



A DOUBLE DOSE OF INEQUALITY

PHARMA COMPANIES AND THE COVID-19 VACCINES CRISIS

AMNESTY
INTERNATIONAL



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Cover photo: A woman walks past the entrance of a vaccination centre that was shut due to Covid-19 coronavirus vaccine stock shortage in Mumbai on 9 July 2021. © PUNIT PARANIPE/AFP via Getty Images.

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EXECUTIVE SUMMARY

The rapid development of effective Covid-19 vaccines in 2020 gave hope to the world in the darkest days of the deadly pandemic. Ensuring vaccine access for as many people as quickly as possible is the most effective route out of this unprecedented health and human rights crisis. The handful of companies that developed these vaccines at record speeds could, and should, have been heroes, supplying doses fairly around the world and taking all necessary measures to ramp up production.

This report assesses what major western vaccine makers did instead, tracing their business decisions which favoured a small number of wealthier countries, while blocking other manufacturers from producing their own vaccines. This resulted in predictable – and artificial – vaccine scarcity for the rest of the world.

While Europe, the US and a handful of other states emerged from lockdown, enjoying vacations in the summer of 2021, parts of Africa, Asia and Latin America plunged into renewed crises, pushing ill-equipped health systems to the brink and causing tens of thousands of preventable deaths every week.

Of course, this is not only due to actions and omissions of the pharmaceutical industry. Rich states bought up the supply and hoarded doses. But the vaccine manufacturers have played a decisive role in limiting global vaccine production and obstructing fair access to a life-saving health product. Despite receiving billions of dollars in government funding and advance orders which effectively removed risks normally associated with the development of medicines, vaccine developers have monopolized intellectual property, blocked technology transfers, and lobbied aggressively against measures that would expand the global manufacturing of these vaccines. Some companies - Pfizer, BioNTech and Moderna - have so far delivered almost exclusively to rich countries, putting profit before access to health for all.

The path to a more rapid and fair vaccine roll-out is clear. The People's Vaccine Alliance, of which Amnesty International is a member, has outlined the steps needed for vaccines to be produced rapidly at scale and made available for all people, in all countries, free of charge. The World Health Organization has launched several initiatives to try to get states and companies to pool resources to speed up the production and fair distribution of Covid-19 vaccines. But a nexus of wealthy states and powerful corporations remain unwilling to cooperate in these initiatives, severely undermining their effectiveness.

EFFORTS TO POOL RESOURCES

The WHO and others have launched several initiatives to try to get states and companies to pool resources to speed up the fair distribution of Covid-19 vaccines, with only very limited success:

- **The COVAX Facility** functions as a global procurement and distribution mechanism through which available doses can be allocated to participating countries, regardless of income levels. It aimed to make 2 billion doses available by the end of 2021, but by the start of September had shipped only 243 million doses.
- The **WHO-led Covid-19 Technology Access Pool (C-TAP)**, was established to pool intellectual property, data and manufacturing processes, licensing the production to other manufacturers and facilitating technology transfer. To date not a single vaccine manufacturer has shared any patents or know-how through C-TAP.
- In April 2021, the WHO announced that it will also facilitate the establishment of hubs to transfer **mRNA-vaccine technology** and provide appropriate training to manufacturers in low- and middle-income countries. In June 2021, the WHO announced that the first hub will be established in South Africa.

THE CORPORATE RESPONSIBILITY TO RESPECT HUMAN RIGHTS

All businesses have a responsibility to respect human rights wherever they operate in the world. Above all, this responsibility means that companies should “do no harm”. If they discover that they are the cause of human rights abuses, then they must immediately stop their harmful actions and provide remedy.

This is a widely recognized standard of expected conduct as set out in the UN Guiding Principles on Business and Human Rights and the OECD Guidelines for Multinational Enterprises. The corporate responsibility to respect human rights is independent of a state’s own human rights obligations and exists over and above compliance with national laws and regulations protecting human rights.

For the vaccine developers, the responsibility to respect human rights means that they should develop and implement policies that aim to make quality Covid-19 vaccines available, accessible and affordable. They should ensure that they are not creating obstacles and refrain from any action that unduly impacts on states’ abilities to make Covid-19 vaccines available to all.

Amnesty International has assessed six of the companies that now largely hold the fate of billions of people around the world in their hands. They are: AstraZeneca plc, BioNTech SE, Johnson & Johnson, Moderna, Inc., Novavax, Inc. and Pfizer, Inc. These were the six largest vaccine developers by delivery agreements in doses according to the UNICEF’s COVID-19 Vaccine Market Dashboard in July 2021.

- AstraZeneca is a British-Swedish pharmaceutical company that is manufacturing and distributing the coronavirus vaccine developed by the University of Oxford.
- Johnson & Johnson is a multinational corporation headquartered in New Jersey, United States. Its 100% owned subsidiary, the Netherlands-based Janssen Vaccines & Prevention B.V., developed its viral vector Covid-19 vaccine, which is a one-shot vaccine.
- Moderna is a biotechnology company based in Cambridge, Massachusetts, in the USA.
- Novavax is a biotechnology company based in Maryland, USA. In contrast to the other vaccine developers assessed in this report, Novavax’s vaccine candidate has not yet gained regulatory approval for use.

- Pfizer is a US-based multinational pharmaceutical company headquartered in New York, which has partnered with vaccine developer, BioNTech, based in Mainz, Germany.

Drawing on the UN Guiding Principles on Business and Human Rights and other standards, Amnesty International assessed each company's published human rights policy, pricing structure, their records on intellectual property, knowledge and technology-sharing, the global allocation of available vaccine doses and transparency.

Amnesty International wrote to each company before publication. Five companies – AstraZeneca, BioNTech, Johnson & Johnson, Moderna and Pfizer – responded, along with institutional investors Baillie Gifford, BlackRock and UBS. Amnesty International reviewed the responses, which can be found in annex, and took appropriate account of information provided in updating its findings.

In addition, Amnesty International reviewed each company's published human rights policies, sustainability reports, annual reports, corporate filings and press releases, statements in the media and secondary sources related to the vaccine roll-out. Data on vaccine sales, supply commitments, manufacturing licensing agreements and distribution was drawn from Airfinity, a science information and analytics company, as well as the UNICEF and WHO Covid-19 dashboards and other secondary sources. Figures on global deaths and vaccinations are from Oxford University's Our World in Data.

This report does not assess in detail the Russian and Chinese companies that have successfully developed vaccines as there is a lack of transparency around their operations that makes it impossible to fully compare them to the others.

HUMAN RIGHTS POLICIES

AstraZeneca, Johnson & Johnson, Pfizer and BioNTech have published human rights policies that reference the UN Guiding Principles on Business and Human Rights. Moderna's human rights policy does not, while Novavax has published a statement referencing its commitment to equitable vaccine access but does not mention human rights. However, all companies have fallen short of their stated aspirations, in some instances with huge gulfs between rhetoric and reality.

FAIR PRICING

AstraZeneca and Johnson & Johnson have committed to producing vaccines on a not-for-profit basis for emergency pandemic use, although lack of transparency on actual costs of production and sources of external funding make these commitments difficult to fully assess. Their prices are, however, at the lower end of the industry spectrum. In contrast, Pfizer/BioNTech and Moderna have charged higher prices for their vaccines, making significant profit. According to the projections from Airfinity, the three companies' predicted 2021-22 revenue from sales of Covid-19 vaccines totals over US\$130 billion. Novavax has not yet begun its vaccine roll-out, so it is not possible to assess its pricing policy.

INTELLECTUAL PROPERTY AND TECHNOLOGY SHARING

All companies assessed have so far refused to participate in internationally coordinated initiatives designed to boost global supply by sharing technology such as C-TAP, and Covid-19 mRNA hubs. All have also opposed proposals to relax intellectual property rules, such as those put forward by India and South Africa to the WTO Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS). None of the companies have issued global, non-exclusive licences to other companies. Johnson & Johnson sees itself as having "an opportunity to positively impact the protection of human rights within our sphere of influence." But since February 2021 the company has refused to provide a licence to, or

share technology with, Canadian company Biolyse. This company had estimated that it could produce up to 20 million doses of Covid-19 vaccines per year and pledged to supply Bolivia with the first 15 million, which could inoculate the country's entire adult population. Following this refusal, Biolyse applied for a compulsory licence, yet the Canadian government has not yet responded, and Covid-19 vaccines have still not been added to the list of health products eligible for compulsory licences. In contrast, AstraZeneca has stated that it has shared its technology and knowledge with over 20 supply partners across 15 countries, including four regional sublicensing agreements in Brazil, China, India and Russia.

GLOBAL VACCINE ALLOCATION

Pfizer has said that “fair and equitable distribution was our North Star from day one”; BioNTech has said that it aims to make its vaccines “available worldwide as quickly as possible”; and Moderna has committed to “provide effective and affordable vaccines and therapeutics to all populations”. Yet Pfizer/BioNTech and Moderna have allocated almost all of their vaccines so far delivered to higher income countries. At the beginning of September, 98% of Pfizer/BioNTech deliveries have been allocated to high and upper-middle-income countries. This is also the case for 88% of Moderna's deliveries to date.

For Johnson & Johnson, 79% of its deliveries to date have been to high- and upper-middle-income countries, though planned deliveries to COVAX and the African Union means that its orders for the year are more balanced at 53%, if it meets its commitments. In contrast, for AstraZeneca some 34% of its deliveries went to high- and upper-middle-income countries.

Pfizer/BioNTech and Moderna have so far delivered small percentages of their current production into the COVAX Facility. Most doses currently pledged will only be delivered in 2022 – well after many poorer regions have been wracked by further deadly Covid-19 outbreaks. Just 3.4% of Moderna's 2021 production and 8% of Pfizer/BioNTech's is due to go COVAX. Novavax has taken a more responsible approach, with over 60% of their agreed sales to date allocated to COVAX.

TRANSPARENCY

One of the major obstacles to ensuring fair access to Covid-19 vaccines is lack of transparency, which makes contracts, pricing, technology and knowledge transfer impossible to accurately map and optimize. Yet no company assessed has fully disclosed the actual costs of production, individual cost items, sources of external funding, prices charged in different countries, contractual terms and conditions, or information about discounting, donations and advance order guarantees.

OVERALL ASSESSMENT

While the vaccine developers claim to respect human rights, all of them - to differing degrees – have failed to meet their responsibilities. Through their actions and omissions, they have ended up causing or contributing to human rights harms suffered by billions of people lacking access to the Covid-19 vaccine. Companies have caused human rights harms through their decisions not to share intellectual property and technology and contributed to violations of the rights to life and health by repeatedly selling most of their scarce stock to wealthier countries, often at significant profit.

Pfizer/BioNTech and Moderna have charged high prices for their vaccines and allocated almost all of vaccines so far delivered (as opposed to pledged) to high-income countries, putting profits before access to essential medicines. Despite the huge potential of Johnson & Johnson's single-dose vaccine for reaching poorer parts of the world, the company has been slow to move beyond high- and upper-income markets, and has actively obstructed efforts to license its technology. If Novavax is able to

follow through on its significant commitments to supply COVAX, this would be a major boost to the scheme and support fair access to essential medicines. While AstraZeneca should be recognized for its approach to the crisis, the scale of the global health emergency requires much greater action from all of the vaccine producers, including AstraZeneca itself, which has opposed measures to share intellectual property, technology and know-how.

Writing in November 2020, a group of UN human rights experts warned that “industry and private benefit cannot be prioritized over the rights to life and health of billions,” and that business enterprises “should refrain from causing or contributing to adverse impacts on the rights to life and health by invoking their intellectual property rights and prioritizing economic gains.” Regrettably, those words have not been heeded.

THE TOP TEN INSTITUTIONAL INVESTORS

Institutional investors in vaccine manufacturers also have human rights responsibilities. For this report, Amnesty International has identified the ten largest of these - mainly US-based asset managers and banks - which have combined holdings worth more than US\$250 billion in the vaccine developers. The single largest is Vanguard Group Inc. which holds shares worth a total of more than US\$66 billion in AstraZeneca, Johnson & Johnson, Moderna, Novavax and Pfizer. BlackRock Inc has more than US\$62 billion invested in all six featured companies.

These investors and asset managers must assess the extent to which these companies are causing or contributing to human rights harm through their approach to the crisis. Having identified adverse impacts, they should then engage with these companies and exert their leverage to mitigate the impacts.

In the context of the Covid-19 vaccines, the leverage that this small group of institutional investors has is significant. While none of the top ten institutional investors own or manage more than 10% in any one company, the size of their joint holdings, as well as their total portfolios across the whole sector, give them a significant role in the vaccine developers. Combined, for instance, they own and manage 23.5% of AstraZeneca’s shares, 27.9% of Johnson & Johnson’s, 24.7% of Moderna’s, 17.4% of Novavax’s, and 32.7% of Pfizer’s.

Some investors have recognized, at least partially, the need for them to try to influence the vaccine makers. Almost 150 institutional investors joined a public call in February 2021 for pharma companies to support “a fair and equitable global response to the pandemic”. While in communications with Amnesty International Baillie Gifford, BlackRock and UBS recognized their human rights responsibilities in relation to the pharmaceutical industry, none of the top ten institutional investors or asset managers were among the signatories.

CONCLUSION AND KEY RECOMMENDATIONS

The starkly unequal distribution of Covid-19 vaccines around the globe indicates that states have not taken the necessary steps to ensure that Covid-19 vaccines are available, accessible, affordable and of good quality for everyone without discrimination, in line with their international human rights obligations.

Rather than take concrete measures to ensure global access to Covid-19 vaccines, states with the power to do so have largely left these decisions around availability, accessibility and affordability in the hands of businesses. As this report demonstrates, the failure of businesses to take all steps at their disposal to achieve fair global access to Covid-19 vaccines means that these companies have fallen short of their human rights responsibilities and in so doing have caused and contributed to human rights harms.

To achieve a fair, rapid roll-out, vaccine developers must suspend their intellectual property rights by either issuing global, open and non-exclusive licences or by participating in C-TAP. They must share their knowledge and technology and train qualified manufacturers committed to contribute to the ramp-up of the production of Covid-19 vaccines. They should not seek to use their influence over governments to obstruct measures designed to facilitate intellectual property and technology sharing, such as the proposed World Trade Organization TRIPS waiver.

With regards to fair pricing policies, companies must not put their economic interests before their human rights responsibilities. Profit must not become an obstacle to states' capacity to ensure access to the vaccine. All companies must prioritize increasing availability of vaccines in less wealthy regions and countries by devoting a significant share of their 2021 production runs to the COVAX Facility, as well as other initiatives providing vaccines to lower-income countries such as those coordinated by the African Union, and sustaining high levels of deliveries into these mechanism throughout 2022. Transparency across all aspects of vaccine development and delivery is vital for optimizing supply and ensuring fair vaccine allocation.

As market-driven models alone are unlikely to deliver essential medicines in line with international human rights standards, stronger laws and regulations - especially around accessibility and affordability – are needed for states and companies to deliver on their human rights obligations and responsibilities.

100-DAYS COUNTDOWN

In July, a task force set up by the leaders of the WHO, WTO, IMF and World Bank set a target to vaccinate 40% of people in low and lower-middle income countries by the end of 2021, to protect them and others from Covid-19. With 100 days until the end of the year, less than 10% of people in these countries are fully vaccinated, and tens of thousands of people are dying each week.

As the world reaches a critical phase of the pandemic, Amnesty International is launching a campaign calling on states and pharmaceutical companies to deliver 2 billion vaccines to 82 low- and lower-middle income countries over the next 100 days, in order to fully vaccinate an additional 1.2 billion people. To reach this goal, companies and states need to adopt a radically different approach to vaccine allocation: companies must distribute 50% of their production to low- and lower-middle income countries, preferably through the COVAX Facility or other multilateral initiatives; states must urgently redistribute hundreds of millions of surplus vaccines currently in their stocks. Only through concerted, coordinated actions will states and companies be able to bridge the gap.

METHODOLOGY

In response to the Covid-19 pandemic, Amnesty International launched a global campaign calling on states and companies to uphold the right to health of millions of people by taking measures to increase the supply and affordability of Covid-19 vaccines, diagnostics and treatments, and to ensure that everyone, everywhere, without discrimination, can benefit from the global efforts against Covid-19.¹ In 2020, Amnesty International published a policy briefing, *A Fair Shot, Ensuring Universal Access to Covid-19 Diagnostics, Treatments and Vaccines*, outlining state obligations and business responsibilities in relation to access to Covid-19 diagnostics, treatments, and vaccines.²

This report focuses on the extent to which leading Covid-19 vaccine developers are meeting their responsibility to respect human rights. Amnesty International selected the six largest vaccine developers by delivery agreements in doses according to the UNICEF's COVID-19 Vaccine Market Dashboard as of 20 July 2021.³ These are: AstraZeneca plc (AstraZeneca), BioNTech Manufacturing GmbH (BioNTech), Johnson & Johnson (owner of Janssen Pharmaceutical Companies), Moderna, Inc. (Moderna), Novavax, Inc. (Novavax), and Pfizer, Inc. (Pfizer).⁴ Amnesty International wrote to each company, asking them a series of questions related to intellectual property, sharing of technology and know-how, pricing and vaccine allocation. At the time of writing AstraZeneca, Moderna, and Pfizer have replied. The substance of their responses has been incorporated into the report. Full replies can be found in Annex 2.

Amnesty International reviewed each company's response, their published human rights policies, sustainability reports, annual reports, U.S. Securities and Exchange Commission (SEC) filings, corporate press releases, statements in the media and secondary sources related to the vaccine roll-out.⁵ Drawing on the UN Guiding Principles on Business and Human Rights (UN Guiding Principles) and other standards, Amnesty International assessed each company's human rights policy, vaccine pricing structure, their records on intellectual property and technology-sharing, the fair allocation of available vaccine doses and transparency. Amnesty International also identified the ten largest

1. Amnesty International has also joined the People's Vaccine Alliance, a worldwide movement campaigning for vaccines to be produced rapidly at scale and made available for all people, in all countries, free of charge. The People's Vaccine, peoplesvaccine.org/

2. Amnesty International, *A Fair Shot: Ensuring Universal Access to Covid-19 Diagnostics, Treatments and Vaccines* (Index: POL 30/3409/2020), 8 December 2020, www.amnesty.org/en/documents/pol30/3409/2020/en/

3. UNICEF COVID-19 Vaccine Market Dashboard, Covid-19 vaccine supply agreements (by vaccine supplier) as of 20 July 2021, www.unicef.org/supply/covid-19-vaccine-market-dashboard

4. The six largest vaccine developers by delivery agreements in doses according to the UNICEF COVID-19 Vaccine Market Dashboard as of 20 July 2021.

5. See in particular Oxfam, *A shot at recovery*, 22 April 2020, oi-files-d8-prod.s3.eu-west-2.amazonaws.com/s3fs-public/2021-04/A%20Shot%20at%20Recovery%20April%202021%20Update_0.pdf; Human Rights Watch, *Universal and Equitable Access to Covid-19 Vaccines, Testing, Treatments: Companies' Human Rights Responsibilities: Questions and Answers*, www.hrw.org/news/2021/02/11/universal-and-equitable-access-covid-19-vaccines-testing-treatments-companies-human; Médecins sans frontières, *WTO COVID-19 TRIPS Waiver Proposal: Myths, realities and an opportunity for governments to protect access to medical tools in a pandemic*, msfaccess.org/wto-covid-19-trips-waiver-proposal-myths-realities-and-opportunity-governments-protect-access

investors in these companies and outlined their human rights responsibilities under the UN Guiding Principles. Information on investor shareholdings is drawn from Bloomberg.

Data on vaccine sales, supply commitments, manufacturing licensing agreements and distribution was drawn from Airfinity, the UNICEF and World Health Organisation COVID-19 dashboards, Knowledge Portal and The Duke Global Health Center's The Launch and Scale Speedometer and other secondary sources. Figures on global deaths and vaccinations are from Oxford University's Our World in Data.⁶

Prior to publication, Amnesty International contacted the companies assessed in this report for a second time, along with the top ten institutional investors and asset managers, outlining its main findings and inviting responses. AstraZeneca, BioNTech, Johnson & Johnson, Pfizer, Baillie Gifford, BlackRock and UBS responded.

Amnesty International reviewed the responses, which can be found in annex and took appropriate account of information provided in updating its findings.

This report does not assess in detail the Russian and Chinese companies that have successfully developed vaccines and are currently manufacturing them, as unlike their US, UK and EU-based counterparts, these companies disclose less corporate information. This lack of transparency makes it impossible to fully compare them to the others.

6. UNICEF, COVID-19 Market Dash Board, www.unicef.org/supply/covid-19-vaccine-market-dashboard; WHO, Coronavirus Dashboard, covid19.who.int/; Graduate Institute, Geneva, Knowledge Portal, www.knowledgeportalia.org/covid-19; Duke Global Health Center, The Launch and Scale Speedometer, launchandscalefaster.org/COVID-19; Our World in Data: Coronavirus (COVID-19) Vaccinations, ourworldindata.org/covid-vaccinations

1. HUMAN RIGHTS AND ACCESS TO COVID-19 VACCINES

“Industry and private benefit cannot be prioritized over the rights to life and health of billions.”

UN Human Rights Experts, 9 November 2020⁷

1.1 BACKGROUND

Just weeks after the sequencing of the coronavirus genome was published in January 2020, the pharmaceutical industry and research institutes began developing candidate vaccines.⁸ Moving at unprecedented speed, they ran large-scale clinical trials and manufacturing in parallel throughout 2020.⁹

In the EU, UK and USA, this immense undertaking was bankrolled by billions of dollars of public funding and advance purchase agreements.¹⁰ For example, the US government’s funding of the development, clinical trials, manufacturing and purchase of Moderna’s vaccine was approximately US\$5.75 billion. A further US\$1.4 billion funded the development of the Janssen/Johnson & Johnson vaccine.¹¹ Ninety-seven percent of funding for the Oxford-AstraZeneca vaccine and its underlying technology came from government and charitable institutions with the UK government providing US\$96.7 million.¹² The Pfizer/BioNTech vaccine benefited from US\$443 million in funding from the

7. OHCHR, “Statement by UN Human Rights Experts Universal access to vaccines is essential for prevention and containment of COVID-19 around the world”, November 2020, www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26484&LangID=E

8. Nature, “SARS-CoV-2 vaccines in development”, 23 September 2020, www.nature.com/articles/s41586-020-2798-3

9. In one case, just 248 days after Pfizer announced plans to collaborate with BioNTech, the company submitted to the US Food and Drug Administration (FDA) for emergency use authorization, see Edited Transcript PFE.N - Q4 2020 Pfizer Inc Earnings Call, 2 February 2021, s21.q4cdn.com/317678438/files/doc_financials/2020/q4/PFE-USQ_Transcript_2021-02-02.pdf

10. See breakdown in Knowledge Portal, COVID-19 Vaccine R&D Investments, www.knowledgeportalia.org/covid19-r-d-funding

11. U.S. Department of Health & Human Service, “Biden Administration purchases additional doses of COVID-19 vaccines from Pfizer and Moderna”, 11 February 2021, www.hhs.gov/about/news/2021/02/11/biden-administration-purchases-additional-doses-covid-19-vaccines-from-pfizer-and-moderna.html; US DoD, “HHS, DOD Collaborate With Johnson & Johnson to Produce Millions of COVID-19 Investigational Vaccine Doses”, 5 August 2020, www.defense.gov/Newsroom/Releases/Release/Article/2301220/hhs-dod-collaborate-with-johnson-johnson-to-produce-millions-of-covid-19-invest/

12. Cross et al, “Who funded the research behind the Oxford-AstraZeneca COVID-19 vaccine? Approximating the funding to the University of Oxford for the research and development of the ChAdOx vaccine technology”, 10 April 2021, preprint, MedRxiv, doi.org/10.1101/2021.04.08.21255103

German government and US\$17.3 billion in advance purchase agreements from the EU and the USA.¹³ Despite this massive support, these states did not place broader conditions on pharmaceutical companies to ensure they shared their innovations, technology and data with other manufacturers or pursued policies that would ensure a fair vaccine roll-out, in line with their human rights responsibilities. This left vital decision-making on vaccine production, pricing and allocation to the companies themselves.

As the roll-out proceeds, the diligence and innovation that produced Covid-19 vaccines has been lacking in dose allocation. These vaccines are key for the protection of millions of lives.¹⁴ But their delivery has been massively skewed towards wealthy nations – which received doses in far greater quantities and at a much faster rate than poorer ones. For example, as of 6 September 2021, vaccine developers (including those in China and Russia which are not assessed in this report), delivered 71% percent of doses to upper-middle or high-income countries.¹⁵ When in June 2021 world leaders at the G7 summit discussed the state of the Covid-19 vaccine roll-out, the English county of Cornwall, where the G7 Summit took place, and which has a population of just over half a million, had administered more vaccinations than 22 African countries combined.¹⁶

By September 2021, the World Health Organization (WHO) had officially recorded over 4.5 million Covid-19-related deaths,¹⁷ but the true figure is likely to be much higher. On 15 May 2021, The Economist published modelling which factored in excess death data, suggesting that 10 million or more may have died from Covid-19, with most of the uncounted deaths in low- or middle-income countries.¹⁸

“Billions of people in the Global South are being left behind. They see vaccines as a mirage or a privilege for the developed world,” a group of UN experts said on the eve of the June 2021 G7 summit. “This situation will unnecessarily prolong the crisis, drastically increase the death toll and deepen economic distress, possibly sowing the seeds of social unrest.”¹⁹

13. The Lancet, “Data on public and non-profit funding for the research, development, and production of COVID-19 vaccines”, p. 8, “BioNTech to Receive up to €375M in Funding from German Federal Ministry of Education and Research to Support COVID-19 Vaccine Program BNT162”, September 15, 2020, investors.biontech.de/news-releases/news-release-details/biontech-receive-eu375m-fundinggerman-federal-ministry; Knowledge Portal, COVID-19 Vaccine R&D Investments, Figure 3.2. Vaccine R&D Funding Flow: Advanced purchase agreements, www.knowledgeportal.org/covid19-r-d-funding

14. WHO, *Coronavirus disease (COVID-19)*, [www.who.int/news-room/q-a-detail/coronavirus-disease-\(covid-19\)-vaccines](https://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccines).

