

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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Dear Mr. Ella,

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 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 by Bharat Biotech International Ltd. related to the development and the distribution of COVID-19 vaccine Covaxin. We

Bharat Biotech International Ltd.

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 dose¹ compared with almost 50 per cent of fully vaccinated in high-income countries.² The WHO recently announced that even though more than 5 billion vaccines had been administered worldwide, progress has been highly uneven: almost 75 per cent of those doses have been administered in just 10 countries.³ According to a recent estimate of 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 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 It seems that many business actors remain publicly opposed to the WTO TRIPS waiver that could open new avenues for manufacturing, and/or allegedly lobbying Governments for opposing the waiver.

A WHO COVID-19 Technology Access Pool (C-TAP) was set up in May 2020 with the intention “to accelerate the development and manufacturing of products needed to fight COVID-19, including vaccines, and remove barriers to accessing these products.”⁷ The voluntary initiative of sharing know-how and data to facilitate technology transfer has not found effective and timely support among business actors, despite the fact that emerging virus variants may raise the possibility of the need for further vaccinations in the future and that numerous vaccines development efforts benefited from public money.

Moreover, we are concerned by **the lack of transparency in contracts between States and pharmaceutical companies including the limited publication**

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

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

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

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

⁵ 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

⁶ Idem.

⁷ WHO Director-General's opening remarks for panel “Is Africa ready to finance its own vaccine?” Conference of African Ministers of Finance, Planning and Economic Development. Economic Commission for Africa, 23 March 2021

of contracts worldwide, and significant redactions of key information of public interest in the few contracts that were published.⁸ 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 vaccines⁹ 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 countries¹⁰, and how this affects in particular those in vulnerable situation, who are frequently neglected in terms of health care.¹¹

Earlier this year, the Human Rights Council called for “equitable, affordable, timely, and universal access for all countries.”¹² 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 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 (...)”.

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 to the application of scientific progress necessary to enjoy the highest attainable standard

⁸ WHO Collaborating Center for Governance, University of Toronto and Transparency International, May 2021, [For-Whose-Benefit-Transparency-International.pdf \(ti-health.org\)](#)

⁹ OHCHR Guidance on Access to COVID-19 vaccines, available at: [COVID-19_AccessVaccines_Guidance.pdf \(ohchr.org\)](#)

¹⁰ [OHCHR | UN experts: G7 Governments must ensure vaccines' access in developing countries](#)

¹¹ A/HRC/47/28 para 101-104.

¹² 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>

of health; the Committee on Economic, Social and Cultural Rights (CESCR) adopted a specific general comment (No 25) and public statements on this issue.¹³ In the current context of the pandemic, the CESCR stated that unequal access to vaccines for least developed and developing countries is discriminatory and undermines progress on achieving the Sustainable Development Goals.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, intellectual property rights cannot become a barrier to the effective enjoyment of the human right to health.¹⁵

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 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’).¹⁶

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. In addition to that, all businesses have a responsibility to respect human rights, including pharmaceutical companies and others involved in the response to COVID-19. The Guiding Principles on Business and Human Rights require businesses to know and show that they have taken all reasonable measures to prevent and mitigate any human rights impacts from their COVID-19 responses. This means that companies should undertake human rights due diligence. In this context, due diligence would require that pharmaceutical companies make realistic assessments of harmful side effects of any drug, including Covaxin and mitigate these effects to the greatest extent possible before distributing the drug to the public.

Similarly, companies’ decisions regarding pricing and distribution must consider the adverse impacts such decisions will have on discriminatory access to vaccines, particularly for those individuals in situations of vulnerability and marginalisation. To the extent that such decisions might adversely impact the right to health, companies should take appropriate action to prevent and mitigate any harms, including through exerting leverage to influence the actions of other potentially responsible parties. The Guiding Principles clarify that the responsibility of businesses extends beyond the business’ own activities, either when contributing to adverse impacts caused by others, or when directly linked to their operations, products or

¹³ 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.

¹⁴ 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 \(undocs.org\)](https://undocs.org/E/C.12/2021/1-E/E.C.12/2021/1-Desktop)

¹⁵ 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.

services through adverse impacts caused by business relationships.¹⁷

We would also like to remind you of article 1 of the Declaration on the Right to Development adopted by the United Nations General Assembly¹⁸, 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. 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 all actors, including institutions, businesses and investors, who produce information about development projects should provide that information transparently (para 45).

In this context, we would like to inquire the views of Bharat Biotech International Ltd. on the **proposed temporary waiver of certain COVID-19 TRIPS protections and on how to ensure that legal protection for intellectual property and patents do not undermine the right of everyone to get access to a safe, timely and effective vaccine with a low-cost production and expanded supply.**

Please kindly provide information about the **human rights due diligence policies and processes** put in place by Bharat Biotech International Ltd. to identify, prevent, mitigate and remedy adverse human rights impacts of your company's activities throughout its operations, in line with the Guiding Principles on Business and Human Rights.

We would be also interested in knowing more about the steps taken by Bharat Biotech International Ltd. to support initiatives whose objective is to accelerate the scale-up of manufacturing and the removal of barriers to access in order to make products available globally by **participating in open and free sharing and transfer of know-how, scientific knowledge, technology, equipment, data, and material inputs for the prevention and treatment of COVID-19**, e.g. by joining the WHO COVID-19 Technology Access Pool (C-TAP) or/and by supporting the COVID-19 ACT-Accelerator, or/and by signing technology transfer agreements so that your company that owns a vaccine patent can license it to another company. Sharing know-how, scientific knowledge, technology, equipment, data, and material inputs is particularly important because emerging virus variants may raise the possibility of the need for further vaccinations in the future.

Finally, we would like to enquire about **policies of your company on full transparency on full transparency in its contracts with States purchasing vaccines, including all elements of vaccine development, procurement, and provision** to ensure that your company's business activities comply with international law and your company's related responsibilities can be effectively monitored and enforce, 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.

¹⁷ UN Working Group on the issue of human rights and transnational corporations and other business enterprises, Ensuring that business respects human rights during the Covid-19 crisis and beyond: The relevance of the UN Guiding Principles on Business and Human Rights, 28 April 2020, available at: <https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=25837&LangID=E>.

¹⁸ Declaration on the right to Development, adopted by General Assembly resolution 41/128 of 4 December 1986.

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 company 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 company 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 many other pharmaceutical companies producing or developing COVID-19 vaccines, Governments where pharmaceutical companies are domiciled or/and Governments that are influential in the decision-making process of the above presented issues, as well as to the World Trade Organisation and the European Commission.

Please accept, Mr. Ella, the assurances of our highest consideration.

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