their operation.

We would also like to remind you of article 1 of the Declaration on the Right to Development adopted by the United Nations General Assembly<sup>19</sup>, by virtue of which every human person and all peoples are entitled to participate in, contribute to, and enjoy economic, social, cultural and political development. We also wish to recall Article 6, which raises the need for co-operation by states with a view to promoting, encouraging and strengthening universal respect for and observance of all human rights and fundamental freedoms, which are interdependent; equal attention and urgent consideration should be given to the implementation, promotion and protection of civil, political, economic, social and cultural rights. The Declaration further calls on States to take all necessary measures for the realization of the right to development and to ensure equality of opportunity for all in their access to basic resources, education, health, food, housing and employment (art. 8). We refer to the Guidelines and recommendations on the practical implementation of the right to development, which find that sustainable development is based on active, meaningful and informed participation, and that Governments and international cooperation partners should establish participatory and effective decision-making mechanisms, that involve groups affected by particular development policies, programmes and projects (para 24). The Guidelines further recommend that States should establish mechanisms that provide easy access to information related to development policies and processes and enact legislation guaranteeing access to information, including information about project financing (para 32); be mandated to produce and disclose information in a timely fashion and that legal remedies should be provided to ensure that access to information is not denied (para 33). States should guarantee that all stakeholders are meaningfully included in the process of negotiating international agreements and information on upcoming initiatives should be made available at the national level at

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<sup>17</sup> Rome Declaration of leaders of G20 and other states, Global Health Summit in Rome, May 21, 2021.

<sup>18</sup> Principles 5 and 12 of the Rome Declaration

<sup>19</sup> Declaration on the right to Development, adopted by General Assembly resolution 41/128 of 4 December 1986.

an early stage so that civil society and concerned communities can participate in multilateral negotiation processes (para 41).

Finally, the Draft Declaration on human rights and international solidarity,<sup>20</sup> which calls for countries to avoid being blinded by national or local self-interest and encourages more cooperation between countries as the imperative to address these issues, has taken on a renewed importance and urgency. In the context of COVID-19 pandemic, the need for a speedy adoption by Member States of the Draft Declaration should also become a priority.

In this context, and acknowledging the European Parliament's recent resolution on meeting the global COVID-19 challenge regarding the effects of the waiver of the WTO TRIPS Agreement<sup>21</sup>, we would like to inquire **about the position of the European Union on the proposed temporary waiver of certain COVID-19 TRIPS protections** to ensure that intellectual property rights on the vaccines do not become a barrier to the effective enjoyment of the fundamental human rights. In this regard we would like to draw your attention to Principle 10 of the Guiding Principles on Business and Human Rights, which provides that: "States, when acting as members of multilateral institutions that deal with business-related issues, should: (a) Seek to ensure that those institutions neither restrain the ability of their member States to meet their duty to protect nor hinder business enterprises from respecting human rights".

Please kindly also inform us about the steps that the European Union has taken, or is considering to take, **including policies, legislation, and regulations, to protect against any actual or potential human rights impacts related to pharmaceutical companies within its territory and/or jurisdiction producing or developing COVID-19 related vaccines**, and ensuring that such business enterprises conduct effective human rights due diligence to identify, prevent, mitigate and account for how they address their impacts on human rights throughout their operation, as set forth by the Guiding Principles on Business and Human Rights.

We would also welcome information about **the European Union's relevant regional policies, laws, and practices** that support States in using compulsory licence orders under the TRIPS Agreement to produce and distribute vaccines in the public interest, to scale up production of vaccines and treatments against COVID-19 and opening up more opportunities for dissemination to a larger number of the population.

We would be interested in knowing about **the ways in which the European Union supports efforts for international economic and scientific cooperation and international solidarity** to avoid vaccine hoarding and to ensure global vaccine procurement and distribution, to provide financial and technical assistance to governments of low- and middle-income countries to address the human rights consequences of the current crisis (i.e. by strengthening the capacity of the health systems of such countries to produce vaccines themselves and to distribute them in an equitable manner).

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<sup>20</sup> Annex of report A/HRC/35/35 of the Independent Expert on human rights and international solidarity.

<sup>21</sup> European Parliament resolution of 10 June 2021 on meeting the global COVID-19 challenge: effects of the waiver of the WTO TRIPS Agreement on COVID-19 vaccines, treatment, equipment and increasing production and manufacturing capacity in developing countries (2021/2692(RSP)), available at: [https://www.europarl.europa.eu/doceo/document/TA-9-2021-0283\\_EN.html](https://www.europarl.europa.eu/doceo/document/TA-9-2021-0283_EN.html)



Finally, we would like to enquire about **laws and policies of the European Union on full transparency in its contracts with pharmaceutical companies purchasing vaccines, including all elements of vaccine development, procurement, and provision** to ensure that the European Union and companies domiciled on its territory comply with international law and that their related responsibilities can be effectively monitored and enforced, especially regarding the pricing policies and the human rights impact of indemnification clauses, as well as the partial or full built-in immunity clauses for the case of adverse side effects of the vaccines.

As it is our responsibility under the mandates provided to us by the Human Rights Council, to seek to clarify the above-mentioned concerns, we would like to ask you to provide any additional information and/or any comment(s) you may have on the issues raised.

This communication, as a comment on pending or recently adopted legislation, regulations or policies, and any response received will be made public via the communications reporting [website](#) after 48 hours. They will also subsequently be made available in the usual report to be presented to the Human Rights Council.

Please be informed that a letter on this subject matter expressing similar concerns has been also sent to a number of Governments where pharmaceutical companies are domiciled or/and Governments that are influential in the decision-making process of the above presented issues, the World Trade Organization, as well as to pharmaceutical companies producing or developing COVID-19 vaccines.

Please accept, Excellency, the assurances of our highest consideration.

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