15. New York Times, Covid-19 Vaccinations Tracker (accessed on 9 August 2021), www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html

16. Amnesty International, “G7 support for pharma monopolies is putting millions of lives at risk”, 10 June 2021, www.amnesty.org/en/latest/news/2021/06/g7-support-for-pharma-monopolies-putting-millions-of-lives-at-risk/

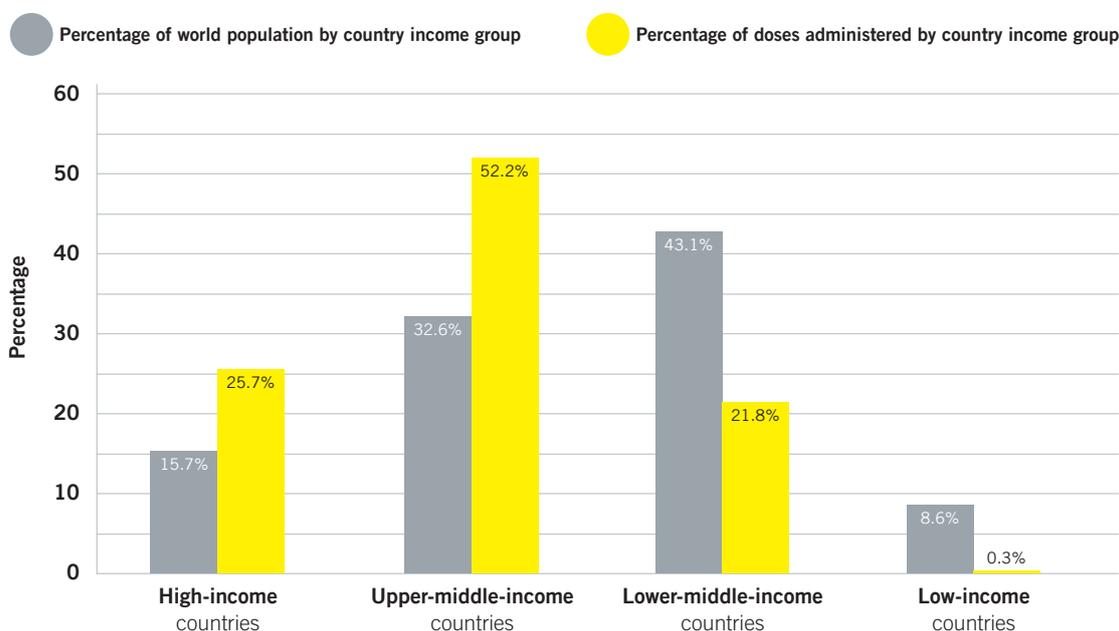
17. On 8 September 2021, the WHO reported 221,648,869 confirmed cases of Covid-19, including 4,582,338 deaths, see WHO, Coronavirus (COVID-19) Dashboard, covid19.who.int/

18. The Economist, “Ten million reasons to vaccinate the world”, 15 May 2021, www.economist.com/leaders/2021/05/15/ten-million-reasons-to-vaccinate-the-world

19. OHCHR, “UN experts: G7 Governments must ensure vaccines’access in developing countries”, 9 June 2021, www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=27156&LangID=E

FIGURE 1: VACCINE ALLOCATION BY COUNTRY INCOME GROUP

Comparison of percentage of Covid-19 vaccine doses administered by world population with doses administered by country income group



Source: World Bank Open Data (Share of world population, Data of 2020) and Our World in Data (percentage of Covid-19 doses administered, 10 September 2021)

POOLING RESOURCES FOR DOSE DISTRIBUTION AND INCREASED MANUFACTURING CAPACITY

The WHO and others have launched several initiatives to try to get states and companies to pool resources to speed up the fair distribution of COVID-19 vaccines, with only very limited success:

- In April 2020, Gavi, the Vaccine Alliance, which includes the WHO, launched the “Access to COVID-19 Tools Accelerator” to facilitate access to Covid-19 health products around the world.²⁰ One of its pillars, **the Covid-19 Vaccines Global Access (COVAX) Facility**, functions as a global procurement and distribution mechanism through which available doses can be allocated to participating countries, regardless of income levels, at the same rate, proportional to their total population size.²¹ Gavi stated in September 2021 that the COVAX Facility, which originally aimed to make more than two billion doses available by the end of 2021,²² had shipped 243 million

20. WHO, “What is the is the ACT-Accelerator”, www.who.int/initiatives/act-accelerator/about; the participating organizations are: the World Health Organization (WHO), the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance, the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), Unitaaid, the Foundation for Innovative New Diagnostics (FIND), the Wellcome Trust, the World Bank Group and the Bill & Melinda Gates Foundation.

21. Gavi, “COVAX explained” (accessed on 31 August 2021), www.gavi.org/vaccineswork/covax-explained

22. In January 2021, Gavi announced that up to 2.3 billion doses of Covid-19 vaccines could be delivered through the COVAX Facility by end of 2021. In the Global Supply Forecast of July 2021, expectations had shrunk to 1.9 billion. On 8 September 2021, the Global Supply Forecast was again adapted to 1.4 billion doses by end of the year. See also Gavi, “COVAX Supply Forecast reveals where and when COVID-19 vaccines will be delivered”, [COVAX Supply Forecast reveals where and when COVID-19 vaccines will be delivered | Gavi, the Vaccine Alliance](https://www.gavi.org/vaccineswork/what-does-covax-latest-supply-forecast-tell-us); WHO, COVAX Global Supply Forecast, 12 July 2021, www.gavi.org/vaccineswork/what-does-covax-latest-supply-forecast-tell-us, accessed 8 September 2021, p. 3; Gavi, “Global Supply Forecast” 8 September 2021, Presentation title (Arial 40 pt, bold top-aligned) (gavi.org).

vaccines for delivery and expected to deliver a further 1.1 billion vaccines by end of 2021.²³ The **WHO-led COVID-19 Technology Access Pool (C-TAP)**, proposed by Costa Rica, was established in May 2020 to promote open science to accelerate the development of Covid-19 health products and facilitate access to the resulting health technologies.²⁴ It aims to do this by pooling intellectual property, data and manufacturing processes, licensing production to other manufacturers and facilitating technology transfer. C-TAP aims to maximise supply and lower the costs, thereby increasing availability and affordability of Covid-19 diagnostics, treatments, and vaccines. However, C-TAP has not got off the ground in any meaningful way. To date only 43 countries have officially expressed support for C-TAP and not a single vaccine manufacturer has shared any patents or know-how through C-TAP.²⁵

- In April 2021, the WHO announced that it will also facilitate the establishment of hubs to transfer **mRNA-vaccine technology** and provide appropriate training to manufacturers in low- and middle-income countries. The objective is to produce, export and distribute the Covid-19 vaccine in low- and middle-income countries (LMICs), including through the COVAX Facility. The initiative focuses on mRNA technology due to its adaptability to variants of the virus, its efficacy and because many of its technical features are free of intellectual property rights in many countries of the world. For the technology transfer, it will be essential that the technology is either free of intellectual property constraints in LMICs, or that such rights are made available through non-exclusive licences.²⁶ In June 2021, the WHO announced that the first hub will be established in South Africa.²⁷ To date, none of the vaccine developers whose vaccine is based on the mRNA technology has committed to transfer technology through this hub.

1.2 STATE OBLIGATIONS: THE RIGHT TO HEALTH

Every human being is entitled to the enjoyment of the right to health. States have an obligation to ensure that health facilities, goods, and services, including medicines, are available, accessible, acceptable and of good quality - to everyone, without discrimination, irrespective of where they live or their income.²⁸

Access to a Covid-19 vaccine that is safe and effective is an essential element of the right of everyone to the highest attainable standard of physical and mental health.²⁹ States therefore have an obligation “to take all the necessary measures, as a matter of priority and to the maximum of their available resources, to guarantee all persons access to vaccines against Covid-19, without any discrimination.”³⁰

23. Gavi, COVAX vaccine roll-out, www.gavi.org/covax-facility#what, accessed 7 September 2021

24. WHO, “COVID-19 Technology Access Pool” (accessed on 31 August 2021), www.who.int/initiatives/covid-19-technology-access-pool

25. WHO, “Endorsements of the Solidarity Call to Action” (accessed on 31 August 2021), www.who.int/initiatives/covid-19-technology-access-pool/endorsements-of-the-solidarity-call-to-action

26. WHO, “Establishment of a COVID-19 mRNA vaccine technology transfer hub to scale up global manufacturing”, 16 April 2021, www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub-to-scale-up-global-manufacturing

27. WHO, “WHO supporting South African Consortium to establish first COVID mRNA vaccine technology transfer hub”, 21 June 2021, www.who.int/news/item/21-06-2021-who-supporting-south-african-consortium-to-establish-first-covid-mrna-vaccine-technology-transfer-hub

28. CESCR General Comment No. 14, para 12; OHCHR, Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, A/63/263, 11 August 2009, www.ohchr.org/documents/issues/health/guidelinesforpharmaceuticalcompanies.doc; For more detail on the state obligation in relation to the right to health, please see Amnesty International, *A Fair Shot: ensuring universal access to Covid-19 diagnostics, treatments and vaccines*, (Index: POL 30/3409/2020), 8 December 2020, www.amnesty.org/download/Documents/POL3034092020ENGLISH.PDF

29. CESCR, *Statement on universal affordable vaccination against coronavirus disease (COVID-19), international cooperation and intellectual property*, 23 April 2021, para 3; Amnesty International, *A Fair Shot: ensuring universal access to Covid-19 diagnostics, treatments and vaccines*, (Index: POL 30/3409/2020), 8 December 2020, www.amnesty.org/download/Documents/POL3034092020ENGLISH.PDF

30. CESCR, *Statement on universal affordable vaccination against coronavirus disease (COVID-19), international cooperation and intellectual property*, 23 April 2021, para 3, docstore.ohchr.org/SelfServices/FilesHandler.ashx?enc=4slQ6QSmIBEDzFEovLCuW1AVC1NkPs

While states should use the maximum of their available resources to secure the right to health,³¹ those that are unable to do so must request international cooperation. States in a position to provide technical or financial assistance must cooperate internationally and provide financial and technical support if needed to uphold the right to health, especially in the face of the global spread of disease.³² 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 a health crisis and promote economic recovery globally.³³ Transparency and accountability are key principles underpinning state obligations to uphold the right to health, and are particularly relevant in relation to decision-making, communication with stakeholders and access to remedy.³⁴

Furthermore, states have the obligation to protect against human rights abuse by third parties, including businesses.³⁵ To do so, states must take “appropriate steps to prevent, investigate, punish and redress such abuse through effective policies, legislation, regulations and adjudication.”³⁶ This obligation extends extraterritorially where states can control or influence the conduct of corporations within their territory or under their jurisdiction. In the context of the right to health, states should adopt legislation or other measures to ensure that private actors, including companies, conform with human rights standards when providing health care or other services.³⁷ States must therefore ensure that vaccine developers’ operations extend access to Covid-19 vaccines and do not impede their own and other states’ ability to ensure access for all.



Garment workers wait in a queue to receive a dose of the Moderna vaccine against the Covid-19 coronavirus in Konabari, about 40 km from Dhaka, Bangladesh, 18 July 2021. © MUNIR UZ ZAMAN/AFP via Getty Images

gUedPIF1vfPMKseJUC1Ci6FclakFK95v85g4Ik7k7QB18EdfqmCITMrvi1V0r1IHIOeN189AlrQBOR2hKpuBKCvHETplGUieZd

31. CESCR, General Comment 25, para 47.

32. WHO, International Health Regulations (2005) Third Edition, 1 January 2016, www.who.int/publications/i/item/9789241580496

33. 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.

34. Amnesty International, *A Fair Shot: ensuring universal access to Covid-19 diagnostics, treatments and vaccines*, (Index: POL 30/3409/2020), 8 December 2020, p. 10 www.amnesty.org/download/Documents/POL3034092020ENGLISH.PDF

35. UN Guiding Principles on Business and Human Rights (UN Guiding Principles), Principle 1.

36. UN Guiding Principles, Principle 1.

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

1.3 VACCINE DEVELOPERS' RESPONSIBILITIES: ACCESS TO VACCINES

Companies, including pharmaceutical companies, have a responsibility to respect all human rights wherever they operate in the world and throughout their operations. This is a widely recognized standard of expected conduct as set out in international business and human rights standards including the UN Guiding Principles on Business and Human Rights (UN Guiding Principles) and the OECD Guidelines for Multinational Enterprises (OECD Guidelines).³⁸ This corporate responsibility to respect human rights is independent of a state's own human rights obligations and exists over and above compliance with national laws and regulations protecting human rights.³⁹

The responsibility to respect human rights requires companies to avoid causing or contributing to human rights abuses through their own business activities, and address impacts in which they are involved, including by remediating any actual abuses. It also requires companies to seek to prevent or mitigate adverse human rights impacts directly linked to their operations, products or services by their business relationships, even if they have not contributed to those impacts.⁴⁰

The UN Guiding Principles establish that to meet their corporate responsibility to respect, companies should have in place an ongoing and proactive human rights due diligence process to identify, prevent, mitigate and account for how they address their impacts on human rights. When conducting human rights due diligence, a company may identify that it may cause or contribute to – or already be causing or contributing to – a serious human rights abuse. In these cases, companies must cease or prevent the adverse human rights impacts.⁴¹ Where impacts are outside of the business enterprise's control but are directly linked to their operations, products or services through their business relationships, the UN Guiding Principles require the company to seek to mitigate the human rights impact by exercising leverage, or seek to improve leverage where leverage is limited, including through collaboration if appropriate.

For pharmaceutical companies developing and manufacturing vaccines in the context of the global health crisis, this means that all decisions and actions related to the vaccine roll-out should be rigorously assessed through proactive, ongoing human rights due diligence. Vaccine manufacturers should directly address gaps in policy and practice by developing and implementing policies that aim to make Covid-19 vaccines available, accessible, and affordable. They should remove all obstacles and refrain from any action that unduly impacts on states' ability to make Covid-19 vaccines available to all. Failures to take the steps needed to ensure fair and comprehensive vaccine roll-out may result in companies causing or contributing to human rights harms.

Further guidance for vaccine developers was provided in the UN Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines (the Human Rights Guidelines for Pharmaceutical Companies) in 2008.⁴² These state that businesses have a "human rights responsibility

38. This responsibility was expressly recognized by the UN Human Rights Council on 16 June 2011, when it endorsed the UN Guiding Principles on Business and Human Rights, 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. See *Human Rights and Transnational Corporations and other Business Enterprises*, Human Rights Council, Resolution 17/4, UN Doc A/HRC/RES/17/4, 6 July 2011; *OECD Guidelines for Multinational Enterprises*, OECD, 2011, www.oecd.org/corporate/mne.

39. UN Guiding Principles, Principle 11 including Commentary.

40. UN Guiding Principles, Principles 11 and 13 including Commentary.

41. UN Guiding Principles, Principle 19 including Commentary.

42. OHCHR, Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines (Human Rights Guidelines for Pharmaceutical Companies), A/63/263, 11 August 2008, www.ohchr.org/documents/issues/health/guidelinesforpharmaceuticalcompanies.doc

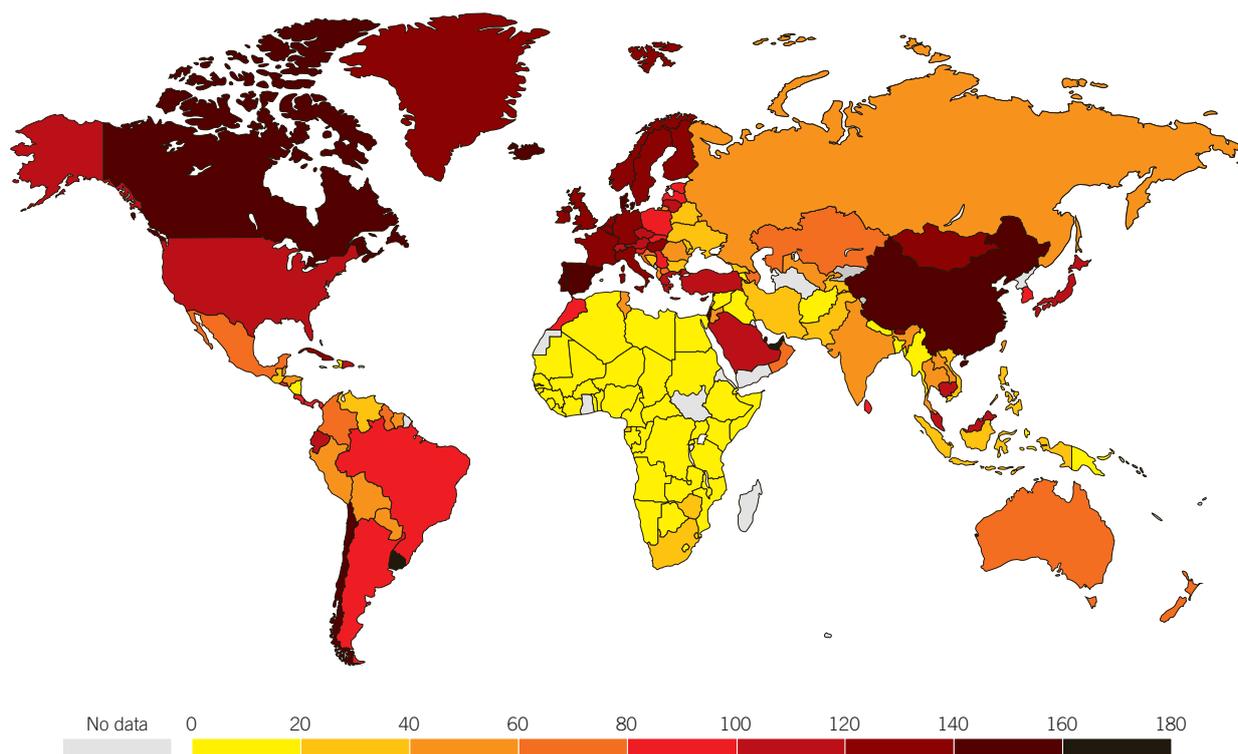
to extend access to medicines for all including disadvantaged individuals, communities and populations”.⁴³ Vaccine developers should develop and implement policy on access to medicines, considering all arrangements at their disposal to ensure that these are affordable to as many people as possible. The Human Rights Guidelines for Pharmaceutical Companies specify 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.⁴⁴ In line with these considerations, the Human Rights Guidelines for Pharmaceutical Companies recommend “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.”⁴⁵

FIGURE 2: VACCINATION RATE - WORLD MAP



Covid-19 vaccines doses administered per 100 people

For vaccines that require multiple doses, each individual dose is counted. As the same person may receive more than one dose, the number of doses per 100 people can be higher than 100.



Source: Our World in Data (2 September 2021)

43. OHCHR, Human Rights Guidelines for Pharmaceutical Companies, Guideline 38.

44. OHCHR, Human Rights Guidelines for Pharmaceutical Companies, Guidelines 5, 30 and 33.

45. OHCHR, Human Rights Guidelines for Pharmaceutical Companies, Guideline 33.

1.4 HOW STATES AND COMPANIES HAVE FAILED

As of September 2021, Covid-19 has led to over 4.5 million deaths and 220 million cases worldwide.⁴⁶ While the world faces the spread of variants and 270 million people are expected to face life-threatening food shortages throughout 2021 - an 80% increase from before the pandemic - the unequal global roll-out of Covid-19 vaccines is a stark reminder of how this pandemic has magnified inequalities especially for marginalized populations in lower income countries.⁴⁷ Countries with wide access to vaccines, such as the UK and the USA, have been able to lift restrictions sooner while countries that have limited to no access to Covid-19 vaccines have faced increasingly severe outbreaks of cases. For example, from April to July 2021, Nepal faced one of the most severe outbreaks along with a shortage of oxygen and vaccines. As of July, Nepal had only fully vaccinated less than three percent of its population, while some wealthy countries enjoyed over 50% vaccination coverage.⁴⁸

This starkly unequal distribution of Covid-19 vaccines around the globe indicates that states have not taken the necessary steps to ensure that Covid-19 vaccines are available, accessible, affordable, and of good quality for everyone without discrimination, in line with its international human rights obligations.⁴⁹ Moreover, the United Nations Committee on Economic Social and Cultural Rights has established that these obligations extend extraterritorially. This means that states must provide financial and technical support to uphold the right to health, especially in the face of the international spread of disease. Such measures could include the sharing of research, knowledge, medical equipment, and supplies. States should ensure that no decision or unilateral measure obstructs access to essential health products and any restriction based on the goal of securing national supply must be proportionate and consider the urgent needs of other countries.⁵⁰

Yet these extraterritorial state obligations have not been met. Rather than take concrete measures to ensure global access to Covid-19 vaccines, states with the power to do so have largely left decisions around availability, accessibility, and affordability in the hands of businesses. As this report demonstrates, the failure of businesses to take all steps at their disposal to achieve fair global access to Covid-19 vaccines means that these companies have fallen short of their human rights responsibilities and in so doing have caused or contributed to human rights harms.

46. On 8 September 2021, the WHO reported 221,648,869 confirmed cases of COVID-19, including 4,582,338 deaths, see WHO, Coronavirus (COVID-19) Dashboard, covid19.who.int/

47. World Food Programme, WFP Global Operational Response Plan, June 2021, p. 5-10, [docs.wfp.org/api/documents/WFP-0000129022/download/? ga=2.212633428.1908339400.1624214515-1052469607.1623686526](https://docs.wfp.org/api/documents/WFP-0000129022/download/?ga=2.212633428.1908339400.1624214515-1052469607.1623686526)

48. Amnesty International, "Covid-19: Four million death toll must spur governments and companies into action", 8 July 2021, www.amnesty.org/en/latest/news/2021/07/covid-19-four-million-death-toll-must-spur-governments-and-companies-into-action/; Amnesty International, "Nepal: lack of a second dose endangers over 1.4 million", (UA: 71/21 Index: ASA 31/4301/2021), 18 June 2021, www.amnesty.org/download/Documents/ASA3143012021ENGLISH.pdf

49. Amnesty International, *A Fair Shot: ensuring universal access to Covid-19 diagnostics, treatments and vaccines*, (Index: POL 30/3409/2020), www.amnesty.org/download/Documents/POL3034092020ENGLISH.PDF

50. CESCR, *Statement on the Coronavirus Disease (COVID-19) Pandemic and Economic, Social and Cultural Rights*, E/C.12/2020/1, para 20, 17 April 2020, digitallibrary.un.org/record/3856957/files/E_C.12_2020_1-EN.pdf

2. OBSTACLES TO VACCINE SUPPLY

“We have all the tools to tame this pandemic everywhere in a matter of months. It comes down to a simple choice: to share or not to share.”

Director General of the World Health Organization, Dr Tedros Adhanom Ghebreyesus⁵¹

2.1 INTRODUCTION

There are many reasons why the global roll-out of vaccines has been so uneven. High-income countries bought up the first tranche of supplies from the major US and European vaccine manufacturers even before the vaccines had been approved for use.⁵² For example, by December 2020, Canada had already secured more than five doses per head of population, the UK over four.⁵³ Rich countries have continued to stockpile well beyond their immediate needs. Some US states now hold more vaccine doses than they can administer, risking significant wastage as stocks reach their expiry date.⁵⁴

However, vaccine developers have also played a key role in creating unequal access to vaccines by prioritizing delivery to high-income countries, refusing to acknowledge intellectual property as a barrier, failing to sufficiently and swiftly share technology and knowledge needed to increase supply, and failing to divulge vital information about contracts, pricing, and dose allocation. These actions and omissions have created obstacles to fair access to Covid-19 vaccines, skewing the distribution of them to wealthier countries.

This is why Amnesty International has joined forces with the People’s Vaccine Alliance, calling on all pharmaceutical companies manufacturing Covid-19 vaccines to openly share their technology and intellectual property through the World Health Organization COVID-19 Technology Access Pool and

51. New York Times, “I Run the W.H.O., and I Know That Rich Countries Must Make a Choice”, 22 April 2021, www.nytimes.com/2021/04/22/opinion/who-covid-vaccines.html

52. Launch and Scale Speedometer, Tab. 1.2 Timeline of COVID vaccine purchase deals, launchandscalefaster.org/covid-19/vaccinepurchases

53. Launch and Scale Speedometer, Vaccination Coverage by Population and COVID-19 Burden, launchandscalefaster.org/covid-19/vaccinepurchases

54. Washington Post, “Millions of vaccines are about to expire. The U.S. might just let them go to waste”, 27 July 2021, www.washingtonpost.com/outlook/2021/07/27/coronavirus-vaccine-waste/; BMJ, “Covid-19: Vaccine doses expire in US as uptake falls by 68%,” 15 June 2021, www.bmj.com/content/373/bmj.n1536

other sharing mechanisms, so that billions more doses can be manufactured and safe and effective vaccines can be available to all who need them.⁵⁵ As a part of the People’s Vaccine Alliance, Amnesty International is also calling on governments to support South Africa and India’s proposal to the World Trade Organization Council to waive intellectual property rights for Covid-19 vaccines, tests, and treatments until everyone is protected. Waiving intellectual property rights, combined with technology transfers and coordination by the WHO, can ramp up spare capacity and empower poorer regions which have found themselves dependent on decision-making in a handful of large pharmaceutical companies.



