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

REFERENCE: OL OTH 224/2021

14 October 2021

## 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 abroad 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 your attention 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.

We acknowledge the efforts so far made in different bodies of the World Trade Organization (WTO) in order to assist Member States in advancing negotiations

towards ensuring equitable, affordable, fair, safe, timely, and universal access to COVID-19 vaccines. We would like to assure you of our support to the work of WTO towards moving beyond existing limitations related to intellectual property rights that have made access to COVID-19 vaccines unequal and unfair around the world, and our willingnesss 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 lowincome 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-19.4

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"5. 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"6. 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.

Moreover, we are concerned by the lack of transparency in contracts between States 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.

Source: Coronavirus (COVID-19) Vaccinations - Statistics and Research - Our World in Data

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

WHO Director General Opening remarks at G20 Health Ministers Meeting – 5 September, 2021.

Source: COVID Vaccines Will Not Reach Poorest Countries Until 2023, by T.V. Padma, Nature magazine, 6 July,

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

WHO Collaborating Center for Governance, University of Toronto and Transparency International, May 2021, For-Whose-Benefit-Transparency-International.pdf (ti-health.org)

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." 11 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 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".

<sup>8</sup> OHCHR Guidance on Access to COVID-19 vaccines, available at: <u>COVID-19 AccessVaccines Guidance.pdf</u> (ohchr.org), <u>December 2020</u>.

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

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

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

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) 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 [...]". 13 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."14

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 2020 the Rome Declaration. This Declaration underlined the urgent 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;

UN 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.

CESCR, Statement on universal and equitable access to vaccines for the coronavirus disease (COVID-19), 15 December 2020,E/C.12/2020/1 available at: https://www.ohchr.org/Documents/HRBodies/CESCR/E C 12 2020 2 AUV.docx.

CESCR, 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)

Doha WTO Ministerial Declaration: Declaration on the TRIPS agreement and public health, 14 November 2001.

Rome Declaration of leaders of G20 and other states, Global Health Summit in Rome, May 21, 2021.

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). 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 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, would like to inquire about the **results of WTO's recent negotiations and anticipated timeline** for the resolution of 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

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

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

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

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".

We would also welcome information related to advances made by member States of the WTO in using already existing national tools and mechanisms, such as the government use of compulsory licensing 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 to open more opportunities for dissemination to a larger number of the population.

We would equally appreciate information on requests received or/and discussions held within the WTO about the provision of technical assistance and support by WTO to States to find solutions at national level if the intellectual property rights on vaccines, medicines, health technologies and therapies would be eventually lifted at international level.

We would also like to inquire about accountability mechanisms available within the WTO for those Member States that might not act in good faith in the pandemic caused health crisis and undermine the right of people to get access to equitable, affordable, fair, safe, timely, and universal access to COVID-19 vaccines, medicines, health technologies and therapies. We would be grateful to learn more about the risks identified and the measures taken in this respect by the bodies of WTO.

Finally, we would like to enquire about regulations and policies of different bodies of WTO on full transparency in States' contracts with pharmaceutical companies purchasing vaccines, including all elements of vaccine development, procurement, and provision to support the efforts of States and companies domiciled on their territory to comply with international law and that their related responsibilities and that such compliance 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 your organisation 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 from your Organisation 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, to the European Commission, as well

as to pharmaceutical companies producing or developing COVID-19 vaccines.

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

Surya Deva

Chair-Rapporteur of the Working Group on the issue of human rights and transnational corporations and other business enterprises

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