Health workers cross the Camana River to inoculate elderly citizens with doses of the Pfizer/BioNTech Covid-19 vaccine, in Arequipa, southern Peru, 2 July 2021. © DIEGO RAMOS/AFP via Getty Images.

2.2 INTELLECTUAL PROPERTY RIGHTS

Efforts to ramp up manufacturing of Covid-19 vaccines face a complex web of global and national legal limitations as the composition of vaccines and their manufacturing processes are often protected by multiple types of intellectual property rights including patents. These allow the creators of a product to restrict the sharing of data around research, development and manufacturing. Patent holders have exclusive rights which allow them to set prices for a period of time. The patented product cannot be produced, imported, sold without the patent holders’ permission.⁵⁶ Companies also often claim manufacturing steps and clinical data as trade secrets, preventing others from learning and using them for production.⁵⁷

55. The People’s Vaccine, peoplesvaccine.org/

56. WTO, Agreement on Trade-Related Aspects of Intellectual property Rights as Amended by the 2005 Protocol Amending the TRIPS Agreement, Article 28.

57. K M Gopakumar, Chetali Rao and Sangeeta Shashikant, “Trade secrets protection and vaccines: The role of medicine regulatory agencies”, Briefing Paper June 2021, Third World Network, June 2021, twn.my/title2/briefing_papers/twn/Trade%20secrets%20TWNBP%20Jun%202020%20Gopakumar%20et%20al.pdf

Intellectual property rights can therefore limit the availability, accessibility and affordability of vaccines by blocking other manufacturers from production. The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) foresees flexibilities to the strict protection of intellectual property rights, allowing states to amend their laws to better fulfil their public health obligations and provide medicines for all. For example, these flexibilities allow states to determine patentability criteria, issue compulsory licences, and place limitations on, or make exceptions to, exclusive rights, among other measures. However, these flexibilities have proven unsuitable and insufficient during health emergencies, given that these are time-consuming processes that often must be carried out on a country-by-country, case-by-case, and drug-by-drug basis.⁵⁸

To address these challenges, in October 2020, India and South Africa submitted to the WTO TRIPS Council a proposal to allow countries to temporarily waive certain provisions, including those concerning patents and undisclosed information, of the TRIPS Agreement for the prevention, containment and treatment of Covid-19.⁵⁹ The goal of the proposal was "to mobilise global manufacturing capacity and to diversify supply options."⁶⁰ The current proposal suggests that the waiver should last for at least three years.⁶¹ Lifting restrictions around intellectual property rights would remove legal barriers that currently impede qualified manufacturers from producing Covid-19 vaccines and other important health products such as diagnostics and treatments. Equally, governments would have the space to intervene to facilitate exports or technology transfer without trade retaliation.

The campaign to waive certain intellectual property protections received a boost in May 2021, when the US government expressed its support, albeit only with regards to vaccines and not other products.⁶²

As of August 2021, a revised proposal had over 60 co-sponsors, and over 100 of 164 WTO member states supporting the initiative.⁶³ However, the European Union (EU), and states such as Switzerland, Norway and the UK, still opposed it.⁶⁴ The EU tabled its own proposal aiming to maintain the current rules and the use of compulsory licences.⁶⁵

58. Sustainable Development Goal 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. However, developing countries have long faced political and economic pressure from high income countries not to make use of the TRIPS flexibilities. Under Article 31bis of the TRIPS Agreement, which establishes rules for compulsory licensing particularly with regard to the protection of public health, only one compulsory licence for pharmaceutical product has ever been granted. TRIPS flexibilities also apply on a country-by-country, and product-by-product basis and are considered over complicated and impractical, making them ill-suited and too time-consuming for use in a health crisis. Indeed, despite a number of countries having made changes to their domestic legislations that would allow the issuing of compulsory licences or make the process to do so easier, no compulsory licence for a Covid-19 vaccine has yet been issued.

59. WTO, "Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of Covid-19 - joint statement of co-sponsors," 17 May 2021, docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=274186_273996,273770,273787,273460,273297,271981,271520,271383,271259&CurrentCatalogueIdIndex=1&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True

60. WTO, "Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of covid-19 - joint statement of co-sponsors," 17 May 2021, docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=274186_273996,273770,273787,273460,273297,271981,271520,271383,271259&CurrentCatalogueIdIndex=1&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True

61. WTO, "Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of covid-19 - joint statement of co-sponsors," 17 May 2021, docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=274186_273996,273770,273787,273460,273297,271981,271520,271383,271259&CurrentCatalogueIdIndex=1&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True

62. Office of the United States Trade Representative, *Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver*, 5 May 2021, ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver

63. WTO, "Members approach text-based discussions for an urgent IP response to COVID-19", 9 June 2021, www.wto.org/english/news_e/news21_e/trip_09jun21_e.htm; Reliefweb, EU, UK, Switzerland, Norway must stop blocking negotiations on landmark pandemic monopoly www.waiverreliefweb.int/report/world/eu-uk-switzerland-norway-must-stop-blocking-negotiations-landmark-pandemic-monopoly;

64. UK Government, "World Trade Organization General Council, July 2021: UK statements", 28-29 July 2021, www.gov.uk/government/speeches/world-trade-organization-general-council-july-2021-uk-statements; European Commission, "European Union Statements at the General Council Meeting", 27 July 2021, eeas.europa.eu/delegations/world-trade-organization-wto/102481/european-union-statements-general-council-meeting-27-july-2021_en; Reuters, "Switzerland says U.S. stance on vaccine patent waiver leaves questions", 6 May 2021, www.reuters.com/business/healthcare-pharmaceuticals/switzerland-says-us-announcement-vaccine-patent-waiver-leaves-questions-2021-05-06/.

65. European Commission, "EU proposes a strong multilateral trade response to the COVID-19 pandemic", 4 June 2021, ec.europa.eu/commission/presscorner/detail/en/ip_21_2801



People jostle to register for a dose of the Moderna vaccine at a vaccination center in Peshawar on 6 July, 2021 © AFP via Getty Images

The pharmaceutical industry has also firmly opposed this proposal. Leading companies, acting through industry organizations including the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the Pharmaceutical Research and Manufacturers of America (PhRMA), Biotechnology Innovation Organization (BIO), and the European Federation of Pharmaceutical Industries and Association (EFPIA) have lobbied governments and made numerous statements in the media opposing the TRIPS waiver. In March 2021, PhRMA sent a letter to US President Biden calling for the USA to support “innovation and American jobs by continuing to oppose the TRIPS IP waiver”.⁶⁶ PhRMA has also started a digital advertising campaign targeting the US decision to support a waiver for intellectual property rights of Covid-19 vaccines.⁶⁷ In May 2021, EFPIA called the Biden administration’s support for the TRIPS waiver a “short-sighted and ineffectual decision”.⁶⁸ BIO said the Biden administration’s support for the waiver was a “myopic decision” which set a “dangerous precedent”; the organization has argued that a better strategy would be not to diversify global production but to “make the United States the world’s ‘arsenal of vaccines’”.⁶⁹

2.3 KNOWLEDGE TRANSFER AND TECHNOLOGY SHARING

The waiving of intellectual property rights could lift legal and bureaucratic deterrents to manufacturing Covid-19 vaccines. Their suspension alone would not, however, automatically accelerate manufacturing and thus increase availability of the Covid-19 vaccine. Vaccines cannot easily be reverse engineered.

66. PhRMA, “Letter from PhRMA to President Biden”, 5 March 2021, patentdocs.typepad.com/files/2021-03-05-phrma-letter.pdf

67. Google Transparency Report, campaign screenshots on file; CNBC, “Big Pharma lobbyists launch campaign against Biden over Covid vaccine patent waiver”, 1 June 2021, www.cnbc.com/2021/06/01/big-pharma-launches-campaign-against-biden-over-covid-vaccine-patent-waiver.html

68. IFPMA, “IFPMA Statement on WTO TRIPS Intellectual Property Waiver”, 5 May 2021, www.ifpma.org/resource-centre/ifpma-statement-on-wto-trips-intellectual-property-waiver/

69. BIO, “Support of ‘TRIPS’ waiver sets dangerous precedent”, 5 May 2021, www.bio.org/press-release/support-trips-waiver-sets-dangerous-precedent

Their manufacture requires specific expertise and information about production processes.⁷⁰ Patent applications do not contain all the necessary knowledge and data, because the current intellectual property regime allows companies to shield their trade secrets which can contain all types of commercially-valuable technical, scientific, or engineering information.⁷¹ There is also non-codified, tacit knowledge, which can only be transferred through training or staff secondments.⁷² These gaps must be addressed through sharing of both codified and tacit knowledge, technology transfer, and training – along with the suspension of intellectual property rights.

Knowledge sharing and technology transfer should also aim to geographically diversify production, to address the risks of potential supply blockages. These risks were exposed in March 2021, when the Indian government embargoed the export of Covid-19 vaccines in reaction to a rise in domestic infections, affecting delivery of vaccines to over 60 other countries.⁷³ Diversification could help ramp up spare capacity and empower poorer regions which have found themselves dependent on decision-making in a handful of large companies.

Vaccine developers have so far only shared their knowledge and technology through a handful of bilateral production agreements, but not on a scale which allows sufficient production to meet the current emergency.⁷⁴ This has led to an unnecessary global shortage of Covid-19 vaccines. Research by Public Citizen has concluded that with adequate resource and knowledge sharing, existing facilities can be repurposed to produce mRNA vaccines in six months – a feat which Moderna itself carried out with the Swiss health care manufacturer, Lonza and which BioNTech achieved by acquiring a manufacturing facility in Marburg.⁷⁵

Not sharing knowledge and technology to upskill manufacturing capacity is a major omission on the part of company decision-making, representing a significant obstacle to states' capacity to respond to the global health crisis and ensure fair access to vaccines around the world. Lack of transparency on potential production sites and agreements also hampers effective use of resources.



People queue to receive a dose of the Oxford-AstraZeneca Covid-19 vaccine at a vaccination centre on the outskirts of Yemen's embattled province of Marib in the country's northeast, 7 July 2021. © AFP via Getty Images

70. Devex, "70% of G-7 citizens support sharing COVID-19 vaccine knowledge", 6 May 2021, www.devex.com/news/70-of-g-7-citizens-support-sharing-covid-19-vaccine-knowledge-99840.

71. WTO, TRIPS Agreement, Article 39.

72. Science, "Knowledge transfer for large-scale vaccine manufacturing," 13 August 2020, [science.sciencemag.org/content/early/2020/08/12/science.abc9588?versioned=true](https://www.sciencemag.org/content/early/2020/08/12/science.abc9588?versioned=true)

73. Reuters, "Exclusive: India delays big exports of AstraZeneca shot, as infections surge", 24 March 2021, www.reuters.com/article/health-coronavirus-india-vaccine-exclusi-idUSKBN2BG27D; Gavi, "COVAX updates participants on delivery delays for vaccines from Serum Institute of India (SII) and AstraZeneca", 25 March 2021, www.gavi.org/news/media-room/covax-updates-participants-delivery-delays-vaccines-serum-institute-india-sii-az

74. Knowledge Portal, COVID-19 Vaccine Manufacturing, Number of COVID-19 Vaccine Manufacturing Arrangements Over Time, by Vaccine Developer, www.knowledgeportal.org/covid19-vaccine-manufacturing

75. Public Citizen, "How to Make Enough Vaccine for the World in One Year", 26 May 2021, www.citizen.org/article/how-to-make-enough-vaccine-for-the-world-in-one-year/?eType=EmailBlastContent&eld=0cba1c99-0eee-442b-8129-623b21b76771; Lonza, Moderna and Lonza Announce Worldwide Strategic Collaboration to Manufacture Moderna's Vaccine (mRNA-1273) Against Novel Coronavirus, [www.Lonza.com/~media/Files/japan/News/200501_Press_Release_Moderna_Lonza_COVID_FINAL.pdf](https://www.lonza.com/~media/Files/japan/News/200501_Press_Release_Moderna_Lonza_COVID_FINAL.pdf); BioNTech, BioNTech to Acquire GMP Manufacturing Site to Expand COVID-19 Vaccine Production Capacity in First Half 2021, investors.biontech.de/news-releases/news-release-details/biontech-acquire-gmp-manufacturing-site-expand-covid-19-vaccine

JOHNSON & JOHNSON AND CANADA REJECT EFFORTS TO INCREASE MANUFACTURING OF COVID-19 VACCINES

Since February 2021, the Canadian pharmaceutical company Biolyse has unsuccessfully attempted to obtain a licence to produce a biosimilar version of the Johnson & Johnson vaccine.⁷⁶ Johnson & Johnson rejected its request for a voluntary licence with the justification that the company was not exploring new manufacturing in Canada as part of efforts to expand global production for the pandemic. Biolyse subsequently filed for a compulsory licence from the Canadian government, pursuant to the WTO TRIPS Agreement Article 31bis. This stipulation allows countries to grant a compulsory licence to export health products to countries that do not have manufacturing capacity to make these domestically. If granted, Biolyse reported that it could produce up to 20 million doses of Covid-19 vaccines per year and pledged to supply Bolivia with the first 15 million, which could inoculate the country's entire adult population.⁷⁷

Despite these attempts, the compulsory licence process has remained at a standstill with no response from the Canadian government. In fact, the Canadian authorities have not added Covid-19 vaccines to its list of health products that are eligible for compulsory licences even though a product can be added to Schedule 1 if it “may be used to address public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics”.⁷⁸

As a result, Biolyse has been unable to move forward with their request, which also depends on Johnson & Johnson's willingness to cooperate with the knowledge and technology transfer that would allow Biolyse to produce in a timely fashion. Meanwhile, Bolivia faces a death toll that is more than double that of Canada's (1,529 versus 703 cumulative deaths per million people) and only 24.7% of the population is fully vaccinated, while Canada has fully immunized nearly 68% of its people.⁷⁹ This inequality is seen across the globe as 71% of vaccine doses have been administered in high- and upper-middle-income countries, while only 0.3% of doses have been given to low-income countries.

2.4 PRICING POLICIES AND PROFIT

States have the primary obligation to ensure the availability and affordability of Covid-19 vaccines, making them freely available for all those who need them.⁸⁰ However, their ability to do so may be impacted by a company's pricing of vaccines. The higher the costs for procuring vaccines, the higher the risk of limiting a state's ability to purchase sufficient quantities of Covid-19 vaccines. High prices might even make Covid-19 vaccines inaccessible to countries that cannot afford them.

This is in a context where the vaccine developers received significant public and philanthropic subsidies, as well as advance orders. These reduced or even eliminated the risk that is typically linked to investment in the research and development of a vaccine.

76. Knowledge Ecology International, “Canada based Biolyse Pharma Seeks to Manufacture COVID-19 Vaccines or Low-Income Countries, may test Canada's compulsory licensing for export law”, March 2021, www.keionline.org/35587

77. Knowledge Ecology International, “Bolivia seeks to import Covid-19 vaccines from Biolyse, if Canada grants them a compulsory license”, May 2021, www.keionline.org/36119

78. Knowledge Ecology International, “Canadian Experience with Compulsory Licensing under the Canadian Access to Medicines Regime”, March 2021, www.keionline.org/wp-content/uploads/KEI-Briefing-Note-2021-2-CAMR-Canadian-Compulsory-Licensing.pdf; Government of Canada, Government Owned Patents, laws-lois.justice.gc.ca/eng/acts/p-4/page-5.html?wbdisable=true

79. Our World in Data, “COVID-19 deaths” and “COVID-19 Vaccinations” ourworldindata.org/covid-vaccinations accessed 10 September.

80. OHCHR, CESCR General comment No. 14: The right to the highest attainable Standard of Health (Art. 12), paras 12, 42, www.ohchr.org/Documents/Issues/Women/WRGS/Health/GC14.pdf

According to the Human Rights Guidelines for Pharmaceutical Companies, companies should consider all the arrangements at their disposal to ensure that its medicines are affordable to as many people as possible. Given the millions of lives at stake, companies should approach pricing arrangements with “urgency, creativity and boldness”.⁸¹ Companies should pay particular attention to ensuring its medicines are accessible to disadvantaged individuals, communities, and populations, including those living in poverty and the very poorest in all markets. The arrangements should include, for example, differential pricing between countries.⁸²

While pharmaceutical companies, such as Pfizer and Moderna, claim they are adopting responsible pricing policies, they are also making enormous profits.⁸³ Pfizer has reported US\$3.5 billion in revenues from the sale of its Covid-19 vaccine, with a projected revenue of \$33.5 billion from the Covid-19 vaccine for 2021 (with the gross margin to be split evenly with BioNTech).⁸⁴ Moderna’s revenue has increased exponentially since the development of its Covid-19 vaccine, from US\$67 million in the second quarter of 2020 to US\$4.4 billion in the same period of 2021.⁸⁵ While there is little transparency around profits on Covid-19 vaccine sales, Pfizer has stated its pre-tax margin for the Covid-19 vaccine “to be in the high 20’s as a percentage of revenue, factoring in manufacturing and distribution costs, royalty expenses, shared R&D expenses and a 50% gross margin split with BioNTech”. On pricing and profit, Pfizer disputed that the company had “disproportionally gained as the result of the Covid-19 vaccine”.⁸⁶ According to estimates based on research by Public Citizen, producing the Pfizer/BioNTech vaccine at mass scale could cost as little as US\$1.20 per dose to manufacture – a calculation disputed by Pfizer - and the Moderna vaccine around \$2.85 per dose.⁸⁷ In contrast, Pfizer is charging up to US\$23.50 per dose in some countries, and Moderna up to US\$37. Pfizer has said that it expects to significantly increase prices “beyond a pandemic-pricing environment”, which, combined with lower unit costs from greater volumes, represented “a significant opportunity for [...] margins to improve.”⁸⁸ According to projections by Airfinity in August 2021, Pfizer and Moderna are set to increase revenue in 2022 by 80% and 72%, respectively.⁸⁹

Writing in November 2020, a group of UN human rights experts has warned that “industry and private benefit cannot be prioritized over the rights to life and health of billions,” and that business enterprises “should refrain from causing or contributing to adverse impacts on the rights to life and health by invoking their intellectual property rights and prioritizing economic gains.”⁹⁰

81. OHCHR, Human Rights Guidelines, Commentary to Guidelines 33-38.

82. OHCHR, Human Rights Guidelines for Pharmaceutical Companies, Guideline 33.

83. Pfizer told Amnesty International that “we priced our vaccine consistent with the urgent global health emergency” using a tiered pricing model. Moderna has said it uses a differential pricing framework. Letter from Dr. Albert Bourla to Amnesty International, 15 June 2021, on file. Moderna, “Moderna’s Commitment to Vaccines and Therapeutics Access”, 23 December 2020, investors.modernatx.com/news-releases/news-release-details/modernas-commitment-vaccines-and-therapeutics-access; Corporate Watch, Vaccine Capitalism, “A run-down of the huge profits being made from Covid-19 vaccines”, corporatwatch.org/vaccine-capitalism-a-run-down-of-the-huge-profits-being-made-from-covid-19-vaccines/#sdendnote1sym

84. Pfizer, “Pfizer reports second-quarter 2021 results”, s21.q4cdn.com/317678438/files/doc_financials/2021/q2/Q2-2021-PFE-Earnings-Release.pdf

85. Moderna, “Moderna Reports First Quarter Fiscal Year 2021 Financial Results and Provides Business Updates”, 6 May 2021, investors.modernatx.com/news-releases/news-release-details/moderna-reports-first-quarter-fiscal-year-2021-financial-results

86. Pfizer, “Pfizer reports second-quarter 2021 results”, p. 4, s21.q4cdn.com/317678438/files/doc_financials/2021/q2/Q2-2021-PFE-Earnings-Release.pdf; Pfizer Email to Amnesty International, 13 September 2021, on file.

87. Public Citizen, “How to Make Enough Vaccine for the World in One Year”, 26 May 2021, www.citizen.org/article/how-to-make-enough-vaccine-for-the-world-in-one-year/. This is based on estimates to make 8 billion vaccine doses worldwide. Pfizer told Amnesty International that “we have reviewed the cost calculation by Public Citizen and disagree with that estimated number,” Pfizer Email to Amnesty International, 13 September 2021, on file.

88. Pfizer, Edited Transcript PFE.N - Q4 2020 Pfizer Inc Earnings Call, 2 February 2021, s21.q4cdn.com/317678438/files/doc_financials/2020/q4/PFE-USQ_Transcript_2021-02-02.pdf

89. Airfinity, COVID-19 Vaccine Weekly Intel Report, 6 August 2021, p. 34.

90. 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, www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26484&LangID=E

2.5 VACCINE ALLOCATION AND SEQUENCING

While governments are primarily responsible for ensuring access to medicines, companies have significant decision-making power over the allocation of Covid-19 vaccines through the brokering of advance purchasing agreements, and sequencing of the vaccine production and roll-out. In some situations, governments may end up lacking timely access to vaccines as a result of vaccine developers' market prioritization.

In prioritizing large scale bilateral agreements with a small number of wealthy countries, companies have focused their limited supply in a way that has put initiatives such as COVAX and poorer countries at the back of the queue. This issue is once more arising in relation to the supply of boosters to low-risk individuals in high-income countries.⁹¹

In practice, a series of decisions made by both governments and companies has meant that 5.56 billion doses have been administered globally, but only 0.3% of these have been in low-income countries.⁹² In early September, COVAX had shipped only 243 million doses.⁹³ Pledges for future supplies into COVAX are not addressing immediate, critical need. Moderna, for example, committed 500 million future doses to the COVAX Facility in May 2021, but 446 million (93%) of these will not be delivered until 2022.⁹⁴ Moderna has so far delivered 84% of its vaccines to high-income countries.⁹⁵

2.6 LACK OF TRANSPARENCY

One of the major obstacles to ensuring fair access to Covid-19 vaccines is lack of transparency, which makes contracts, pricing, technology, intellectual property licensing and knowledge transfer impossible to accurately map and optimize. It also undermines the negotiating power of states. What should be a coordinated global effort to address a global health crisis has been overshadowed by a complex series of bilateral negotiations between high-income states and powerful companies.

Vaccine developers have been reluctant to publish commercial contracts, or detailed information on pricing, production, and distribution. In some cases, companies have actively sought to obstruct attempts to access information. For example, Pfizer and Johnson & Johnson have fought resolutions filed by activist shareholders for the disclosure of information about how public funding will be taken into consideration in the decision-making on access to vaccines and pricing.⁹⁶ Also contracts between companies and COVAX, CEPI and Gavi have not been disclosed.

As a result, many states have been forced to negotiate contracts blind, unaware of conditions offered in neighbouring countries or other regions. Research carried out in March 2021 by Red Palta, a collaboration of South American newspapers, in partnership with the Argentina-based Fundación Directorio Legislativo, found that 12 governments signed contracts which agreed to significant

91. Financial Times, "Booster shot debate takes centre stage as global Covid cases rise," 17 July 2021, www.ft.com/content/ec0cf69c-9d3c-48c6-88dd-2bafa1c61f90

92. New York Times, "Tracking vaccinations around the world", 9 August 2021, www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html

93. Gavi, "COVAX", www.gavi.org/covax-vaccine-roll-out, accessed on 9 September 2021.

94. Gavi, "GAVI signs agreement with Moderna to secure doses on behalf of COVAX facility", 3 May 2021, www.gavi.org/news/media-room/gavi-signs-agreement-moderna-secure-doses-behalf-covax-facility

95. Airfinity, Covid-19 Vaccine Weekly Intel report, 5 August 2021.

96. Skadden, Arps, Slate, Meagher & Flom "LLP to US Securities Exchange Commission, Johnson & Johnson", 11 December 2020, www.sec.gov/divisions/corpfin/cf-noaction/14a-8/2020/oxfamjohnson121120-14a8-incoming.pdf; Newsweek, "COVID-19 Vaccine Developers Ask the SEC to Help Keep the Secret of How They Set Prices", 2 January 2021, www.newsweek.com/covid-19-vaccine-developers-ask-sec-help-keep-secret-how-they-set-prices-1565904

concessions while restricting public access to information about the terms agreed, including the prices paid for vaccines in each country.⁹⁷ Ultimately, lack of transparency reinforces companies' control over allocation, weakens governments' negotiating powers and potentially drives up prices – all of which directly affect a government's ability to ensure access to Covid-19 vaccines.⁹⁸

Transparency is a “cardinal principle of international human rights, including the right to the highest attainable standard of health”.⁹⁹ According to the Human Rights Guidelines for Pharmaceutical Companies “the company should be as transparent as possible. There is a presumption in favour of the disclosure of information, held by the company, which relates to access to medicines.”¹⁰⁰ In the current context, it is key for these companies to publicly disclose disaggregated costs of research, development, production, marketing, distribution, intellectual property licensing and technology transfer information and all other relevant data in a timely and accessible fashion.

2.7 WHAT COMPANIES SHOULD DO

As part of their human rights responsibilities, pharmaceutical companies should remove obstacles that are hindering the faster and fairer supply of Covid-19 vaccines to all parts of the world. As the UN Guiding Principles set out, “[w]here a business enterprise causes or may cause an adverse human rights impact, it should take the necessary steps to cease or prevent the impact”.¹⁰¹

To begin with, they should forgo the various intellectual property rights needed for vaccine productions. In addition, to concretely accelerate and facilitate production by alternative producers, they should share both their codified and tacit knowledge and technology, as well as train qualified manufacturers committed to contribute to the ramp-up of the production of Covid-19 vaccines. They should do so through C-TAP and, where applicable, cooperating with technology transfer hubs being established by the WHO.¹⁰²

The companies should also stop lobbying governments to obstruct the TRIPS waiver proposal.¹⁰³ They should not seek to use their influence over governments to obstruct measures designed to facilitate intellectual property and technology sharing, such as the TRIPS waiver and C-TAP.

With regards to pricing, companies must not put their economic interests before their human rights responsibilities. In the context of the current global health crisis, this means that profit must not become an obstacle to states' capacity to ensure access to the vaccine.

97. PODER, “Pharmaceutical companies sold vaccines to Latin American with legal and tax benefits”, 9 March 2021, poderlatam.org/en/2021/03/pharmaceutical-companies-sold-vaccines-to-latin-american-with-legal-and-tax-benefits/

98. BMJ, “Price transparency is a step towards sustainable access in middle income countries,” 13 January 2020, www.bmj.com/content/368/bmj.l5375

99. OHCHR, Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, Commentary to Guidelines 6-8, A/63/263, 11 August 2008, www.ohchr.org/documents/issues/health/guidelinesforpharmaceuticalcompanies.doc

100. OHCHR, Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, Commentary to Guidelines 6-8, A/63/263, 11 August 2008, www.ohchr.org/documents/issues/health/guidelinesforpharmaceuticalcompanies.doc, pp. 17-18

101. UN Guiding Principles, Commentary to Principle 19.

102. WHO, “Establishment of a COVID-19 mRNA vaccine technology transfer hub to scale up global manufacturing”, 21 June 2021, who.int; “South Africa to become Africa's first mRNA vaccine manufacturing hub”, Health Policy Watch, 21 June 2021, healthpolicy-watch.news/africas-first-mrna-hub-to-be-set-up/

103. The Committee on Economic, Social and Cultural Rights (CESCR) has established that intellectual property and patent legal regimes must not undermine the enjoyment of economic, social and cultural rights. Equally, the DOHA Declaration on the WTO's Trade Related Aspects of Intellectual property Rights (TRIPS), which regulates the principles of intellectual property protection at an international level, states that the international intellectual property regime should be interpreted in a manner supportive to the protection of public health and in particular to advance access to medicines for all.

When conducting their human rights due diligence as set out in the UN Guiding Principles, vaccine developers must take into account the potential negative impact their pricing policy might have. In line with the Human Rights Guidelines for Pharmaceutical Companies, the vaccine developer should “give particular attention to ensuring its medicines are accessible to disadvantaged individuals, communities and populations, including those living in poverty and very poorest in all markets”, for example by applying differential pricing between countries or not-for-profit voluntary licensing.¹⁰⁴

Vaccine developers must also ensure that the negotiation process of prices with potential purchasing states are aimed at guaranteeing timely availability of the Covid-19 vaccines, and that no delaying tactics are applied to influence pricing. They should make their pricing policies and arrangements transparent, including the actual costs of production, individual cost items, sources of external funding, prices charged in different countries under what contractual terms and conditions, and information about discounting, donations and advance order guarantees.¹⁰⁵ Transparency in pricing is vital for ensuring fair and open contract negotiations so that buying states are fully aware of market prices and there is consistency around prices charged across and between regions. Lack of transparency can lead to price increases, especially for countries with weak negotiating power.¹⁰⁶

Vaccine developers must align their policies and decision-making on vaccine allocation and market prioritization with their responsibility to extend access to vaccines for all. Vaccine developers should prioritize increasing availability of vaccines in poorer regions and countries where the roll-out of vaccination has so far been delayed. To ensure fair access to vaccines and distribution to every country in the world, vaccine developers should devote a significant share of their production to the COVAX Facility. By prioritizing rich countries when vaccine supplies are scarce, pharmaceutical companies are contributing to violations of the rights to life and health.

Vaccine developers should engage with states with whom they have previous supply commitments and seek contractual flexibility regarding delivery terms to ensure that those most at risk globally get access to the vaccines in a timely manner, particularly where there are sudden Covid-19 outbreaks requiring urgent responses.

The terms and conditions of some advance purchase agreements prevent states from selling or donating any surplus of Covid-19 vaccine doses to other countries, including for donation via NGOs or the WHO, without prior consent of the manufacturer.¹⁰⁷ These contractual restrictions impede states’ ability to extend access to vaccines. Vaccine developers should immediately lift these barriers.

To extend access to vaccines, vaccine developers should publicly disclose how they identify and address human rights risks related to their business operations. Under the UN Guiding Principles, the responsibility to respect human rights requires business enterprises to “know and show that they respect human rights in practice.”¹⁰⁸

104. OHCHR, Human Rights Guidelines for Pharmaceutical Companies, Principle 33.

105. OHCHR, Human Rights Guidelines for Pharmaceutical Companies, Principle 38.

106. BMJ, “Pricing of pharmaceuticals is becoming a major challenge for health systems”, 13 January 2020, www.bmj.com/content/368/bmj.l4627

107. See Advance Purchase Agreement between CureVac and the European Union, Article I. 10.2, ghiaa.org/wp-content/uploads/2021/01/Curevac_-_redacted_advance_purchase_agreement.pdf; in contrast, in the Advance Purchase Agreement between AstraZeneca and the European Union, the right to resell excess doses is granted to Participating Member States, see Article 8.3, www.euractiv.com/wp-content/uploads/sites/2/2021/01/EU_AstraZeneca.pdf

108. UN Guiding Principles, Commentary to Principle 21.



Doctors inoculate 85-year-old local resident with the Pfizer/BioNTech vaccine at a mobile vaccination centre situated in a modified bus in Grosshartmannsdorf, Germany, February 21, 2021. © Matthias Rietschel/Getty Images.

2.8 WHAT GOVERNMENTS MUST DO

The current failure of states to lift intellectual property rights protections that constitute a barrier to scaling up global production of Covid-19 vaccines is a failure of states' obligation to protect. As the UN Guiding Principles point out, in order to protect against human rights harm by third parties, states must take "appropriate steps to prevent, investigate, punish and redress such abuse through effective policies, legislation, regulations and adjudication."¹⁰⁹

States should put measures in place, including legislation, to require vaccine developers to engage in knowledge and technology transfer. They should take an active role in facilitating and resourcing vaccine developers' sharing capacities, taking into account public funding vaccine developers have already received for the research and development of the Covid-19 vaccines. States should support C-TAP and ensure that vaccine developers in their jurisdiction share knowledge and technology by participating in C-TAP and through other means. States should further support vaccine developers in facilitating cooperation in the supply chain and tackling practical and legal impediments, including lifting export restrictions,¹¹⁰ and providing financial and technical support to scale up global manufacturing capacity.¹¹¹

109. UN Guiding Principles, Foundational Principles, p. 4.

110. See intervention by the US government to facilitate manufacturing collaboration between Merck and Johnson & Johnson, HHS.gov, "Biden Administration Announces Historic Manufacturing Collaboration Between Merck and Johnson & Johnson to Expand Production of COVID-19 Vaccines", www.hhs.gov/about/news/2021/03/02/biden-administration-announces-historic-manufacturing-collaboration-between-merck-johnson-johnson-expand-production-covid-19-vaccines.html; for examples of countries which have established export restrictions the US, see The Economist, "American export controls threaten to hinder global vaccine production", 24 April 2021, www.economist.com/science-and-technology/2021/04/22/american-export-controls-threaten-to-hinder-global-vaccine-production; and in the EU, European Commission, "Commission strengthens transparency and authorisation mechanism for exports of COVID-19," 21 March 2021, vaccine.ec.europa.eu/commission/presscorner/detail/en/ip_21_1352

111. See South African cooperation on a technology transfer hub, SAMRC, "South Africa establishes world class consortium to create first technology transfer hub for Covid-19 vaccines in Africa", 24 June 2021, www.samrc.ac.za/media-release/south-africa-establishes-world-class-consortium-create-first-technology-transfer-hub

States should further ensure the transparency of the Covid-19 vaccine market, in line with the WHO resolution on transparency of the pharmaceutical market, including ensuring transparency of intellectual property licensing through mandatory registration and publication of licensing terms.¹¹² They must also refrain from taking actions, such as bilateral deals with vaccine developers, that could compromise the ability of other states to extend access to vaccines, which includes “hoarding” of vaccines beyond what is needed for priority, at-risk populations.¹¹³ They should, for instance, bring forward commitments to share doses and allow pharmaceutical companies to prioritize deliveries to poorer and less vaccinated countries. States must cooperate globally and remove any potential barriers to ensure that vaccines are developed and manufactured in sufficient supply, and then distributed in a timely and inclusive manner around the globe.

States must condition the public funding of pharmaceutical companies on transparency, knowledge and intellectual property sharing, fair pricing and access to vaccines on the basis of need. This applies particularly to the largest investors in vaccine research and development, such as the EU, the UK and the USA.¹¹⁴

States should share vaccine doses they have purchased to rapidly reach frontline workers and the most vulnerable globally, instead of vaccinating those at home considered low risk.¹¹⁵ States should also allow contractual flexibility to the delivery terms of vaccine developers, so that they can deliver doses in response to urgency and need.



Health workers wait to administer the Johnson & Johnson vaccine at the Chris Hani Baragwanath Hospital in Soweto, 17 February 2021.
© EMMANUEL CROSET/AFP via Getty Images

112. WHO, “WHA72.8 - Improving the transparency of markets for medicines, vaccines, and other health products” WHA72.8 - Improving the transparency of markets for medicines, vaccines, and other health products (who.int).

113. For further background, see Amnesty International, *A fair shot*, (Index: POL 30/3409/2020), p. 13.

114. Knowledge Portal, COVID-19 Vaccine R&D Investments, www.knowledgeportal.org/covid19-r-d-funding

115. See for instance vaccination of children not at risk in Belgium, The Brussels Times, “12 to 15 years old can get vaccinated with parental consent”, 26 June 2021, www.brusselstimes.com/news/belgium-all-news/health/176517/12-to-15-year-olds-can-get-vaccinated-with-parental-consent

2.9 RESPONDING TO INDUSTRY ARGUMENTS

Major pharmaceutical companies and industry bodies have responded to public pressure for a fairer and faster roll-out with a number of counter arguments, seeking to justify opposition to the proposed TRIPS waiver, and wider knowledge and technology sharing. They have argued that intellectual property, knowledge, and technology sharing will stifle innovation, create competition for scarce raw materials in the supply chain, and will not accelerate global production.

Innovation and intellectual property protection

Vaccine developers have argued that “IP is the key driver of innovation” and that waiving these protections will make “it harder to fund research and development into high-risk, high-reward innovations over a long-time horizon.”¹¹⁶ This overlooks the fact that scientific innovation for Covid-19 vaccines was largely underwritten by public funding and de-risked through advance orders.¹¹⁷

Furthermore, the proposed TRIPS waiver is time-limited and restricted to Covid-19 related technologies, and thus does not question intellectual property protection as a basic principle or how it applies to other health products. Research on the development of previous vaccines has shown that intellectual property protections, which includes restrictions around knowledge and technology sharing, have reduced supply and kept prices artificially high, impeding access for low- and middle-income countries.¹¹⁸

Vaccine developers also argue that voluntary bilateral licence arrangements with selected partners, often in exchange for payment of a royalty, are the appropriate instrument to overcome intellectual property barriers.¹¹⁹ This approach, however, has so far not been sufficient to overcome the persistent imbalance in dose allocation or to meet the global demand for vaccines. Through open and non-exclusive licensing and collaborative mechanisms such as C-TAP, companies could share and license their products to the patent pool, which in turn would make sub-licences available to qualified generics manufacturers, where necessary in return of royalties on sales.

Supply chain challenges and intellectual property protection

In an open letter to Pfizer employees, CEO Albert Bourla argued that the proposed waiver to the WTO TRIPS Agreement would “unleash a scramble for the critical inputs,” and “threaten[s] to disrupt the flow of raw materials”.¹²⁰ Novavax stated that a “TRIPS waiver could further constrain resources by diverting them to entities incapable of manufacturing safe and effective vaccines in the near term.”¹²¹

However, challenges in the supply chain cannot be solved by allowing exclusive access to resources to only a limited number of vaccine developers whose joint production capacity does not meet global

116. AstraZeneca, Letter to Amnesty International, 8 June 2021, on file; Moderna, Letter to Amnesty International, on file.

117. The Lancet, “Data on public and non-profit funding for the research, development, and production of COVID-19 vaccines”, 21 February 2021, [www.thelancet.com/cms/10.1016/S0140-6736\(21\)00306-8/attachment/f9fb0ae9-7f86-46c3-a57c-ada598458fa3/mmc2.pdf](http://www.thelancet.com/cms/10.1016/S0140-6736(21)00306-8/attachment/f9fb0ae9-7f86-46c3-a57c-ada598458fa3/mmc2.pdf); Knowledge Portal, COVID-19 Vaccine R&D Investments, www.knowledgeportalia.org/covid19-r-d-funding

118. Subhashini Chandrasekharan et al, “Intellectual property rights and challenges for development of affordable human papillomavirus, rotavirus and pneumococcal vaccines: Patent landscaping and perspectives of developing country vaccine manufacturers”, 17 November 2015, Volume 33, Issue 46, 17 November 2015, Pages 6366-6370, www.sciencedirect.com/science/article/pii/S0264410X15011913?via%3Dihub; Médecins Sans Frontières, “A Fair Shot for Vaccine Affordability: Understanding and addressing the effects of patents on access to newer vaccines”, September 2017, msfaccess.org/sites/default/files/2018-06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf

119. Moderna, Letter to Amnesty International, on file.

120. Pfizer, “An open letter from Pfizer Chairman and CEO Albert Bourla to colleagues”, www.pfizer.com/news/hot-topics/an_open_letter_from_pfizer_chairman_and_ceo_albert_bourla

121. Novavax, “Novavax Statement in Opposition to the WTO TRIPS Waiver”, 7 May 2021, ir.novavax.com/2021-05-07-Novavax-Statement-in-Opposition-to-the-WTO-TRIPS-Waiver

need. Instead coordinated approaches are required, which aim to address impediments in the supply chain collaboratively. States should support vaccine developers by facilitating cooperation in the supply chain and tackling practical and legal impediments, including removing trade barriers such as export restrictions.¹²²

Other raw materials bottlenecks arise from the intellectual property rights architecture itself, which gives a small number of companies exclusive rights over certain essential supply chain technologies and designs. For instance, one of the reasons for shortages of bioreactor bags which are essential hardware for vaccine production is industry consolidation protected by intellectual property rights.¹²³ Other bottlenecks are due to political decisions that undermine international cooperation which is vital in times of a public health crisis.

Global manufacturing capacities and intellectual property protection

Vaccine developers have argued against waiving intellectual property rights claiming that lifting protections will not automatically accelerate production due to lack of manufacturing expertise and capacity.¹²⁴ However, waiving intellectual property rights must be combined with knowledge sharing and technology transfer to enable other skilled manufacturers to produce the vaccine. Suspending intellectual property protections provides the legal basis for qualified manufacturers to manufacture Covid-19 products without fear of legal reprisal and would allow governments to intervene to facilitate export or technology transfer without trade or legal retaliation.

Experience has shown how adversely intellectual property rights can impact on access to medicines. For a long period, HIV medication was only accessible for a few high-income countries, until generic manufacturing led to dramatically lower prices at the turn of the millennium.¹²⁵ Generic production was then possible in countries where national law did not allow patents on pharmaceutical products. This has changed under the WTO TRIPS Agreement which requires WTO member states to ensure intellectual property rights protection for pharmaceutical products.¹²⁶

122. See for instance the intervention by the US government to facilitate manufacturing collaboration between Merck and Johnson & Johnson, HHS.gov, "Biden Administration Announces Historic Manufacturing Collaboration Between Merck and Johnson & Johnson to Expand Production of COVID-19 Vaccines", www.hhs.gov/about/news/2021/03/02/biden-administration-announces-historic-manufacturing-collaboration-between-merck-johnson-johnson-expand-production-covid-19-vaccines.html; for examples of countries which have established export restrictions the US, see The Economist, "American export controls threaten to hinder global vaccine production," 24 April 2021, www.economist.com/science-and-technology/2021/04/22/american-export-controls-threaten-to-hinder-global-vaccine-production; and in the EU, European Commission, "Commission strengthens transparency and authorisation mechanism for exports of COVID-19," 21 March 2021, vaccinesec.europa.eu/commission/presscorner/detail/en/ip_21_1352

123. Between 1995 and 2020, 2,800 patents were filed for single-use bioreactors which are used in the vaccine production. Cision PR Newswire, "Outlook on the Single-Use Bioreactors Global Market to 2030 - Featuring Cytiva, Merck Millipore & Pall Among Others", 6 April 2021, www.prnewswire.com/news-releases/outlook-on-the-single-use-bioreactors-global-market-to-2030---featuring-cytiva-merck-millipore--pall-among-others-301263304.html

124. See The Straits Times, "Gzero video: IP waivers not the issue, says Moderna's CEO", 14 June 2021, www.straitstimes.com/world/united-states/gzero-video-ip-waivers-not-the-issue-says-modernas-ceo

125. Ellen 't Hoen, Jonathan Berger, Alexandra Calmy, and Suerie Moon, "Driving a decade of change: HIV/AIDS, patents and access to medicines for all", 27 March 2011, Journal of the International Aids Society, www.ncbi.nlm.nih.gov/pmc/articles/PMC3078828/

126. Ellen 't Hoen, Jonathan Berger, Alexandra Calmy, and Suerie Moon, "Driving a decade of change: HIV/AIDS, patents and access to medicines for all", 27 March 2011, Journal of the International Aids Society, www.ncbi.nlm.nih.gov/pmc/articles/PMC3078828/

3. COMPANY ASSESSMENTS

This assessment covers the six largest vaccine developers by delivery agreements in doses according to the UNICEF COVID-19 Vaccine Market Dashboard as of 20 July 2021: AstraZeneca, BioNTech, Johnson & Johnson, Moderna, Novavax, and Pfizer.¹²⁷ Amnesty International assessed the companies' human rights responsibilities against the UN Guiding Principles on Business and Human Rights (UN Guiding Principles) and related human rights law and standards. The companies were assessed on their human rights policies, their vaccine pricing structure, their records on intellectual property/technology sharing, fair allocation of available vaccine doses globally and transparency. At the time of writing, AstraZeneca, BioNTech, Johnson & Johnson, Moderna, and Pfizer, had replied to Amnesty International. Their responses, elements of which have been incorporated into the following assessments, can be read in Annex 2.

3.1 ASTRAZENECA

OVERVIEW

AstraZeneca is a British-Swedish pharmaceutical company that is manufacturing and distributing the coronavirus vaccine developed by the University of Oxford.¹²⁸ Uniquely among the companies featured in this report, AstraZeneca has pledged to supply its vaccine, “broadly and equitably at no profit during the pandemic.” The company noted that its “aim is to meet an urgent need and support healthcare systems and economies to recover. It is through this that we hope to improve the lives and health of people globally, an objective that is underpinned by our commitment to human rights.”¹²⁹

In the first half of 2021 the company reported revenues of US\$15.54 billion - including US\$ 1.169 billion from the Covid-19 vaccine, up from US\$275m in the first quarter.¹³⁰ Airfinity estimated AstraZeneca's revenue from the Covid-19 vaccine would rise to up to US\$ 8.57 billion.¹³¹ AstraZeneca has said it will deliver up to 3 billion doses of Covid-19 vaccine by the end of 2021;¹³² by early September, it had delivered 1.9 billion doses according to Airfinity.¹³³

127. UNICEF COVID-19 Vaccine Market Dashboard, Covid-19 vaccine supply agreements (by vaccine supplier) as of 20 July 2021, www.unicef.org/supply/covid-19-vaccine-market-dashboard

128. University of Oxford, “Oxford University announces landmark partnership with AstraZeneca”, 30 April 2020, www.ox.ac.uk/news/2020-04-30-oxford-university-announces-landmark-partnership-astrazeneca-development-and.

129. AstraZeneca, Email to Amnesty International, 8 June 2021, on file.

130. AstraZeneca, “H1 2021 results”, 29 July 2021, www.astrazeneca.com/content/dam/az/PDF/2021/h1-2021/H1_2021_results_announcement.pdf

131. Airfinity, Covid-19 Vaccine Weekly Intelligence Report, 6 August 2021.

132. AstraZeneca, “Pushing boundaries to deliver COVID-19 vaccines across the Globe”, www.astrazeneca.com/what-science-can-do/topics/technologies/pushing-boundaries-to-deliver-covid-19-vaccine-across-the-globe.html

133. Airfinity, Covid-19 vaccines database, 9 August 2021.

HUMAN RIGHTS POLICY

AstraZeneca has published a human rights policy on its website.¹³⁴ AstraZeneca states that “health is a human right and therefore enabling access to our medicines is vital,” and that “it is our responsibility to understand how we are contributing to or hindering human rights due to our operations.”¹³⁵

AstraZeneca’s human rights policy specifically references the UN Guiding Principles, affirming its responsibility to “prevent human rights violations by proactively identifying any issues in our business and responding promptly with appropriate action.”¹³⁶ AstraZeneca has expressed its commitment to “broad, timely and equitable access” to the University of Oxford’s Covid-19 vaccine and to “accelerate vaccine production”, and said that its entire focus “is on playing our part in ending the current pandemic and helping in our shared objective of vaccinating the world.”¹³⁷ The policy makes no reference to the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines (Human Rights Guidelines for Pharmaceutical Companies).

PUBLIC FUNDING AND VACCINE PRICING POLICIES

According to a study published as a MedRxiv preprint on public funding sources for the Oxford-AstraZeneca vaccine and the underlying ChAdOx technology which analyzed peer-review articles published between 2002 and 2020, 97.1% of the research and development (R&D) funding was from government and charitable institutions mainly from the UK, the USA and the European Commission, with the UK government providing US\$96.7 million.¹³⁸ The US government awarded US\$1.3 billion in funding to AstraZeneca for vaccine trials, manufacturing and distribution of vaccine doses to the US government.¹³⁹ AstraZeneca reached a US\$750m advanced market commitment with the Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi to support the manufacturing, procurement and distribution of 300 million doses in June 2020.¹⁴⁰ AstraZeneca has said that “while we cannot comment on behalf of the University of Oxford regarding any public funding received by the University to develop the underlying ChAdOx technology” AstraZeneca continues “incurring significant ongoing R&D costs that are not directly reimbursed by governments.”¹⁴¹

Regarding its pricing policy, AstraZeneca has provided some detail:

“At the start of the pandemic we made a commitment to make the vaccine available to as many countries as possible at no profit to support broad and equitable access around the world. However, given the complexity of global supply chains, cost of the vaccine can vary depending on supply chain, location and volumes requested by countries. This explains price differentiations

134. AstraZeneca, *Human Rights Statement*, www.astrazeneca.com/content/dam/az/PDF/2017/AZ-Human-Rights-Statement.pdf; AstraZeneca “Human Rights”, www.astrazeneca.com/sustainability/ethics-and-transparency/human-rights.html

135. AstraZeneca, *Human Rights Statement*.

136. AstraZeneca, *Human Rights Statement*.

137. AstraZeneca, Email to Amnesty International, 8 June 2021, on file.

138. Cross et al, “Who funded the research behind the Oxford-AstraZeneca COVID-19 vaccine? Approximating the funding to the University of Oxford for the research and development of the ChAdOx vaccine technology”, 10 April 2021, preprint, MedRxiv, doi.org/10.1101/2021.04.08.21255103

139. GovTribe, “Other Transaction IDV W15QKN2191003, Federal Contract IDV Award”, govtribe.com/award/federal-idv-award/other-transaction-idv-w15qkn2191003; GovTribe, Definitive Contract 75A50120C00114, Federal Contract Award, 2020, govtribe.com/award/federal-contract-award/definitive-contract-75a5120c00114

140. AstraZeneca, “Agreements with CEPI and Gavi and the Serum Institute of India will bring vaccine to low and middle-income countries and beyond”, 4 June 2020, www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-covid-19-vaccine.html

141. AstraZeneca said on the issue of public funding that “AZ/Oxford received funding from the UK Government that covered the majority of Oxford’s costs specific to AZD1222, but AstraZeneca has not received any funding from the UK Government for its own R&D costs incurred since the partnership was formed. AstraZeneca also received support from the US Government for the development programme of the vaccine including a Phase 3 clinical trial, but no direct funding to cover the R&D costs of the vaccine has been received by any other government.” AstraZeneca, Email to Amnesty International, 13 September 2021, on file.

between different countries. In addition to the manufacturing costs, AstraZeneca is incurring costs globally that include clinical development, regulatory, distribution, pharmacovigilance and other expenses.”¹⁴²

However, AstraZeneca has not disclosed the actual costs of production, individual cost items, sources of external funding, prices charged in different countries, or contractual terms and conditions, and information about discounting, donations, and advance order guarantees. This makes it hard to assess its commitment to providing the vaccine at no profit during the pandemic.

Numerous media reports show that prices charged for some vaccines manufactured under licence by the Serum Institute of India (SII) under the brand name COVISHIELD™ have been more expensive than otherwise charged when manufactured by AstraZeneca and other subcontractors.¹⁴³ This has resulted, for example, in South Africa, Mexico, Brazil, Bangladesh and Uganda, which are low-to-middle-income countries, paying more than high-income countries in the European Union. AstraZeneca has said that the India Serum Institute’s “COVISHIELD™ is priced “according to our global no profit commitment” and that any pricing differential is due to “supply chain, location and volumes requested by countries”.¹⁴⁴ The AstraZeneca’s vaccine is currently priced at between US\$2.12 and US\$8 per dose.¹⁴⁵

AstraZeneca’s pricing commitment extends to “the pandemic period,” while its partner the University of Oxford stated that a “key element of Oxford’s partnership with AstraZeneca is the joint commitment to provide the vaccine on a not-for-profit basis for the duration of the pandemic across the world, and in perpetuity to low- and middle-income countries.”¹⁴⁶ CEO Pascal Soriot has said: “We can’t be at no profit for ever, but we will never intend to make large profits. We’ll definitely have affordable prices, which tier the pricing at different levels depending on the wealth of the various countries.”¹⁴⁷ It is unclear what prices will be charged “post-pandemic”, or how “post-pandemic” will be defined.¹⁴⁸

INTELLECTUAL PROPERTY RIGHTS AND KNOWLEDGE/TECHNOLOGY SHARING

AstraZeneca was assigned exclusive patent rights by the University of Oxford whose default position had originally been to donate intellectual property rights through “non-exclusive, royalty-free licences”.¹⁴⁹ At the urging of the Bill Gates Foundation, which argued that the University of Oxford needed to partner with a pharmaceutical company to bring the vaccine to market, the University

142. AstraZeneca, Email to Amnesty International, 8 June 2021, on file.

143. The Guardian, “South Africa paying more than double EU price for Oxford vaccine”, 22 January 2021, www.theguardian.com/world/2021/jan/22/south-africa-paying-more-than-double-eu-price-for-oxford-astrazeneca-vaccine; Government of Mexico, Foreign Affairs-Health-Defense-BIRMEX-IMSS Joint Press Release, “Mexico receives shipment of 870,000 doses of SARS-CoV-2 vaccine”, 14 February 2021, www.gob.mx/sre/prensa/mexico-receives-shipment-of-870-000-doses-of-sars-cov-2-vaccine; Ihar Digital, “AstraZeneca vaccine is two and a half times more expensive in Brazil than in Europe”, 22 January 2021, olhardigital.com.br/en/2021/01/22/noticias/vacina-da-astrazeneca-e-duas-vezes-e-meia-mais-cara-no-brasil-que-na-europa/; BBC Bangla, “Corona virus vaccine: How much will Bangladesh have to pay, who will not be vaccinated” (in Bengali), 12 January 2021, www.bbc.com/bengali/news-55634668; The East African, “Uganda’s price of Oxford vaccine raises concern”, 10 February 2021, www.theeastafrican.co.ke/tea/news/east-africa/uganda-s-price-of-oxford-vaccine-raises-concern-3285774; AstraZeneca told Amnesty International that the Serum Institute does not supply COVISHIELD™ vaccines to Brazil or Mexico, Email to Amnesty International, 13 September 2021, on file.

144. AstraZeneca, Email to Amnesty International, 8 June 2021, on file, see AstraZeneca’s full statement on R&D funding in Annex 3.

145. Knowledge Portal, Reported Price/Dose for Covid-19 Vaccine Candidates, www.knowledgeportal.org/covid19-vaccine-arrangements

146. University of Oxford, “Oxford University breakthrough on global COVID-19 vaccine”, 23 November 2020, www.ox.ac.uk/news/2020-11-23-oxford-university-breakthrough-global-covid-19-vaccine

147. Financial Times, “AstraZeneca reveals strong Covid vaccine sales but warns of US approval delays”, 29 July 2021, www.ft.com/content/8e14257f-8bf8-4dc7-9680-9d489654d2b6

148. Financial Times, “AstraZeneca vaccine document shows limit of no-profit pledge”, 7 October 2020, www.ft.com/content/c474f9e1-8807-4e57-9c79-6f4af145b686; Guardian, “AstraZeneca vaccine price pledge omits some poor countries, contract shows”, 17 June 2021, www.theguardian.com/world/2021/jun/17/astrazeneca-vaccine-price-pledge-omits-some-poor-countries-contract-shows

149. Oxford University Innovation, “Technologies Available”, innovation.ox.ac.uk/technologies-available/technology-licensing/expedited-access-covid-19-related-ip/

subsequently sold exclusive rights to its vaccine technology to AstraZeneca.¹⁵⁰ AstraZeneca has publicly opposed sharing of intellectual property through C-TAP, describing it as a block on innovation.¹⁵¹ AstraZeneca has also lobbied the US Biden administration to oppose proposals put forward by India and South Africa to the WTO Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) to suspend critical intellectual property provisions of the TRIPS Agreement.¹⁵² A letter signed by its Chief Executive Officer with those of other leading pharmaceutical companies, argued that the sharing of copyrights, industrial designs, patents and trade secrets would not widen distribution of the vaccine.¹⁵³ The Pharmaceutical Research and Manufacturers of America, which represents AstraZeneca and other companies, has actively lobbied the US Congress against the TRIPS waiver.¹⁵⁴ In April 2021, AstraZeneca joined other pharmaceutical companies to launch the 'IP Pact', a declaration of 10 principles on intellectual property, which promotes intellectual property protection as the "cornerstone" for a "dynamic and thriving research ecosystem."¹⁵⁵

AstraZeneca has stated that it has shared its technology and knowledge with over 20 supply partners across 15 countries, including four regional sublicensing agreements in Brazil, China, India and Russia.¹⁵⁶ While AstraZeneca's licence agreements have contributed to an increased production, including for local markets, its reluctance to issue a global, non-exclusive licences or participate in C-TAP remain barriers to fair access to the Covid-19 vaccine.

VACCINE ALLOCATION AND SEQUENCING

According to AstraZeneca, over one billion doses of its viral vector Covid-19 vaccine have been supplied to over 170 countries globally to date.¹⁵⁷ AstraZeneca has agreed to supply 410 million doses with an option for a further 310 million to the COVAX Facility, and was the first vaccine developer to commit doses to COVAX.¹⁵⁸ In June 2021, AstraZeneca said that it had delivered "96 percent of the 70m+ doses supplied to over 120 countries through COVAX".¹⁵⁹ However, due to India's export ban on Covid-19 vaccines in April 2021, delivery of the AstraZeneca vaccine manufactured by the Serum Institute of India (SII) has been stalled to date: between February and May 2021, SII was supposed to have supplied COVAX with more than 100 million doses, but delivered only 29.9 million.¹⁶⁰ AstraZeneca's supply commitment to COVAX relied mainly on production in India and not on diversified supply.¹⁶¹

150. Washington Post Live, "Melinda Gates on whether Oxford should've allowed their vaccine to be open sourced," 27 January 2021, www.washingtonpost.com/video/washington-post-live/wplive/melinda-gates-on-whether-oxford-shouldve-allowed-their-vaccine-to-be-open-sourced/2021/01/27/7475d269-1ae8-4d7b-8cd6-66476dd8f538_video.html

151. See comment by Pascal Soriot, CEO of AstraZeneca, "If you don't protect IP then essentially there is no incentive for anyone to innovate.", quoted by The Financial Times, "Pandemic reopens wounds on IP rights", 18 June 2020, www.ft.com/content/9ed5ca5e-9360-11ea-899a-f62a20d54625

152. Reuters, "Top U.S. trade negotiator meets Pfizer, AstraZeneca execs on COVID-19 IP waiver", 5 May, 2021, www.reuters.com/business/healthcare-pharmaceuticals/top-us-trade-negotiator-meets-pfizer-astrazeneca-execs-covid-19-ip-waiver-2021-04-27/

153. Letter from PhRMA to President Biden, 5 March 2021, patentdocs.typepad.com/files/2021-03-05-phrma-letter.pdf

154. The Intercept, "Documents reveal pharma plot to stop generic covid-19 vaccine waiver", 14 May, 2021, theintercept.com/2021/05/14/covid-vaccine-waiver-generic-phrma-lobby/

155. IP Principles for Advancing Cures and Therapies, 26 April 2021, www.interpat.org/wp-content/uploads/IP-PACT.pdf

156. AstraZeneca, "Agreements with CEPI and Gavi and the Serum Institute of India will bring vaccine to low and middle-income countries and beyond", 4 June, 2020. AstraZeneca, "Significant milestone reached as 100 countries receive vaccine through COVAX", 8 April 2021, www.astrazeneca.com/media-centre/articles/2021/significant-milestone-reached-as-100-countries-receive-vaccine-through-covax.html

157. AstraZeneca, Email to Amnesty International, 8 June 2021, on file.

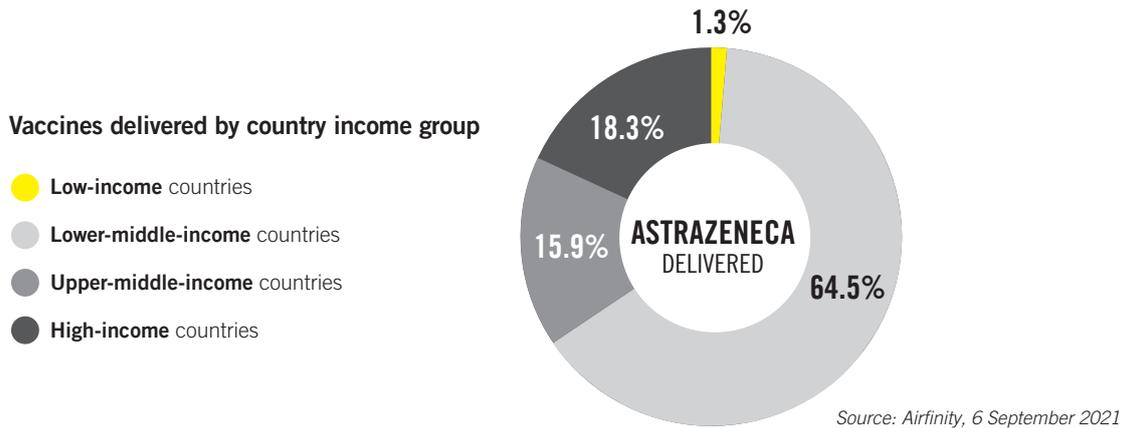
158. UNICEF, Covid-19 Vaccine Market Dashboard, Number of agreements, AstraZeneca, www.unicef.org/supply/covid-19-vaccine-market-dashboard; Gavi, "Gavi launches innovative financing mechanism for access to COVID-19 vaccines", 4 June 2020, www.gavi.org/news/media-room/gavi-launches-innovative-financing-mechanism-access-covid-19-vaccines

159. AstraZeneca, Email to Amnesty International, 8 June 2021, on file.

160. Gavi, Vaccine Rollout, www.gavi.org/covax-vaccine-roll-out

161. Business Today India, "WHO working with AstraZeneca, SII, Indian govt to restart Covid-19 shipments", 27 July 2021, www.businesstoday.in/latest/economy-politics/story/who-working-with-astrazeneca-sii-indian-govt-to-restart-covid-19-vaccine-shipments-299131-2021-06-19

As of August 2021, over half of the vaccine doses delivered by COVAX had been supplied by AstraZeneca, as donations by the USA of Moderna and Johnson & Johnson vaccines increased their relative proportions.¹⁶² According to data gathered by Airfinity, 27.4% of AstraZeneca's orders for 2021 are for high-income countries, compared to 16.8% for upper-middle-income countries, 33.7% for lower-middle income countries, 1.7% low-income countries and 20.4% for COVAX.¹⁶³ In terms of deliveries, including those through COVAX, 18.3% of vaccines delivered by AstraZeneca were in high-income countries, 15.9% were in upper-middle-income countries, 64.5% in lower-middle-income countries and 1.3% in low-income countries.¹⁶⁴ This includes over 66 million doses bought by countries including Australia, Canada, Denmark, France, India, Japan, Mexico, New Zealand and the UK, and then donated either bilaterally or via COVAX.



SUMMARY

AstraZeneca has a human rights policy in place which references the UN Guiding Principles. The company has committed to selling its vaccines at cost price, which is to be welcomed. There is a lack of transparency around its pricing policy, but prices are at the lower end of the industry spectrum. AstraZeneca has provided the majority of the supplies to date for COVAX, though India's export ban has significantly reduced its capacity to deliver due to a lack of diversification of supply. Over 20% of AstraZeneca's supply for 2021 is committed to COVAX, and a further 35% is committed to low and lower-middle-income countries, which is substantially more than some of its industry peers.¹⁶⁵ AstraZeneca has shared knowledge and technology through more than 20 supply partnerships, including four regional sublicensing agreements, however the company's reluctance to share intellectual property more widely and fully cooperate with the WHO's knowledge-sharing initiatives remain barriers to fair access to the Covid-19 vaccine. Additionally, AstraZeneca's lobbying activities which aim to discourage countries from supporting the TRIPS waiver are also in conflict with its human rights responsibilities.

162. Airfinity, Covid-19 vaccines database, 9 August 2021.

163. Airfinity, Covid-19 vaccines database, 9 August 2021. Note that Airfinity estimates that 75% of COVAX deliveries go to low- and lower middle-income countries.

164. Airfinity, Covid-19 vaccines database, 6 September 2021.

165. AstraZeneca has added that "approximately 62% of the 1.2 billion doses released for supply by AstraZeneca and its sublicense partners have gone to low and middle income countries," Email to Amnesty International, 13 September 2021, on file.



People gather for a protest demanding German Chancellor Angela Merkel, Pfizer, and wealthy nations make the coronavirus vaccine and treatments more accessible during a protest in Manhattan in New York, on 14 July 2021. © Michael M. Santiago/Getty Images.

3.2 JOHNSON & JOHNSON

OVERVIEW

Johnson & Johnson is a multinational corporation headquartered in New Jersey, in the USA, developing medical devices, pharmaceuticals and consumer goods.¹⁶⁶ Its 100% owned subsidiary, the Netherlands-based Janssen Vaccines and Prevention B.V. developed its viral vector Covid-19 vaccine, which was approved in the USA in February 2021 and in the EU the following month.¹⁶⁷ Johnson & Johnson reported US\$264 million in sales for its Covid-19 vaccine for the first two quarters of 2021 and has stated that it forecasts US\$2.5 billion in sales in 2021 with production levels at 500 to 600 million doses.¹⁶⁸ By early September 2021, Johnson & Johnson had delivered just over 109 million doses.¹⁶⁹

In contrast to other approved vaccines, the Janssen/Johnson & Johnson vaccine is single dose and is easy to store and ship, making it particularly effective for use in remote and marginalized populations and in countries with poorly provisioned health care systems where follow-up doses may be difficult to achieve. Johnson & Johnson has said that the company is “committed to equitable, global access to new COVID-19 vaccines.”¹⁷⁰ Similar to AstraZeneca, the company also pledged to distribute its vaccine “on a not-for-profit basis for emergency pandemic use.”¹⁷¹

166. Johnson & Johnson, www.jnj.com

167. U.S. Food and Drug Administration, “FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine,” 27 February 2021, www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine; European Medicines Agency, “EMA recommends COVID-19 Vaccine Janssen for authorisation in the EU,” 11 March 2021, www.ema.europa.eu/en/news/ema-recommends-covid-19-vaccine-janssen-authorisation-eu

168. Johnson & Johnson, “Sales of key products/franchises”, johnsonandjohnson.gcs-web.com/static-files/3544469e-12e1-4995-91cc-c47496ffb09a; Reuters, “J&J forecasts \$2.5 bln in 2021 COVID-19 vaccine sales, sets lower production target Johnson & Johnson” 21 July 2021, www.reuters.com/business/healthcare-pharmaceuticals/johnson-johnson-forecasts-25-blm-2021-sales-covid-19-shot-2021-07-21/

169. Airfinity, Covid-19 vaccine database, 6 September 2021.

170. Johnson & Johnson, “Johnson & Johnson Announces Advance Purchase Agreement with the African Vaccine Acquisition Trust for the Company’s COVID-19 Vaccine Candidate”, 29 March 2021, <https://www.janssen.com/johnson-johnson-announces-advance-purchase-agreement-african-vaccine-acquisition-trust-companys-0>

171. Johnson & Johnson, “Johnson & Johnson COVID-19 Vaccine Authorized by U.S. FDA For Emergency Use - First Single-Shot Vaccine in Fight Against Global Pandemic,” 27 February 2021, www.jnj.com/johnson-johnson-covid-19-vaccine-authorized-by-u-s-fda-for-emergency-use-first-single-shot-vaccine-in-fight-against-global-pandemic

HUMAN RIGHTS POLICY

Johnson & Johnson has published a human rights policy on its website.¹⁷² The company says that its commitment to human rights is “guided” by the UN Guiding Principles and other international standards.¹⁷³ The policy makes no reference to the Human Rights Guidelines for Pharmaceutical Companies.¹⁷⁴ The company states that it sees itself as having “an opportunity to positively impact the protection of human rights within our sphere of influence”.

PUBLIC FUNDING AND VACCINE PRICING POLICIES

Johnson & Johnson has not publicly disclosed the actual costs of production, individual cost items, sources of external funding, prices charged in different countries, or contractual terms and conditions, and information about discounting, donations, and advance order guarantees. This makes it difficult to assess its commitment to provide its Covid-19 vaccine on a not-for-profit basis, or what it means when it states that this commitment only extends “for emergency pandemic use”.¹⁷⁵ In its letter to the company, Amnesty International asked whether it intended to increase the price of the vaccine after the pandemic was declared over, however that was defined.¹⁷⁶ Johnson & Johnson did not clarify its intention relating to future pricing, but stated that they “currently charge the same not-for-profit price globally”.¹⁷⁷

Johnson & Johnson (along with Pfizer) has fought resolutions filed by activist shareholders for the disclosure of information about how public funding will be taken into consideration in the decision-making on access to vaccines and pricing.¹⁷⁸ According to the U.S. Department of Health and Human Services and Department of Defense Johnson & Johnson’s subsidiary Janssen Vaccines has received US\$456 million for clinical trials and approximately US\$1 billion to support manufacture from the US government’s Biomedical Advanced Research and Development Authority (BARDA).¹⁷⁹ According to the Knowledge Portal, Johnson & Johnson’s vaccines have been priced at between US\$3.50 - \$10.¹⁸⁰ Prices tweeted by a Belgian government minister indicated that the EU has paid US\$8.50 per dose; according to UNICEF the African Union and the USA have paid US\$10 per dose.¹⁸¹ While in May 2021, Johnson & Johnson was reported stating that price differentials were due to net costs of the vaccine and production volumes,¹⁸² in September 2021 the company wrote in an email to Amnesty International that the provisional not-for-profit price in Advance Purchase Agreements (APAs) had

172. Johnson & Johnson, “Position on human rights”, www.jnj.com/about-jnj/policies-and-positions/our-position-on-human-rights; Janssen Pharmaceuticals also uses Johnson & Johnson’s human rights policy, see www.janssen.com/uk/modern-slavery-act-statement-2019

173. Johnson & Johnson, “Better Health for All”, healthforhumanityreport.jnj.com/better-health-for-all

174. Johnson & Johnson, “Position on human rights”, www.jnj.com/about-jnj/policies-and-positions/our-position-on-human-rights

175. Johnson & Johnson, “Johnson & Johnson COVID-19 Vaccine Authorized by U.S. FDA For Emergency Use - First Single-Shot Vaccine in Fight Against Global Pandemic,” 27 February 2021, www.jnj.com/johnson-johnson-covid-19-vaccine-authorized-by-u-s-fda-for-emergency-use-first-single-shot-vaccine-in-fight-against-global-pandemic

176. Amnesty International, Letter to Johnson & Johnson, 26 May 2021, on file.

177. Johnson & Johnson, Email to Amnesty International, 14 September 2021, on file.

178. Skadden, Arps, Slate, Meagher & Flom, “LLP to US Securities Exchange Commission, Johnson & Johnson”; 11 December 2020, www.sec.gov/divisions/corpfin/cf-noaction/14a-8/2020/oxfamjohnson121120-14a8-incoming.pdf; Newsweek, “COVID-19 Vaccine Developers Ask the SEC to Help Keep the Secret of How They Set Prices”, 2 January 2021, www.newsweek.com/covid-19-vaccine-developers-ask-sec-help-keep-secret-how-they-set-prices-1565904

179. US Department of Defense, “HHS, DOD Collaborate with Johnson & Johnson to Produce Millions of COVID-19 Investigational Vaccine Doses”, 5 August 2020, www.defense.gov/Newsroom/Releases/Release/Article/2301220/hhs-dod-collaborate-with-johnson-johnson-to-produce-millions-of-covid-19-invest/

180. Knowledge Portal, Covid-19 Vaccine Access, Reported Price/Dose for COVID-19 Vaccines, www.knowledgeportal.org/covid19-vaccine-arrangements

181. UNICEF, COVID-19 Vaccine Market Dashboard, www.unicef.org/supply/covid-19-vaccine-market-dashboard; New York Times, “A European Official Reveals a Secret: The U.S. Is Paying More for Coronavirus Vaccines,” 18 December 2020, www.nytimes.com/2020/12/18/upshot/coronavirus-vaccines-prices-europe-united-states.html

182. Reuters, “J&J forecasts \$2.5 bln in 2021 COVID-19 vaccine sales, sets lower production target”, 21 July 2021, www.reuters.com/business/healthcare-pharmaceuticals/johnson-johnson-forecasts-25-bln-2021-sales-covid-19-shot-2021-07-21/

been agreed not to exceed US\$10, but that the price had later been fixed at US\$7.50 and would apply “globally, regardless of country”.¹⁸³

INTELLECTUAL PROPERTY RIGHTS AND KNOWLEDGE/TECHNOLOGY SHARING

Johnson & Johnson has refused to share its technology through the WHO’s COVID-19 Technology Access Pool (C-TAP), and lobbied the US Biden administration to oppose proposals put forward by India and South Africa to the WTO Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) to suspend critical intellectual property provisions of the TRIPS Agreement.¹⁸⁴ A letter signed by Johnson & Johnson’s Executive Vice President, along with CEOs from other leading pharmaceutical companies, argued that the sharing of copyrights, industrial designs, patents and trade secrets would not widen distribution of the vaccine.¹⁸⁵ The Pharmaceutical Research and Manufacturers of America, which represents Johnson & Johnson among other pharmaceutical companies, has actively lobbied the US Congress against the TRIPS waiver.¹⁸⁶ In April 2021, Johnson & Johnson joined other pharmaceutical companies to launch the ‘IP Pact’, a declaration of 10 principles on intellectual property, which promotes intellectual property protection as the cornerstone for innovation.¹⁸⁷

Johnson & Johnson has announced plans to scale up production through partnerships with the US Department of Health and Human Services and the pharmaceutical company Merck.¹⁸⁸ Johnson & Johnson is currently manufacturing its vaccine in France, Germany, India, Italy, the Netherlands, Spain, South Africa and the USA, but has rejected a request for a voluntary licence from Canadian company, Biolyse Pharma which is now seeking a compulsory licence from the Canadian government to manufacture the Johnson & Johnson vaccine to supply Bolivia.¹⁸⁹

Johnson & Johnson has entered into a limited number of bilateral licence agreements with partners in Europe, North America, India and South Africa.¹⁹⁰ The South African manufacturer has been contracted to ‘fill and finish’ vaccines but had to stall production following the contamination of material during production in Baltimore.¹⁹¹ An arrangement whereby Johnson & Johnson was shipping millions of Covid-19 vaccine doses to Europe that had been filled and finished in South Africa was suspended after media reports and intervention from the South African president.¹⁹² Johnson & Johnson’s reluctance to issue a global, non-exclusive licences or participate in C-TAP and fully cooperate with the WHO’s knowledge-sharing initiatives remain barriers to fair access to the Covid-19

183. Johnson & Johnson, Email to Amnesty International, 14 September 2021, on file.

184. The Telegraph, “WHO patent pool for potential Covid-19 products is ‘nonsense’, pharma leaders claim,” 29 May 2020, www.telegraph.co.uk/global-health/science-and-disease/patent-pool-potential-covid-19-products-nonsense-pharma-leaders/

185. PhRMA, “Letter to US President Joseph R. Biden”, 5 March 2021, patentdocs.typepad.com/files/2021-03-05-phrma-letter.pdf

186. The Intercept, “Documents reveal pharma plot to stop generic COVID-19 vaccine waiver”, 14 May 2021, theintercept.com/2021/05/14/covid-vaccine-waiver-generic-pharma-lobby/

187. IP Principles for Advancing Cures and Therapies, 26 April 2021, cdn.pfizer.com/pfizercom/IP_PACT_DOCUMENT_FINAL.pdf

188. Johnson & Johnson, “Statement on Collaboration with Merck U.S. Department of Health and Human Services,” 2 March 2021, www.jnj.com/johnson-johnson-statement-on-collaboration-with-merck; “Biden Administration announces historic manufacturing collaboration between Merck and Johnson & Johnson to expand production of COVID-19 vaccines”, 2 March 2021, www.hhs.gov/about/news/2021/03/02/biden-administration-announces-historic-manufacturing-collaboration-between-merck-johnson-johnson-expand-production-covid-19-vaccines.html

189. Knowledge Portal, COVID-19 Vaccine Manufacturing, Locations of COVID-19 Vaccine Manufacturers, www.knowledgeportalia.org/covid19-vaccine-manufacturing; PRI, “A Canadian company challenges vaccine rules to increase access,” 1 April 2021, www.pri.org/stories/2021-03-31/canadian-company-challenges-vaccine-rules-increase-access

190. Knowledge Portal, COVID-19 Vaccine Manufacturing, Locations of COVID-19 Vaccine Manufacturers, www.knowledgeportalia.org/covid19-vaccine-manufacturing

191. Reuters, “S.Africa to analyse J&J vaccines made at U.S. plant halted over error,” 12 June 2021, www.reuters.com/world/africa/safrica-analyse-ji-vaccines-made-us-plant-halted-over-error-2021-06-12/

192. Reuters, “J&J vaccine shipments from S.Africa to Europe halted, AU says”, 2 September 2021, [J&J vaccine shipments from S.Africa to Europe halted, AU says \(msn.com\)](http://www.reuters.com/world/africa/jj-vaccine-shipments-from-safrica-to-europe-halted-au-says-2021-09-02/)

vaccine. Additionally, Johnson & Johnson’s lobbying activities which aim to discourage countries from supporting the TRIPS waiver are also in conflict with its human rights responsibilities.

VACCINE ALLOCATION AND SEQUENCING

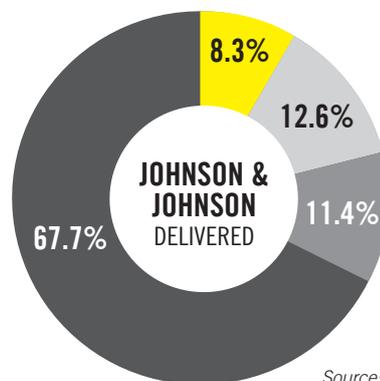
Johnson & Johnson has announced plans to supply 500 million doses to the COVAX Facility - a commitment of 200 million doses and an option to procure an additional 300 million doses – as well as a contract for a further 220 million doses for the African Union (AU) with an option for a further 180 million doses. However the company stated that its deliveries will only commence in the third quarter of 2021, and are predominantly due in 2022.¹⁹³ Only 50 million doses under the AU contract are expected to be delivered in 2021.¹⁹⁴ Johnson & Johnson has also reached agreements to supply countries including: Brazil (38 million); Canada (38 million); Chile (4 million); Colombia (9 million); the European Union (236 million), New Zealand (5 million), South Africa (31 million); Philippines (5 million); UK (52 million); and the USA (300 million).¹⁹⁵

According to data gathered by Airfinity, 46.8% of Johnson & Johnson’s orders for 2021 are for high-income countries, compared to 6.4% for upper-middle-income countries, 26.8% for lower-middle-income countries, 0.6% for low-income countries, and 19.4% for COVAX.¹⁹⁶ Deliveries to date are even further skewed towards high-income countries. By 6 September 2021, 67.7% of vaccines delivered by Johnson & Johnson were in high-income countries, compared to 11.4% in upper-middle-income countries, 12.6% in lower-middle income countries, and 8.3% in low-income countries. This includes 20 million doses bought by the US and donated to COVAX, and a further nine million donated bilaterally.¹⁹⁷

Slow delivery through COVAX and Johnson & Johnson’s decision to commit over half of its doses in 2021 to high- and upper-middle-income countries show that the company is failing to discharge its human rights responsibilities. This is particularly concerning as there had been high expectations that this vaccine would make a significant impact in effective vaccination rates as a single dose vaccine, allowing more transient populations to become fully immunized with a single shot and achieving higher inoculation rates in a shorter period of time.

Vaccines delivered by country income group

- Low-income countries
- Lower-middle-income countries
- Upper-middle-income countries
- High-income countries



Source: Airfinity, 6 September 2021

193. Johnson & Johnson, “Johnson & Johnson Announces Agreement in Principle with Gavi to Supply Janssen’s COVID-19 Vaccine Candidate to Lower-Income Countries in 2021”, 18 December 2020, www.jnj.com/our-company/johnson-johnson-announces-agreement-in-principle-with-gavi-to-supply-janssens-covid-19-vaccine-candidate-to-lower-income-countries-in-2021; Devex, “African Union struggles to garner interest in its J&J vaccines”, 10 May, 2021, www.devex.com/news/african-union-struggles-to-garner-interest-in-its-j-j-vaccines-99859

194. UNECA, “Africa announces the rollout of 400m vaccine doses to the African Union Member States and the Caribbean”, 5 August 2021, www.un.org/africarenewal/news/africa-announces-rollout-400m-vaccine-doses-african-union-member-states-and-caribbean

195. UNICEF COVID-19 Vaccine Market Dashboard, “Bilateral/multilateral agreement: secured doses by manufacturer”, www.unicef.org/supply/covid-19-vaccine-market-dashboard, accessed on 9 September 2021.

196. Airfinity, Covid-19 vaccines database, 9 August 2021. Note that Airfinity has included the agreed supply of doses to the African Union in the lower middle-income category, as it is not yet known how many will be delivered to each country. Airfinity also estimate that 75% of COVAX deliveries go to low- and lower middle-income countries.

197. Airfinity, Covid-19 vaccines database, 9 August 2021.

SUMMARY

Johnson & Johnson has a human rights policy based on international standards of corporate responsibility and the right to health. Like AstraZeneca, it has committed to selling its vaccine on a not-for-profit basis which is a positive step. While difficult to assess due to lack of transparency, Johnson & Johnson vaccines are priced at the low end of the industry spectrum. On dose allocation, a majority of doses so far delivered have been committed to upper-middle- and high-income countries. Johnson & Johnson has made significant commitments towards COVAX and the African Union, but roll-out sequencing means most of these doses will not be delivered until 2022. Given this vaccine's great potential for reaching poor and remote communities, Johnson & Johnson's decisions on vaccine allocation represent a missed opportunity for ensuring wide access to essential medicines to those in need. Johnson & Johnson's reluctance to widely share intellectual property, knowledge, and technology transfers – even when directly requested by Biolyse - and fully cooperate with the WHO's knowledge-sharing initiatives have reduced potential production and remain barriers to fair access.¹⁹⁸



Scientists at work in the VirPath University laboratory in Lyon, France on 5 February, 2020, as they try to find an effective treatment against the coronavirus. © JEFF PACHOUD/AFP via Getty Images

3.3 MODERNA

OVERVIEW

Moderna is a biotechnology company based in Cambridge, Massachusetts, in the USA. Founded in 2010, Moderna is a pioneer in developing mRNA technology.¹⁹⁹ It has made no commitment to distribute its vaccine equitably or at cost price, unlike AstraZeneca and Johnson & Johnson. But in contrast to the other vaccine developers, in October 2020, Moderna announced that, “it will not enforce its COVID-19 related patents against those making vaccines intended to combat the pandemic”.²⁰⁰ Moderna has agreements to supply 1 billion doses in 2021, and by 6 September 2021 446.5 million doses had been delivered.²⁰¹

198. Johnson & Johnson has stated that the company has used its intellectual property “to foster innovation and scale manufacturing in the most effective and efficient way to produce the vaccine and address the human right to health” and that the company has developed “12 partnerships across four continents” each involving the sharing of technology and know-how, Email to Amnesty International, 14 September 2021, on file.

199. Moderna, “About us”, www.modernatx.com/about-us

200. Moderna, “Statement by Moderna on Intellectual property Matters during the COVID-19 Pandemic”, 8 October 2020, investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19

201. Airfinity, Covid-19 vaccine database, 9 August 2021.

Moderna's financial situation has been dramatically improved by sales of its Covid-19 vaccine. It reported a total revenue of \$803 million in 2020, compared to only \$60 million in 2019.²⁰² More recently it reported that it had received revenues of \$4.4 billion for the second quarter of 2021, a huge increase on the US\$67 million it reported having earned during the same period in 2020.²⁰³ Moderna, with estimated sales of US\$18.4 billion in 2021, could yield profits of US\$8 billion.²⁰⁴ Airfinity has estimated that Moderna's revenue from Covid-19 vaccines will increase again sharply in 2022, to \$25.9 billion.²⁰⁵

HUMAN RIGHTS POLICY

Moderna has published a human rights policy on its website.²⁰⁶ This states that human rights are inherent in its "values and our commitments."²⁰⁷ The policy recognizes the positive role that Moderna's vaccines can play in "improving human rights through improved health outcomes." But the policy makes no reference to the UN Guiding Principles, or the Human Rights Guidelines for Pharmaceutical Companies. On 23 December 2020, Moderna published a document entitled, "Moderna's Commitment to Vaccines and Therapeutics Access."²⁰⁸ This includes a commitment to "provide effective and affordable vaccines and therapeutics to all populations".

PUBLIC FUNDING AND VACCINE PRICING POLICIES

The US government has provided Moderna with substantial support to develop its mRNA-1273 vaccine. The vaccine was "co-developed" with scientists from a US public health institution, the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health.²⁰⁹ These agencies also supported the vaccine's non-clinical studies and clinical trials.²¹⁰ Another US governmental agency, the Biomedical Advanced Research and Development Authority (BARDA), also supported clinical trials, as well as "vaccine manufacturing scale up and other development activities".²¹¹

BARDA awarded Moderna with a total of US\$955 million dollars to support the vaccine's development in April and July 2020.²¹² The USA has also committed to purchasing 500 million doses from Moderna, more than any other country.²¹³ In February 2021, the US federal government announced that its total investment in Moderna, including "vaccine development, clinical trials, manufacturing and purchase"

202. Moderna, "Moderna Reports Fourth Quarter and Fiscal Year 2020 Financial Results and Provides Business Updates", 25 February 2021, investors.modernatx.com/news-releases/news-release-details/moderna-reports-fourth-quarter-and-fiscal-year-2020-financial

203. Moderna, "Moderna Reports Second Quarter Fiscal Year 2021 Financial Results and Provides Business Updates", 5 August 2021, <https://investors.modernatx.com/node/12566/pdf>

204. Financial Times, "Pfizer expects \$15bn in Covid vaccine revenue this year", 2 February 2021, www.ft.com/content/0f1ab138-401d-40ff-824f-f6879704f10e

205. Airfinity, "Covid-19 vaccine weekly intel report", 5 August 2021.

206. Moderna, "CRS Policies and Data", www.modernatx.com/responsibility/csr-policies-data

207. Moderna, Human Rights Policy, www.modernatx.com/sites/default/files/content_documents/Human-Rights-Policy.pdf

208. Moderna, "Moderna's Commitment to Vaccines and Therapeutics Access", 23 December 23 2020, investors.modernatx.com/news-releases/news-release-details/modernas-commitment-vaccines-and-therapeutics-access

209. U.S. Department of Health & Human Service, "Biden Administration purchases additional doses of COVID-19 vaccines from Pfizer and Moderna", 11 February 2021 www.hhs.gov/about/news/2021/02/11/biden-administration-purchases-additional-doses-covid-19-vaccines-from-pfizer-and-moderna.html

210. U.S. Department of Health & Human Service, "Biden Administration purchases additional doses of COVID-19 vaccines from Pfizer and Moderna", 11 February 2021 www.hhs.gov/about/news/2021/02/11/biden-administration-purchases-additional-doses-covid-19-vaccines-from-pfizer-and-moderna.html

211. U.S. Department of Health & Human Service, "Biden Administration purchases additional doses of COVID-19 vaccines from Pfizer and Moderna", 11 February 2021 www.hhs.gov/about/news/2021/02/11/biden-administration-purchases-additional-doses-covid-19-vaccines-from-pfizer-and-moderna.html

212. Moderna, "Moderna Announces Expansion of BARDA Agreement to Support Larger Phase 3 Program for Vaccine (mRNA-1273) Against COVID-19," 26 July 2020, investors.modernatx.com/news-releases/news-release-details/moderna-announces-expansion-barda-agreement-support-larger-phase

213. Moderna, "U.S. Government Purchases Additional 200 Million Doses of Moderna's COVID-19 Vaccine", June 16, 2021, investors.modernatx.com/news-releases/news-release-details/us-government-purchases-additional-200-million-doses-modernas

was approximately \$5.75 billion.²¹⁴ This is on top of up to \$125 million that BARDA gave Moderna in 2016 to develop an earlier vaccine.²¹⁵ In total, the company announced it had signed purchase agreements worth \$19.2 billion in 2021.²¹⁶

Moderna stated it will price its products through differential pricing frameworks, with Gavi-eligible countries getting its lowest prices.²¹⁷ Moderna added that this commitment will be subject to an “annual independent third-party audit,” but provided no further information or commitment to make the result of these audits public.²¹⁸ Moderna has explained that its pricing strategy has two phases. During the pandemic, as defined by the World Health Organization, the company stated that it “will be responsible on pricing” and price the vaccine “below value” without explaining how this would be defined and calculated.²¹⁹ During the next phase, once the pandemic has been declared over, Moderna stated that it will “look to price in line with other innovative vaccines” and take market forces into account.

Moderna has only disclosed certain limited information about the prices it has charged to date and did not respond to an Amnesty International request for transparency on this issue. Moderna has stated that it had charged some governments US\$32-37 per dose for small volumes, with lower prices for higher volumes.²²⁰ Up to 31 December 2020 it said it had signed deals with different countries to supply a total of approximately 520 million doses, for US\$11.7 billion.²²¹ This is an average of US\$22.5 per dose (US\$45 per completed course). The company had earlier said it had sold the US government 100 million doses for between US\$12-15 per dose.²²² By contrast, South Africa reported that Moderna had offered it 200,000 doses at US\$30- US\$42 a dose.²²³ Moderna charged the EU US\$18 per dose, according to a Belgian government official, who tweeted the details, along with a list of prices from other vaccine deals.²²⁴ This price was raised to \$25.50 per dose in supply contracts concluded at a later stage.²²⁵ According to this list, Moderna charged the EU considerably more than any other vaccine developer. According to estimates based on research by Public Citizen, the Moderna vaccine could cost under US\$3 per dose to manufacture at large scale, meaning profit margins could be vast.²²⁶ Overall, Moderna’s high prices and profits, as well as its lack of transparency on pricing regimes, represent an obstacle to fair, universal access to vaccines.

214. U.S. Department of Health & Human Service, “Biden Administration purchases additional doses of COVID-19 vaccines from Pfizer and Moderna,” 11 February 2021 www.hhs.gov/about/news/2021/02/11/biden-administration-purchases-additional-doses-covid-19-vaccines-from-pfizer-and-moderna.html

215. Genetic Engineering and Biotechnological News, “Moderna Wins Up to \$125M from BARDA toward Zika mRNA Vaccine”, 7 September 2016, www.genengnews.com/topics/omics/moderna-wins-up-to-125m-from-barda-toward-zika-mrna-vaccine/

216. Moderna, “Moderna Reports First Quarter Fiscal Year 2021 Financial Results and Provides Business Updates”, 6 May 2021, <https://investors.modernatx.com/news-releases/news-release-details/moderna-reports-first-quarter-fiscal-year-2021-financial-results/>

217. Fifty-seven low-income countries are eligible to apply for vaccine support from Gavi; for country list and criteria see Gavi, “Eligibility”, www.gavi.org/types-support/sustainability/eligibility

218. Moderna, “Moderna’s Commitment to Vaccines and Therapeutics Access”, 23 December 23 2020, investors.modernatx.com/news-releases/news-release-details/modernas-commitment-vaccines-and-therapeutics-access

219. Moderna, “Second Quarter 2020 Conference Call”, 5 August 2020, edge.media-server.com/mmc/p/oybp8b26.

220. Moderna, “Second Quarter 2020 Conference Call”, 5 August 2020, edge.media-server.com/mmc/p/oybp8b26.

221. Moderna, “2020 Annual Report”, investors.modernatx.com/static-files/5105e98c-e3e7-4c09-820b-c03812af81b6

222. United States Securities and Exchange Commission, Moderna Form 8-K, 11 August 2020, , Inc., investors.modernatx.com/static-files/5ca1f25d-3452-4a63-b292-cfaf56ba49e0

223. Reuters, “South Africa says term sheet signed for 9 million J&J vaccine doses”, 5 February 2021, www.reuters.com/article/uk-health-coronavirus-safrica-vaccines-idUSKBN2A51BD

224. Guardian, “Belgian minister tweets EU’s Covid vaccine price list to anger of manufacturers”, 18 December 2020, www.theguardian.com/world/2020/dec/18/belgian-minister-accidentally-tweets-eus-covid-vaccine-price-list

225. Financial Times, “Pfizer and Moderna raise EU Covid vaccine prices”, 1 August 2021, www.ft.com/content/d415a01e-d065-44a9-bad4-f9235aa04c1a

226. Public Citizen, “How to Make Enough Vaccine for the World in One Year”, 26 May 2021, hmkus3lurbh3lbztg254fzode-wpengine.netdna-ssl.com/wp-content/uploads/mRNA-vaccine-roadmap-May-26-final.pdf; Oxfam, “Vaccine monopolies make cost of vaccinating the world against COVID at least 5 times more expensive than it could be”, 29 July 2021, www.oxfam.org/en/press-releases/vaccine-monopolies-make-cost-vaccinating-world-against-covid-least-5-times-more

INTELLECTUAL PROPERTY RIGHTS AND KNOWLEDGE/TECHNOLOGY SHARING

In contrast to the other vaccine developers, Moderna has announced that “it will not enforce its COVID-19 related patents”.²²⁷ Moderna stated that it was also “willing to license our intellectual property for COVID-19 vaccines to others for the post pandemic period.” However, the company has not publicly agreed to share its manufacturing know-how or transfer its technology to other manufacturers through bilateral agreements or via the WHO’s C-TAP or mRNA technology transfer hubs. The company argues that these are not “effective ways of rapidly expanding access”.²²⁸ In a letter to Amnesty International, the company added that it thought that “weakening intellectual property protections could impede future innovation by making it harder to fund research and development into high-risk, high-reward innovations over a long time horizon.”²²⁹ Moderna is also a member of the industry body Biotechnology Innovation Organization (BIO), which has called the proposed TRIPS waiver “a dangerous precedent” and called on the US government to “protect American companies from the coerced transfer of technology by foreign governments”.²³⁰

In response to the news that the US government would support the suspension of Covid-19 vaccine patents, Moderna’s CEO, Stephane Bancel, stated that he was “not losing sleep.” This was because, he argued, “there is no idle mRNA manufacturing capacity in the world. This is a new technology, you cannot go hire people who know how to make mRNA — those people don’t exist.”²³¹ The company has, however, demonstrated itself the possibility of expanding manufacturing and supply. Despite claiming that it was hard to “hire people who know how to make mRNA”, Moderna entered its first external partnership to manufacture its vaccine on 1 May 2020 with Lonza, a Swiss company.²³² Moderna also told Amnesty International that it was “engaged in active conversations with governments and private companies in middle- and low-income countries about partnerships to expand the manufacturing process in those countries.”²³³ The company has said it expects to be able to produce up to 3 billion doses in 2022 by ramping up its voluntary licensing agreements. Moderna’s reluctance to issue global, non-exclusive licences or participate in C-TAP and fully cooperate with the WHO’s knowledge-sharing initiatives, such as the WHO’s mRNA technology transfer hub remain barriers to fair access to the Covid-19 vaccine.

VACCINE ALLOCATION AND SEQUENCING

Moderna has supplied or agreed to supply the vast bulk of its vaccines to wealthy states, hindering fair access to essential medicines. The US has purchased 800 million doses.²³⁴ The EU has purchased 460 million.²³⁵ Moderna has also reached agreements to supply countries including Australia (25

227. Moderna, “Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic”, 8 October 2020, investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19

228. Moderna, Letter to Amnesty International, 8 June 2021, on file.

229. Moderna, Letter to Amnesty International, 8 June 2021, on file.

230. BIO, “Support of ‘TRIPS’ Waiver Sets Dangerous Precedent,” 5 May 2021, www.bio.org/press-release/support-trips-waiver-sets-dangerous-precedent

231. Financial Times, “Moderna CEO ‘didn’t lose sleep’ over US backing of patent waiver”, 6 May 2021, www.ft.com/content/607bf143-3360-4543-8cb4-b1a1c42fc41f

232. Moderna, “2020 Annual Report 2020”, p. 26, investors.modernatx.com/static-files/5105e98c-e3e7-4c09-820b-c03812af81b6

233. Moderna, Letter to Amnesty International, 8 June 2021, on file.

234. UNICEF COVID-19 Vaccine Market Dashboard, “Bilateral/multilateral agreement: secured doses by manufacturer”, www.unicef.org/supply/covid-19-vaccine-market-dashboard, accessed on 9 September 2021.

235. UNICEF COVID-19 Vaccine Market Dashboard, “Bilateral/multilateral agreement: secured doses by manufacturer”, www.unicef.org/supply/covid-19-vaccine-market-dashboard, accessed on 9 September 2021.

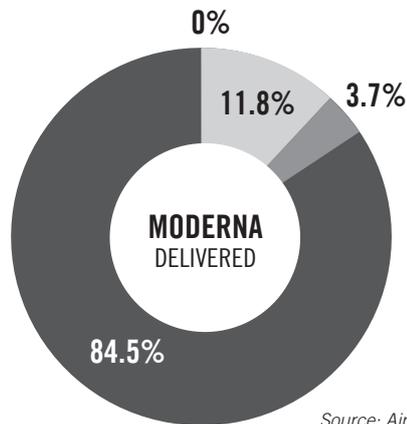
million), Canada (165 million), Japan (100 million), South Korea (40 million), the UK (17 million), Switzerland (27.5 million), Israel (10 million) and Taiwan (40 million).²³⁶ The company has disclosed agreements to supply Colombia (10 million), as well as Qatar, Singapore, the Philippines and Botswana, without providing details.²³⁷ Moderna told Amnesty International that it was in talks with India and other countries, however it provided no further details.²³⁸

In May 2021 – ten months after it began signing supply agreements with high-income countries - Moderna announced that it had reached an agreement to supply 500 million doses to 92 low- and middle-income countries via the COVAX Facility at its lowest price.²³⁹ Moderna stated that this would see it supplying an initial 34 million doses in the fourth quarter of 2021, with an option to eventually supply a further 466 million doses only in 2022.

According to data gathered by Airfinity, 87.5% of Moderna’s orders for 2021 are for high-income countries, compared to 3.6% for upper middle-income countries, 5.5% for lower-middle-income countries, 0.2% for low-income countries and 3.4% for COVAX. In terms of deliveries, by 6 September 2021, the proportions were similar, with 84.5% for high-income countries, 3.7% for upper-middle-income countries, 11.8% for lower middle-income countries and 0% for low-income countries.²⁴⁰ This includes over 43 million doses bought by the USA and donated to COVAX, and a further 15 million doses donated bilaterally.²⁴¹

Vaccines delivered by country income group

- Low-income countries
- Lower-middle-income countries
- Upper-middle-income countries
- High-income countries



Source: Airfinity, 6 September 2021

SUMMARY

Moderna has a limited human rights policy which does not reference core international business and human rights standards. It charges relatively high prices for its vaccines, compared to other companies. It has failed to specify its criteria for differential pricing for different countries during the pandemic and has offered little transparency on what this means in practice. While committing to not enforce its patents, this has meant little in practice. Like all companies assessed here, Moderna

236. UNICEF COVID-19 Vaccine Market Dashboard, “Bilateral/multilateral agreement: secured doses by manufacturer”, www.unicef.org/supply/covid-19-vaccine-market-dashboard, accessed on 9 September 2021.

237. Moderna, “2020 Annual Report”, investors.modernatx.com/static-files/5105e98c-e3e7-4c09-820b-c03812af81b6; Moderna, Letter to Amnesty International, 8 June 2021, on file.

238. Moderna, Letter to Amnesty International, 8 June 2021, on file.

239. Moderna, “Moderna Announces Supply Agreement with Gavi for up to 500 Million Doses of COVID-19 Vaccine Moderna for COVAX To Help End COVID-19 Pandemic in Lowest Income Countries”, 3 May 2021, investors.modernatx.com/news-releases/news-release-details/moderna-announces-supply-agreement-gavi-500-million-doses-covid; For a full list of previous supply agreements, see COVID-19 Vaccine Market Dashboard, Agreements, www.unicef.org/supply/covid-19-vaccine-market-dashboard

240. Airfinity, Covid-19 vaccines database, 9 August 2021. Note that Airfinity estimates that 75% of COVAX deliveries go to low- and lower middle-income countries.

241. Airfinity, Covid-19 vaccines database, 9 August 2021.

has not joined C-TAP or the WHO's mRNA technology transfer hub. The vast majority of Moderna's orders for 2021, and deliveries to date, are for high-income countries. While it has pledged significant quantities of vaccines to the COVAX Facility, over 90% of these will only be delivered in 2022. Moderna is therefore impeding full and fair access to the Covid-19 vaccine through its policies and practices.



A 90-year-old woman receives the second dose of the vaccine in her kitchen during the rural vaccination day on 8 April 2021 in Chaguani, Colombia. © Mariano Vimos/Vizzor Image/Getty Images

3.4 NOVAVAX

OVERVIEW

Novavax is a biotechnology company focusing on the development of vaccines based in Maryland, USA.²⁴² In contrast to the other vaccine developers assessed in this report, Novavax's vaccine candidate has not yet gained regulatory approval for use and therefore vaccine doses have not been distributed. In the second quarter of 2021, the company's revenue was US\$298 million, compared to US\$36 million in the same period in 2020. This increase was due to its activities in relation to its Covid-19 vaccine.²⁴³ According to UNICEF, Novavax has agreed sales of over 2.6 billion doses.²⁴⁴

242. Novavax, www.novavax.com/

243. Novavax, "Novavax reports Second Quarter 2021", 5 August 2021, Novavax Reports Second Quarter 2021 Financial Results and Operational Highlights - Aug 5, 2021

244. Airfinity, Covid-19 vaccine database, 9 August 2021.

HUMAN RIGHTS POLICY

Novavax has not published a human rights policy, but stated the company's commitment "to ensuring fair and equitable access to our vaccine around the world," adding that "we have made it among our core values to ensure that those in economically disadvantaged countries have the opportunity to receive our vaccine in parallel with the rest of the world" and "our aim is that NVX-CoV2373 can address the vast global health need and reach countless individuals, regardless of country-specific income."²⁴⁵ Novavax makes no reference to the UN Guiding Principles, or the Human Rights Guidelines for Pharmaceutical Companies in its company literature.

PUBLIC FUNDING AND VACCINE PRICING POLICY

Novavax has received about US\$2 billion external funding: the biggest share of it through the US government's Operation Warp Speed (US\$1.6 billion).²⁴⁴ Further, the U.S. Department of Defense funds up to US\$70 million for the manufacturing of its vaccine.²⁴⁷ The Coalition for Epidemic Preparedness Innovations (CEPI) agreed to invest up to US\$388 million of funding²⁴⁸ and Novavax has received further US\$15 million from the Bill & Melinda Gates Foundation.²⁴⁹ In its Annual Report section on potential risks, Novavax has listed "decisions we have made and will be making regarding the development, testing, manufacturing, allocation and pricing" as a source of potential reputational harm, given the urgency of the public health emergency and the significant funding the company has received from the US and foreign governments.²⁵⁰

In July 2020, Novavax said it is "in the process of developing a thoughtful pricing strategy" and that Novavax's pricing will be aimed at ensuring "equitable access throughout the globe."²⁵¹ Novavax has said that it expects "to supply doses to primarily high-income countries, with SIPL [Serum Institute of India, SII] providing the majority of supply for low-, middle-, and upper-middle-income countries, utilizing a tiered pricing schedule" though has not specified how this will operate in practice.²⁵² Novavax has licensed its technology to SII and "are jointly committed with SIPL to deliver the 1.1 billion doses to the COVAX Facility" in collaboration with Gavi and the Bill & Melinda Gates Foundation.²⁵³ According to Gavi, the funding by partners such as CEPI, the Bill & Melinda Gates Foundation and SII will ensure that the vaccines will have a ceiling price of US\$3 per dose.²⁵⁴ The USA has made advance purchase agreements at US\$16 a dose.²⁵⁵ Novavax has provided little in the way of information about its pricing policy towards its supplies to other countries, making an overall assessment difficult.

245. Novavax, "Annual Report 2020", p. 11, www.novavax.com/sites/default/files/2021-05/NVAX_2020_Annual_Report_FINAL.pdf

246. Novavax "Creating tomorrow's vaccine today", www.novavax.com/our-pipeline#nvx-cov2373, accessed on 7 May 2021.

247. Novavax "Creating tomorrow's vaccine today", www.novavax.com/our-pipeline#nvx-cov2373, accessed on 7 May 2021.

248. Novavax "Creating tomorrow's vaccine today", www.novavax.com/our-pipeline#nvx-cov2373, accessed on 7 May 2021.

249. Bill Gates Foundation, "Grant commitments", www.gatesfoundation.org/about/committed-grants/2020/07/INV021500, accessed on 7 May 2021.

250. Novavax "Annual Report 2020", p. 55, www.novavax.com/sites/default/files/2021-05/NVAX_2020_Annual_Report_FINAL.pdf

251. Fierce Pharma, "Where do COVID-19 vaccine players stand on pricing?", 20 June 2020, www.fiercepharma.com/pharma/where-do-covid-19-vaccine-players-stand-pricing-no-profit-slight-profit-or-discussions

252. Novavax, "Annual Report 2020", p. 11, www.novavax.com/sites/default/files/2021-05/NVAX_2020_Annual_Report_FINAL.pdf

253. Novavax, "Novavax Reports First Quarter 2021 Financial Results and Operational Highlights", 10 May 2021, ir.novavax.com/press-releases?o=10.

254. Gavi, "New collaboration makes further 100 million doses of COVID-19 vaccine available to low- and middle-income countries", 29 September 2020, www.gavi.org/news/media-room/new-collaboration-makes-further-100-million-doses-covid-19-vaccine-available-low

255. Stat news, "Sanofi and GSK land \$2.1 billion deal with U.S. for Covid-19 vaccine development and 100 million doses", www.statnews.com/2020/07/31/operation-warp-speed-sanofi-gsk-covid19-vaccine/

INTELLECTUAL PROPERTY RIGHTS AND KNOWLEDGE/TECHNOLOGY SHARING

Novavax states that it is partnering with dozens of organizations around the world to increase manufacturing capacity. This has involved “months transferring know-how to our partners to ensure they are able to manufacture doses that meet regulators’ standards for safety and effectiveness around the world.”²⁵⁶ Its production is taking place in Canada, the EU, India, South Korea, the UK, the USA and Japan.²⁵⁷

Novavax has publicly criticized proposals to waive intellectual property protections for vaccines during the pandemic. It has argued that a “TRIPS waiver could increase national barriers to the free flow of materials and vaccine doses, threatening the stability and integrity of the global supply chain.”²⁵⁸ Novavax has stated that it had “experienced a shortage of raw materials, which has impacted the timing by which we expect to realize our anticipated total manufacturing capacity.”²⁵⁹ Novavax has not issued open, non-exclusive production agreements or signed up to participating in C-TAP, potentially creating barriers to fair access to the Covid-19 vaccine.

VACCINE ALLOCATION AND SEQUENCING

Novavax states that it expects to apply for regulatory approval in the third quarter of 2021,²⁶⁰ with production increasing from 100 million doses per month by the end of the third quarter to 150 million doses per month by the fourth quarter.²⁶¹ The company states that it projects that it will produce three billion doses worldwide in 2022.²⁶²

Novavax has provided some details about supply agreements, including its notable pledge to supply countries participating in COVAX with 1.35 billion doses of its candidate vaccine – over 51% of supply commitments to date.²⁶³ It has reached an agreement with the Serum Institute of India to manufacture and distribute 750 million of these.²⁶⁴ Novavax has also reached agreements to supply Australia (51 million), Canada (76 million), the EU (200 million), Georgia (1 million), Indonesia (130 million), New Zealand (10 million), South Korea (40 million), Switzerland (6 million), the UK (60 million), Ukraine (15 million) and the USA (660 million).²⁶⁵

According to data gathered Airfinity, 32.8% of Novavax’s orders are for high-income countries, compared to 2.9% for upper-middle-income countries, 0.9% for lower-middle-income countries, 0% for low-income countries and 63.4% for COVAX.²⁶⁶

256. Novavax Statement in Opposition to the WTO TRIPS Waiver, May 07 2021, ir.novavax.com/news-releases/news-release-details/novavax-statement-opposition-wto-trips-waiver

257. Novavax, “Annual Report 2020”, p. 8, www.novavax.com/sites/default/files/2021-05/NVAX_2020_Annual_Report_FINAL.pdf

258. Novavax, “Statement in Opposition to the WTO TRIPS Waiver”, 7 May 2021, <https://ir.novavax.com/news-releases/news-release-details/novavax-statement-opposition-wto-trips-waiver>

259. Novavax, “Novavax Reports First Quarter 2021 Financial Results and Operational Highlights”, 10 May 2021, ir.novavax.com/press-releases?o=10.

260. Reuters, “EU expects key data on Novavax vaccine around October”, 20 August 2021, www.reuters.com/business/healthcare-pharmaceuticals/eu-expects-key-data-novavax-vaccine-around-october-source-2021-08-20/

261. Reuters, “Novavax delays timelines for COVID-19 vaccine regulatory filings, production”, 10 May 2021, www.reuters.com/business/healthcare-pharmaceuticals/novavax-expects-covid-19-vaccine-us-data-trial-q2-2021-05-10/

262. USA Today, “Novavax plans to present US data on its COVID-19 vaccine as soon as this month, but manufacturing will delay deliveries,” 5 May 2021, eu.usatoday.com/story/news/health/2021/05/10/novavax-ceo-request-fda-covid-vaccine-authorization-coming-soon/5023751001/

263. UNICEF COVID-19 Vaccine Market Dashboard, “Bilateral/multilateral agreement: secured doses by manufacturer”, www.unicef.org/supply/covid-19-vaccine-market-dashboard, accessed on 9 September 2021.

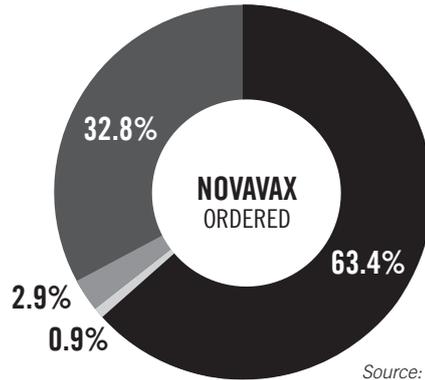
264. Novavax, “Novavax Reports First Quarter 2021 Financial Results and Operational Highlights”, 10 May 2021, ir.novavax.com/press-releases?o=10.

265. Novavax, “Novavax and Gavi Execute Advance Purchase Agreement for COVID-19 Vaccine for COVAX Facility”, 6 May 2021, ir.novavax.com/news-releases/news-release-details/novavax-and-gavi-execute-advance-purchase-agreement-covid-19; according to the Knowledge Portal, outside of COVAX commitments, Novavax has agreed to supply 1.026 billion doses.

266. Airfinity, Covid-19 vaccine database, 5 August 2021.

Novavax' supply commitments by country income group for 2021

- COVAX
- Low-income countries
- Lower-middle-income countries
- Upper-middle-income countries
- High-income countries



Source: Airfinity, 5 August 2021

SUMMARY

Novavax has no human rights policy but said it is committed to accelerate fair access to Covid-19 vaccines. If Novavax is able to follow through on its significant commitments to supply COVAX, Novavax’s overall dose allocation would be a major boost to the scheme and support fair access to essential medicines. Novavax’ opposition to the WTO TRIPS waiver and to participation in C-TAP all amount to a barrier to fair access to the Covid-19 vaccine. Due to the lack of transparency and the fact that Novavax has not yet begun its vaccine roll-out, it is not possible to assess Novavax’ pricing policy.



Members of the public queue to receive a vaccine for Covid-19 in the first drive through mass vaccination centre at Queen Margaret University Campus on 10 February, 2021 in Musselburgh, Scotland. © Jeff J Mitchell/Getty Images

3.5 PFIZER/BIONTECH

OVERVIEW

Pfizer is a US-based multinational pharmaceutical company headquartered in New York.²⁶⁷ For its second quarterly period in July 2021, Pfizer reported revenues of US\$33.6 billion so far this year – a 68% increase compared to the second quarter of 2020 - including US\$11.3 billion from sales of its Covid-19 vaccine. It also anticipated revenue of US\$33.5 billion from the Covid-19 vaccine for 2021,

267. Pfizer, www.pfizer.com/

with the gross margin to be split evenly with BioNTech.²⁶⁸ As such, Pfizer's annual total revenue in 2021 is expected to increase by roughly 89% compared to 2020, with revenue from the Covid-19 vaccine accounting for over 87% of that increase.²⁶⁹ Airfinity estimates for 2022 that Pfizer's overall revenue will again increase by 80%.²⁷⁰

BioNTech is a German pharmaceutical company headquartered in Mainz.²⁷¹ BioNTech developed its vaccine using mRNA technology and partnered with Pfizer to assist in clinic trials, manufacture and roll-out. In the second quarter of 2021 BioNTech reported US\$8.62 billion (€7.36 billion) in revenues from the sale of its Covid-19 vaccine and pre-tax profits of US\$4.57 billion (€3.9 billion). This represents a huge increase from the same period in 2020, when BioNTech reported revenues of US\$81.3 million (€69.4 million) and a net loss of US\$16.6 million (€14.2 million).²⁷² BioNTech attributed this huge growth as "mainly due to rapid increases in the supply of Covid-19 vaccine worldwide."²⁷³

While there is little transparency around profits on Covid-19 vaccine sales, Pfizer has stated its pre-tax margin for the Covid-19 vaccine "to be in the high 20's as a percentage of revenue, factoring in manufacturing and distribution costs, royalty expenses, shared R&D expenses and a 50% gross margin split with BioNTech".²⁷⁴ According to estimates based on research by Public Citizen, the Pfizer/BioNTech vaccines could cost as little as US\$1.20 per dose to manufacture, meaning profit margins could be far higher, though Pfizer has said that it has reviewed the cost calculation by Public Citizen and disagrees with their figures.²⁷⁵ Pfizer has reported that it expects to produce 3 billion doses in 2021.²⁷⁶ As of early September 2021 it had delivered 1.4 billion doses to over 100 countries.²⁷⁷

HUMAN RIGHTS POLICIES

Pfizer has published a human rights policy on its website and has committed to "respect internationally recognized human rights throughout our operations."²⁷⁸ In a letter to Amnesty International, CEO Dr. Albert Bourla has stated that "the right to health is the most salient human rights issue for Pfizer."²⁷⁹ Bourla also wrote in an open letter to staff that "fair and equitable distribution was our North Star from day one."²⁸⁰ Pfizer's policy makes reference to the UN Guiding Principles on Business and Human Rights but does not reference the UN Human Rights Guidelines for Pharmaceutical Companies.

268. Pfizer, "Pfizer reports second-quarter 2021 results", 28 July 2021, [//s21.q4cdn.com/317678438/files/doc_financials/2021/q2/Q2-2021-PFE-Earnings-Release.pdf](https://s21.q4cdn.com/317678438/files/doc_financials/2021/q2/Q2-2021-PFE-Earnings-Release.pdf).

269. Pfizer, "Pfizer reports second-quarter 2021 results", 28 July 2021, [//s21.q4cdn.com/317678438/files/doc_financials/2021/q2/Q2-2021-PFE-Earnings-Release.pdf](https://s21.q4cdn.com/317678438/files/doc_financials/2021/q2/Q2-2021-PFE-Earnings-Release.pdf)

270. Airfinity, "Covid-19 Vaccine Weekly Intelligence Report", 6 August 2021.

271. BioNTech, [biontech.de/](https://www.biontech.de/)

272. BioNTech, "BioNTech Announces Second Quarter 2021 Financial Results and Corporate Update", 9 August 2021, <https://investors.biontech.de/news-releases/news-release-details/biontech-announces-second-quarter-2021-financial-results-and>

273. BioNTech, "BioNTech Announces Second Quarter 2021 Financial Results and Corporate Update", 9 August 2021, investors.biontech.de/news-releases/news-release-details/biontech-announces-second-quarter-2021-financial-results-and

274. Pfizer, "Pfizer reports second-quarter 2021 results", p. 4; Pfizer, Email to Amnesty International, 13 September 2021, on file.

275. Public Citizen, "How to Make Enough Vaccine for the World in One Year", 26 May 2021, [hmkus3lurbh3lbztg254fzode-wpengine.netdna-ssl.com/wp-content/uploads/mRNA-vaccine-roadmap-May-26-final.pdf](https://www.netdna-ssl.com/wp-content/uploads/mRNA-vaccine-roadmap-May-26-final.pdf); Oxfam, "Vaccine monopolies make cost of vaccinating the world against COVID at least 5 times more expensive than it could be", 29 July 2021, www.oxfam.org/en/press-releases/vaccine-monopolies-make-cost-vaccinating-world-against-covid-least-5-times-more

276. BioNTech, "Pfizer and BioNTech to Provide 500 million doses of Covid-19 vaccines to US government for donations to poorest nations", 10 June 2021, <https://investors.biontech.de/news-releases/news-release-details/pfizer-and-biontech-provide-500-million-doses-covid-19-vaccine>

277. BioNTech, "Statement on Amnesty International Publication", 9 September, on file.

278. Pfizer, "Human Rights Statement", www.pfizer.com/purpose/workplace-responsibility/human-rights-statement, accessed 1 September 2021.

279. Pfizer, Letter to Amnesty International, 15 June 2021, on file.

280. Pfizer, "An Open Letter from Albert Bourla to Pfizer Employees", 7 May 2021, www.pfizer.com/news/hot-topics/why_pfizer_opposes_the_trips_intellectual_property_waiver_for_covid_19_vaccines

BioNTech has published a section on human rights in its Code of Business Conduct & Ethics on its website.²⁸¹ This states that BioNTech's vision is "to bring highly effective, individualized, and innovative therapies to market and make them available to patients around the globe". The company has said that its goal is making its Covid-19 vaccine "available to the public worldwide as quickly as possible"²⁸² and that it is "firmly committed to working towards equitable and affordable access for COVID-19 vaccines for all people around the world".²⁸³ BioNTech states that it is committed to complying with the UN Guiding Principles and to "prevent or mitigate adverse human rights impacts that are directly linked to our operations, products or services by our business relationships, even if they have not contributed to those impacts."²⁸⁴ BioNTech's policy makes no reference to the Human Rights Guidelines for Pharmaceutical Companies.²⁸⁵

PUBLIC FUNDING AND VACCINE PRICING POLICIES

Pfizer told Amnesty International that the "development and manufacturing costs relating to the Covid-19 vaccine have been entirely self-funded."²⁸⁶ However, in July 2020, the US government placed an advance order of 100 million doses for US\$1.95 billion, optioning up to 500 million additional doses.²⁸⁷ Other countries made additional advance orders for hundreds of millions of doses.²⁸⁸ Pfizer has also benefited from the public funding of its partner, BioNTech. In the first quarter of 2021, BioNTech received US\$88.22 million (€67.9 million) in government grants, part of up to US\$443 (€375million) in funding from the German Federal Ministry of Education and Research to Support Covid-19 Vaccine Programme.²⁸⁹ BioNTech also received up to €100 million in debt financing from the European Investment Bank to support vaccine development and manufacture.²⁹⁰ BioNTech and Pfizer share research and development costs which rose to US\$762 (€645 million) in 2020 largely due to the vaccine program.²⁹¹

Pfizer (along with Johnson & Johnson) have fought resolutions filed by activist shareholders for the disclosure of information about how public funding will be taken into consideration in the decision-making on access to vaccines and pricing.²⁹²

281. BioNTech, "Code of Business Conduct & Ethics", p. 54, investors.biontech.de/static-files/e2ac32b2-96f8-4ef6-a19e-adbecd4d8af9

282. BioNTech, "BioNTech Announces First Quarter 2020 Financial Results and Corporate Progress", 5 May 2020, [BioNTech Announces First Quarter 2020 Financial Results and Corporate Progress](https://www.biontech.com/en/news-releases/news-release-details/biontech-announces-first-quarter-2020-financial-results-and-corporate-progress) | BioNTech

283. BioNTech, "Statement on Amnesty International Publication", 9 September, on file.

284. BioNTech, "Code of Business Conduct & Ethics", p. 54, investors.biontech.de/static-files/e2ac32b2-96f8-4ef6-a19e-adbecd4d8af9

285. In response to Amnesty International's findings, BioNTech stated that "A human rights due diligence review is planned for 2021/2022. We will establish policies, governance structures and processes to address human rights and related environmental risks in our operations and value chain and regularly report on implementation. The UN Human Rights Guidelines for Pharmaceutical Companies will be included in this due diligence process." Email to Amnesty International, 9 September 2021, on file.

286. Pfizer, Letter to Amnesty International, 15 June 2021, on file.

287. Pfizer, "Pfizer and BioNTech announce an agreement with U.S. government for up to 600 million doses of mRNA-based vaccine candidate against SARS-COV-2", 22 July 2020, www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-agreement-us-government-600

288. For a breakdown, see The Lancet, "Data on public and non-profit funding for the research, development, and production of COVID-19 vaccines", 21 February 2021, pp. 8-9, [www.thelancet.com/cms/10.1016/S0140-6736\(21\)00306-8/attachment/f9fb0ae9-7f86-46c3-a57c-ada598458fa3/mmc2.pdf](https://www.thelancet.com/cms/10.1016/S0140-6736(21)00306-8/attachment/f9fb0ae9-7f86-46c3-a57c-ada598458fa3/mmc2.pdf)

289. BioNTech, "First quarter financial report", p. 29, investors.biontech.de/static-files/9037b63a-f211-4e2f-97fc-16283975b162; The Lancet, "Data on public and non-profit funding for the research, development, and production of COVID-19 vaccines", p. 8; BioNTech "BioNTech to Receive up to €375M in Funding from German Federal Ministry of Education and Research to Support COVID-19 Vaccine Program BNT162", September 15, 2020, investors.biontech.de/news-releases/news-release-details/biontech-receive-eu375m-fundinggerman-federal-ministry

290. European Investment Bank, "Germany: Investment Plan for Europe - EIB to provide BioNTech with up to €100 million in debt financing for COVID-19 vaccine development and manufacturing", 11 June 2020, www.eib.org/en/press/all/2020-144-eib-to-provide-biontech-with-up-to-eur-100-million-in-debt-financing-for-covid-19-vaccine-development-and-manufacturing

291. Global Newswire, "BioNTech Announces Full Year 2020 Financial Results and Corporate Update annual report", 30 March 2021, www.globenewswire.com/news-release/2021/03/30/2201363/0/en/BioNTech-Announces-Full-Year-2020-Financial-Results-and-Corporate-Update.html

292. Skadden, Arps, Slate, Meagher & Flom, "LLP to US Securities Exchange Commission, Johnson & Johnson"; 11 December 2020, www.sec.gov/divisions/corpfin/cf-noaction/14a-8/2020/oxfamjohnson121120-14a8-incoming.pdf; Newsweek, "COVID-19 Vaccine Developers Ask the SEC to Help Keep the Secret of How They Set Prices", 2 January 2021, www.newsweek.com/covid-19-vaccine-developers-ask-sec-help-keep-secret-how-they-set-prices-1565904

Pfizer/BioNTech, like Moderna, have eschewed the not-for-profit approach adopted by other companies. Pfizer has stated that it follows “a tiered pricing approach that was set based on the income level of each country which allowed Governments to distribute our vaccine to their citizens for free”,²⁹³ offering its vaccine to low-income countries at cost, while adding increasing profit margins to middle-income and high-income countries.²⁹⁴ In a letter to Amnesty International, Pfizer stated that “we established pricing principles for the Covid-19 vaccine which are consistent with Pfizer’s commitment to the right to health.”²⁹⁵ However, Pfizer’s CEO, Albert Bourla has said that Covid-19 vaccine developers should not forgo profits on products they make and described the vaccine as a “huge commercial opportunity”.²⁹⁶

Pfizer has not explained the rationale of its pricing policy for high and upper-middle-income countries or provided any more specific information on pricing. According to data gathered by Knowledge Portal, prices range from US\$6.75 – US\$23.50 per dose.²⁹⁷ The African Union (AU) has paid US\$6.75 a dose, middle-income countries South Africa and Colombia agreed to a price of roughly US\$10 a dose and about US\$12 a dose, respectively, with upper-middle-income country Lebanon paying US\$18, the United States US\$19.91 and Israel US\$23.50.²⁹⁸ While the European Commission was originally charged €15.50 (US\$ 18.3)per dose, Pfizer raised the price of its Covid-19 vaccine by more than a quarter to €19.50 (US\$ 22.9) in supply contracts concluded in July 2021.²⁹⁹

Pfizer has also stated that prices are likely to increase, “beyond a pandemic-pricing environment”, which, combined with lower unit costs from greater volumes, represented a “a significant opportunity for [...] margins to improve.”³⁰⁰ Pfizer cited a typical vaccine price of US\$150 or US\$175. Pfizer told Amnesty International that “post the pandemic, we will utilize a market and value-based pricing approach”.³⁰¹ Pfizer’s substantial profits and high prices in comparison to industry peers remain barriers to fair access to the Covid-19 vaccine.

INTELLECTUAL PROPERTY RIGHTS AND KNOWLEDGE/TECHNOLOGY SHARING

Pfizer and BioNTech have opposed C-TAP and have not joined WHO’s COVID-19 mRNA vaccine technology transfer hub.³⁰² Pfizer has lobbied the US Biden administration to oppose proposals put

293. Pfizer, Letter to Amnesty International, 15 June 2021, on file.

294. Pfizer, “An open letter from Pfizer Chairman and CEO to colleagues”, 7 May 2021, www.Pfizer.com/news/hot-topics/why_Pfizer_opposes_the_trips_intellectual_property_waiver_for_covid_19_vaccines.

295. Pfizer, Letter to Amnesty International, 15 June 2021, on file.

296. Axios, “Pfizer says it won’t put ‘huge price’ on coronavirus vaccine,” 10 June 2020, www.axios.com/pfizer-coronavirus-vaccine-price-52a7b1bf-68f0-444b-8d87-2119ed007d7e.html

297. Knowledge Portal, Covid-19 Vaccine Access, Reported Price/Dose for COVID-19 Vaccines, www.knowledgeportalia.org/covid19-vaccine-arrangements

298. UNICEF, Covid-19 vaccine dashboard, Pricing, www.unicef.org/supply/covid-19-vaccine-market-dashboard; Reuters, “Colombia reaches deals with Pfizer, AstraZeneca for COVID-19 vaccines”, 6 April 2021, 19 December 2020, www.reuters.com/business/healthcare-pharmaceuticals/colombia-reaches-deals-with-pfizer-astrazeneca-covid-19-vaccines-2020-12-19/; The Straits Times, “Lower-income countries opted not to order Pfizer vaccine, says CEO”, United States News & Top Stories - The Straits Times; AP, “Lebanon signs with Pfizer for 2.1 million vaccine doses,” 17 January 2021, apnews.com/article/health-lebanon-coronavirus-pandemic-coronavirus-vaccine-5374ad14265a64154460806a5413527e; Knowledge Portal, Reported Price/Dose for Covid-19 Vaccine Candidates, www.knowledgeportalia.org/covid19-vaccine-arrangements; Reuters, “EU agreed 15.50 euros per dose for Pfizer vaccine document”, 21 December 2020, www.reuters.com/article/us-health-coronavirus-eu-vaccine-prices-idUSKBN28V0Y6; BioNTech, “BioNTech Announces Full Year 2020 Financial Results and Corporate Update”, 30 March 2021, investors.biontech.de/news-releases/news-release-details/biontech-announces-full-year-2020-financial-results-and

299. Financial Times, “Pfizer and Moderna raise EU Covid vaccine prices”, 1 August 2021, www.ft.com/content/d415a01e-d065-44a9-bad4-f9235aa04c1a

300. Pfizer, Edited Transcript PFE.N - Q4 2020 Pfizer Inc Earnings Call, 2 February 2021, s21.q4cdn.com/317678438/files/doc_financials/2020/q4/PFE-USQ_Transcript_2021-02-02.pdf

301. Pfizer, Letter to Amnesty International, 15 June 2021, on file.

302. LA Times, “Vaccine companies and the U.S. government snubbed WHO initiative to scale up global manufacturing”, 30 April 2021 www.latimes.com/world-nation/story/2021-04-30/vaccine-companies-and-the-u-s-government-snubbed-who-initiative-to-scale-up-global-manufacturing

forward by India and South Africa to the WTO Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) to suspend critical intellectual property provisions of the TRIPS Agreement, which it describes as a disincentive to investment and innovation.³⁰³

Pfizer replied to Amnesty International that waiving those TRIPS commitments would “send the wrong message to future innovators in the next pandemic” and “could make it harder to resolve the current one, particularly if companies begin to buy up scarce inputs in the hopes of manufacturing a vaccine using technology developed by others”. Pfizer also said that “IP directed to the mRNA COVID-19 vaccine is primarily owned by BioNTech”.³⁰⁴ On C-TAP, the company added: “Pfizer welcomes voluntary initiatives that add to the pool of resources and options available to promote equitable access to COVID-19 therapies and vaccines, and we remain committed to constructive dialogue with all parties.”³⁰⁵ However, Pfizer’s Chairman and CEO Dr. Albert Bourla said of WHO voluntary pools “I think it’s nonsense, and... it’s also dangerous,” as companies are “investing billions to find a solution” but the idea that “if you have a discovery, we are going to take your [intellectual property], I think, is dangerous.”³⁰⁶ In April 2021, Pfizer launched the ‘IP Pact’ jointly with other pharmaceutical companies, a declaration of 10 principles on intellectual property which promotes intellectual property protection as the cornerstone for innovation.³⁰⁷

BioNTech has listed “maintaining, defending, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how” as a key success indicator.³⁰⁸ BioNTech has announced plans to establish mRNA vaccine production facilities in Africa, but CEO Uğur Şahin has stated that this would take up to four years.³⁰⁹ On 21 July, Pfizer and BioNTech announced the signing of a letter of intent with The Biovac Institute, a Cape Town-based, South African biopharmaceutical company, to manufacture the Pfizer-BioNTech Covid-19 Vaccine for distribution within the African Union.³¹⁰ Pfizer/BioNTech is currently manufacturing its Covid-19 vaccine in Germany and Belgium, while fill and finish processes are carried out in Belgium, Germany, Switzerland and France.³¹¹

VACCINE ALLOCATION AND SEQUENCING

Pfizer told Amnesty International that it had proactively reached out to governments “to address the risk this imbalance represented to people in lower income countries because the supply was limited” but that for a variety of reasons, including the fact that mRNA technology was then untested, lack of regulatory approval and governments opting for local production, this was not successful. Pfizer added that “we now expect the supply balance to weigh in favour of middle- and low-income countries in the second half of 2021, and to have virtually enough supply in 2022 for all governments that choose to procure our vaccine.”³¹²

303. Reuters, “Top U.S. trade negotiator meets BioNTech, AstraZeneca execs on COVID-19 IP waiver”, 5 May, 2021, www.reuters.com/business/healthcare-pharmaceuticals/top-us-trade-negotiator-meets-BioNTech-astrazeneca-execs-covid-19-ip-waiver-2021-04-27/

304. Pfizer, Letter to Amnesty International, 15 June 2021, on file.

305. Pfizer, Letter to Amnesty International, 15 June 2021, on file.

306. IFPMA, “Global Biopharma CEO/Top Executives COVID-19 Media Briefing”, Video, 28 May 2020, 59:30, www.youtube.com/watch?v=OwMMwDshed0

307. IP Principles for Advancing Cures and Therapies (IP PACT), https://cdn.pfizer.com/pfizercom/IP_PACT_DOCUMENT_FINAL.pdf

308. CNN, “Supporting a TRIPS waiver is a bad idea, developer of the Pfizer/BioNTech vaccine says”, 6 May 2021, edition.cnn.com/world/live-news/coronavirus-pandemic-vaccine-updates-05-06-21/h.04a5c191b8f9017aab687a9334cb2e28; BioNTech, “US SEC From BioNTech SE for the fiscal year ended December 31, 2020”, p. 22, investors.biontech.de/static-files/e862a8ea-5d90-4672-acfb-34de57b58806

309. Financial Times, “BioNTech prepares expansion into Africa alongside EU,” 10 June 2021, www.ft.com/content/2db9e21f-881d-4da2-8394-3ec732024581

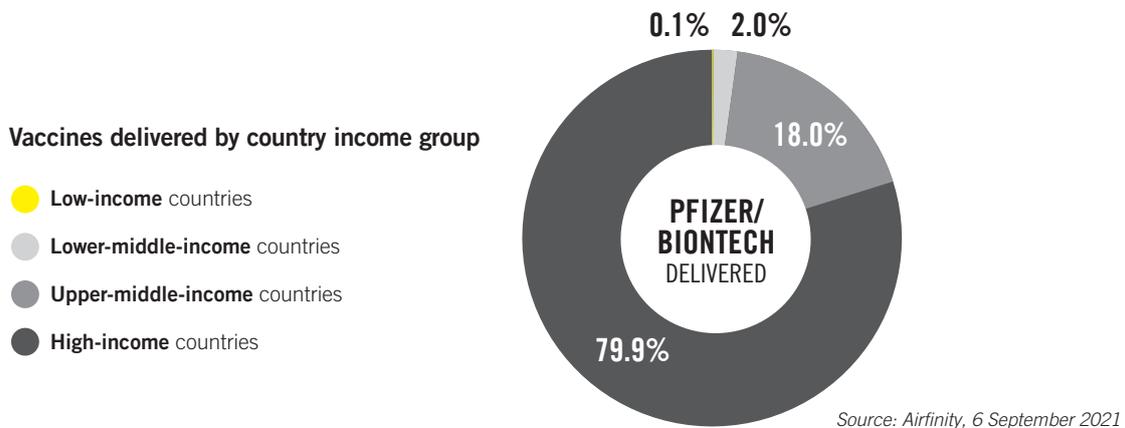
310. Pfizer, “Pfizer and BioNTech announce collaboration with Biovac to manufacture and distribute Covid-19 vaccine doses within Africa”, July 21 2021, www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-collaboration-biovac

311. BioNTech, Email to Amnesty International, 9 September 2021, on file.

312. Pfizer, Letter to Amnesty International, 15 June 2021, on file.

On 10 June 2021, the US government announced plans to buy 500 million Pfizer/BioNTech doses at cost for the COVAX Facility. The US government has said that 200 million doses will be shipped in 2021 and a further 300 million in the first half of 2022 to 92 low- and lower-middle-income countries and the African Union.³¹³ BioNTech stated that the companies “aim to provide 2 billion doses to low- and middle-income countries in 2021 and 2022 – 1 billion each year”.

According to Airfinity, the breakdown on 2021 orders of the Pfizer/BioNTech vaccine by income group is 59.9% for high-income countries, compared to 24% for upper-middle-income countries, 7.7% for lower-middle-income countries, 0.01% for low-income countries and 8.4% for COVAX. In terms of the breakdown of deliveries (including through COVAX) up to 6 September 2021 the proportions are even more heavily skewed towards richer countries, with 79.9% for high-income countries, compared to 18.0% for upper-middle-income countries, 2.0% for lower-middle-income countries, and 0.1% for low-income countries.³¹⁴ This includes over 9 million doses bought by countries, including the EU and the USA, and donated bilaterally.



SUMMARY

Both Pfizer and BioNTech have committed to the UN Guiding Principles in their human rights policies. However, Pfizer has strongly lobbied against the proposed TRIPS waiver and both companies have declined to participate in WHO intellectual property and technology sharing mechanisms. Pfizer/BioNTech have so far delivered almost all of their vaccines to high-income countries and have only belatedly committed significant quantities of doses to the COVAX Facility, the majority of which will not be produced and distributed until 2022. While Pfizer states it has applied a tiered pricing policy, the companies have charged high prices for countries that may appear to have higher-income but face a severe economic crisis such as Lebanon, and mainly delivered its products to high-income countries, putting economic interest before access to Covid-19 vaccines.

313. The White House, “Fact Sheet: President Biden Announces Historic Vaccine Donation: Half a Billion Pfizer Vaccines to the World’s Lowest-Income Nations,” 10 June 2021, www.whitehouse.gov/briefing-room/statements-releases/2021/06/10/fact-sheet-president-biden-announces-historic-vaccine-donation-half-a-billion-pfizer-vaccines-to-the-worlds-lowest-income-nations/; Pfizer and BioNTech, “Pfizer and BioNTech to Provide 500 Million Doses of COVID-19 Vaccine to U.S. Government for Donation to Poorest Nations,” 10 June 2021, investors.biontech.de/news-releases/news-release-details/pfizer-and-biontech-provide-500-million-doses-covid-19-vaccine

314. Airfinity, Covid-19 vaccines database, 9 August 2021. Note that Airfinity estimates that 75% of COVAX deliveries go to low- and lower middle-income countries.

OTHER VACCINE SUPPLIERS: SINOPHARM, SINOVAC BIOTECH LTD AND THE GAMELEYA NATIONAL RESEARCH CENTER

As of September 2021, 330 vaccine candidates were under development and nearly 100 were in clinical trials.³¹⁵ In addition to the companies and vaccines named above, three key vaccines have been widely distributed worldwide. While Amnesty International has not included an in-depth analysis of these companies, below is a summary of their availability across the globe:

In May 2021, the WHO approved for emergency use the Covid-19 vaccine BIBP developed by **Sinopharm** under the state-owned China National Pharmaceutical Group.³¹⁶ As of August 2021, Sinopharm had produced nearly one billion doses and announced an increased annual vaccine production capacity of 5 billion doses,³¹⁷ which would significantly increase available global supply of vaccines. While Sinopharm has not joined C-TAP, it has signed agreements with several countries to manufacture vaccines such as Bangladesh.³¹⁸ So far, the Sinopharm vaccine has been approved for use in Bahrain, China, Egypt, Jordan, Serbia, Iraq, Pakistan, Morocco, Hungary, Peru, Nepal, Argentina, Iran, Jordan, Maldives, Indonesia, Bangladesh, Thailand, Vietnam, Philippines, Malaysia, Myanmar, United Arab Emirates, and Venezuela. Sinopharm is also working on updated vaccines to address the Beta and Delta variants.³¹⁹

In June 2021, the WHO approved for emergency use the vaccine known as CoronaVac, developed by **Sinovac Biotech Ltd** - a Nasdaq-listed company under the state-owned China National Pharmaceutical Group.³²⁰ As of August 2021, Sinovac had produced nearly 1.3 billion doses which can be distributed across Bolivia, China, Indonesia, Turkey, Brazil, Chile, Colombia, Mexico, Cambodia, Hong Kong, Thailand, Tunisia, Ukraine, Pakistan, Malaysia, Egypt, Bangladesh, Nepal, South Africa, and Sri Lanka.³²¹ Although Sinovac has not joined C-TAP, it has signed contracts that include technology transfer with other countries such as Brazil and Indonesia.³²²

Operating under the Russian Ministry of Health since 2020 and financed by the Russian Direct Investment Fund (RDIF), the **Gameleya National Research Center of Epidemiology and Microbiology** developed the two-dose vaccine Gam-COVID-Vac, also known as Sputnik V.³²³ In August 2020, the Russian Ministry of Health approved the use of Sputnik V. One year later, the Gameleya Center has produced 14 million doses of the vaccine worldwide.³²⁴ While over 70 national public health regulatory bodies have approved Sputnik, the WHO still has not approved its use and therefore it has yet to be used by COVAX. The Gameleya Center is also working on a one-dose vaccine called Sputnik-light, which is also pending approval from the WHO and the European

315. Airfinity, Covid-19 vaccine database, 5 August 2021.

316. www.who.int/news-room/feature-stories/detail/the-sinopharm-covid-19-vaccine-what-you-need-to-know

317. Airfinity, COVID-19 Vaccine Weekly Intel Report, 6 August 2021.

318. Knowledge Portal, Vaccine Arrangements, Number of doses purchased to date for each COVID-19 vaccine, www.knowledgeportal.org/covid19-vaccine-arrangements

319. First World Pharma, "China's Sinopharm Working on Modified Vaccines Against Covid-19 Variants", 2 August 2021, new.firstworldpharma.com/story/5364317

320. www.reuters.com/article/health-coronavirus-china-sinovac-biotech/chinas-sinovac-gains-land-and-loans-to-speed-up-work-on-coronavirus-vaccine-idUSL5N2CB0C9

321. Airfinity, COVID-19 Vaccine Weekly Intel Report, 6 August 2021.

322. Reuters, "Sinovac supplies 260 mln Covid-19 vaccine doses globally", 20 April, 2021, www.reuters.com/business/healthcare-pharmaceuticals/sinovac-supplied-260-mln-covid-19-vaccine-doses-globally-2021-04-20/

323. Sputnik V, "Partnerships", sputnikvaccine.com/partnerships/

324. Airfinity, Covid-19 vaccine database, www.airfinity.com/

Medicines Agency (EMA).³²⁵ The Gamaleya and RDIF have not joined C-TAP, but they have signed contracts with local manufacturers in several countries, including Bangladesh, India, Iran and Mexico.³²⁶

Despite claims of lack of transparency around the safety of the vaccine,³²⁷ as of August 2021, Sputnik V has been approved for emergency use in nearly 60 countries and territories.³²⁸

3.6 CONCLUSION

As this assessment has shown, while vaccine developers claim to respect human rights, all of them – to differing degrees – have failed to meet their responsibilities. Through their actions and omissions – particularly through their inaction on intellectual property and technology sharing – these companies have ended up causing or contributing to the human rights harms suffered by those lacking access to the Covid-19 vaccine. Despite billions of dollars of public subsidy, they have catered predominantly to rich countries, leaving poor countries at the back of the queue.

All of the pharmaceutical companies assessed have actively opposed efforts to increase sharing of intellectual property, technology and know-how beyond limited numbers of bilateral agreements. Johnson & Johnson has refused to share its intellectual property, technology and know-how even when explicitly requested to do so by a company seeking to increase access to Covid-19 vaccines in the Global South. No company has yet joined WHO initiatives, such as C-TAP and the mRNA vaccine technology transfer hub designed to scale up global manufacturing. No company has publicly disclosed disaggregated costs of research, development, production, marketing, distribution, and other data crucial for optimizing the vaccine production and allocation.

AstraZeneca and Johnson & Johnson state that they are committed to producing on a not-for-profit basis for emergency pandemic use. In contrast, Pfizer/BioNTech and Moderna have charged high prices for their vaccines, putting profits before access to essential medicines. Pfizer/BioNTech and Moderna have allocated almost all of vaccines so far delivered (as opposed to pledged) to high-income countries. Apart from AstraZeneca, all companies have been slow to deliver doses into the COVAX Facility, meaning that the majority of doses currently pledged will only be delivered in 2022 – very late for many poorer regions now suffering deadly Covid-19 outbreaks. If Novavax is able to follow through on its significant commitments to supply COVAX, this would be a major boost to the scheme and support fair access to essential medicines.

AstraZeneca should be recognized for its approach to the crisis. However, the scale of the global health emergency requires much greater action from all of the vaccine producers, including AstraZeneca itself, which has also obstructed broader measures to share intellectual property, technology and know-how.

325. Nature, “Mounting evidence suggests Sputnik COVID vaccine is safe and effective”, 6 July 2021, www.nature.com/articles/d41586-021-01813-2

326. Sputnik V, “Newsroom”, sputnikvaccine.com/newsroom/

327. Nature, “Mounting evidence suggests Sputnik COVID vaccine is safe and effective”, 6 July 2021, www.nature.com/articles/d41586-021-01813-2

328. These include Algeria, Angola, Antigua and Barbuda, Argentina, Armenia, Bahrain, Bangladesh, Bolivia, Brazil, Cameroon, Chile., Djibouti, Ecuador, Egypt, Gabon, Ghana, Guinea, Guinea-Bissau, Guyana, Honduras, India, Iran, Iraq, Jordan, Kenya, Kyrgyzstan, Laos, Lebanon, Maldives, Mali, Mauritius, Mexico, Moldova, Mongolia, Morocco, Myanmar, Namibia, Nepal, Nicaragua, Nigeria, North Macedonia, Oman, Pakistan, Panama, Paraguay, Philippines, Republic of Congo, Republika Srpska, San Marino, Seychelles, Slovakia, Sri Lanka, State of Palestine, Tunisia, Turkey, Turkmenistan, United Arab Emirates, Venezuela and Vietnam. Several countries have also fully approved its use: Albania, Azerbaijan, Hungary, Kazakhstan, Montenegro, Russia, Saint Vincent and the Grenadines, Serbia, Syria and Uzbekistan.

4. THE TOP TEN INSTITUTIONAL INVESTORS

Each of the companies featured in this report is publicly listed, and therefore owned by numerous individual and institutional investors. But among these, a small group of mainly US-based mega investors and financial service institutions own or manage a significant shareholding across the industry.

For this report, Amnesty International has mapped the ten largest institutional investors who own or manage shares of the six featured companies, as per Bloomberg listings.³²⁹ The total investments owned or managed by these ten financial institutions in the vaccine makers are huge – more than US\$250 billion.

The single largest is Vanguard Group Inc.³³⁰ This group holds shares worth a total of more than US\$66 billion, in AstraZeneca, Johnson & Johnson, Moderna, Novavax and Pfizer. BlackRock Inc has more than US\$62 billion invested in all six featured companies.³³¹ State Street Corporation has more than US\$36 billion invested in all companies assessed except for BioNTech.³³²

THE HUMAN RIGHTS RESPONSIBILITY OF INVESTORS

As outlined above, under the UN Guiding Principles, business enterprises, have a responsibility to respect all human rights wherever they operate in the world and throughout their operations. This responsibility to respect applies not just to the vaccine manufacturers but also to the companies that invest in them, including institutional investors.³³³

To meet their responsibility to respect under the UN Guiding Principles, investors in pharmaceutical companies must undertake proactive and ongoing human rights due diligence.³³⁴

In practice, this would entail identifying human rights impacts linked to their operations and investments (both potential and actual), taking effective action to prevent and mitigate against them, and being transparent about their efforts.³³⁵

329. Mapping based on data from Bloomberg Terminal, as accessed on 26 May 2021.

330. Vanguard, Investors, investor.vanguard.com/corporate-portal/

331. Blackrock, www.blackrock.com

332. State Street Corporation, www.statestreet.com/home.html

333. Scope and applications of ‘business relationships’ in the financial sector under the OECD Guidelines for Multinational Enterprises, mneguidelines.oecd.org/global-forum/GFRBC-2014-financial-sector-document-2.pdf. According to the OECD, “It is interpretive guidance regarding the applicability of the UNGPs by minority shareholders, the OHCHR therefore concludes that (minority) shareholdings of institutional investors constitute a business relationship.” See also UNGPs 10+ and UN B-Tech dialogue on investment and human rights, OHCHR B-Tech, 2020, www.ohchr.org/Documents/Issues/Business/UNGPsBHRnext10/ConceptNote_UNGP10_BTech.pdf, which clarifies that “[T]he term institutional investor’s refers to institutions invested in public equities, fixed income, and private equities, including venture capital funds.”

334. Publicly available information on the human rights commitments of the top ten institutional investors in the six featured companies can be found in Annex 1.

335. UN Guiding Principles, Principles 15 and 17.

TABLE COMPARING MAJOR INVESTORS SHAREHOLDINGS

	AstraZeneca		Pfizer		Moderna		Novavax		Johnson & Johnson		BioNtech		
Value of holding in USD (as of 26.05)	149,217,000,000		217,946,000,000		69,954,000,000		10,929,000,000		445,351,000,000		48,640,000,000		
COMPANY	Total shares (with %)	Company value of holding in USD (as of 26.05)	Total shares (with %)	Company value of holding in USD (as of 26.05)	Total shares (with %)	Company value of holding in USD (as of 26.05)	Total shares (with %)	Company value of holding in USD (as of 26.05)	Total shares (with %)	Company value of holding in USD (as of 26.05)	Total shares (with %)	Company value of holding in USD (as of 26.05)	TOTALS
1. Vanguard Group Inc USA	48395292 (3.69%)	5,506,107,300	450914119 (8.1%)	17,566,447,600	18919030 (4.7%)	3,294,833,400	5893304 (8.0%)	868,855,500	229730647 (8.7%)	38,834,607,200	-	-	66,070,851,000
2. Blackrock Inc USA	95022743 (7.24%)	10,803,310,800	401903070 (7.2%)	15,648,522,800	202681562 (5.2%)	3,602,631,000	5453480 (7.4%)	804,374,400	187283087 (7.1%)	31,664,456,100	742858 (0.3%)	150,784,000	62,674,079,100
3. State Street Corp USA	9621865 (0.7%)	1,089,284,100	274886855 (4.9%)	10,701,148,600	6008874 (1.5%)	1,049,310,000	1441953 (2.0%)	213,115,500	140270595 (5.3%)	23,737,208,300	-	-	36,790,066,500
4. Capital Group Cos Inc USA	100189650 (7.6%)	11,385,257,100	233508378 (4.2%)	9,088,348,200	-	-	-	-	31654686 (1.2%)	5,344,212,000	-	-	25,817,817,300
5. Wellington Management Group LLP USA	44142936 (3.4%)	5,013,691,200	249780583 (4.5%)	9,720,391,600	-	-	-	-	33886162 (1.3%)	5,745,027,900	-	-	20,479,110,700
6. Baillie Gifford USA	-	-	-	-	45337764 (11.2%)	7,834,848,000	-	-	-	-	6738012 (2.8%)	1,357,056,000	9,191,904,000
7. Bank of America Corp USA	-	-	67851406 (1.2%)	2,637,146,600	-	-	-	-	33224329 (1.3%)	5,611,422,600	-	-	8,248,569,200
8. Morgan Stanley USA	-	-	46312028 (0.8%)	1,808,951,800	822788 (2.1%)	1,434,057,000	-	-	24305948 (0.9%)	4,097,229,200	-	-	7,340,238,000
9. Bank of New York Mellon USA	-	-	61955317 (1.1%)	2,419,200,600	-	-	-	-	31956047 (1.2%)	5,388,747,100	-	-	7,807,947,700
10. UBS Switzerland	11178010 (0.9%)	1,268,344,500	40661282 (0.7%)	1,591,005,800	-	-	-	-	22821447 (0.9%)	3,874,553,700	611567 (0.3%)	121,600,000	6,855,504,000

Source: Bloomberg

For investors, this applies to their decisions about which companies to invest in as well as the sectors on which to focus. Investors must undertake human rights due diligence to assess the potential or actual human rights impacts of the companies they choose to support through financial investments – i.e. the potential or actual impacts of those companies’ actions and products. They should also continue to monitor their portfolio companies to identify any new or emerging human rights risks.³³⁶ This equally applies to financial service institutions managing assets owned by others.

Once investors have identified potential or actual adverse impacts, they should engage with their investee company and exert their leverage to mitigate these adverse impacts.³³⁷ They should also insist that their investees conduct their own human rights due diligence.³³⁸

In the context of the Covid-19 vaccines the leverage that this small group of companies has is significant.³³⁹ While none of the top ten investors own more than 10% in any one company, the size of their combined holdings, as well as their total portfolios across the whole sector, give them a significant role in these companies. Combined, for instance, they own and manage 23.5% of AstraZeneca’s shares, 27.9% of Johnson & Johnson’s, 24.7% of Moderna’s, 17.4% of Novavax’s, and 32.7% of Pfizer’s.³⁴⁰

Within the context of the pandemic, some investors have recognized, at least partially, their responsibility to try to influence the vaccine makers to take all necessary steps to extend access to Covid-19 vaccines. Almost 150 institutional investors joined a public call in February 2021 for pharmaceutical companies to support “a fair and equitable global response to the pandemic” through, for example, “cross-industry partnerships to accelerate R&D and expand production, equitable pricing strategies, and voluntary licensing agreements”.³⁴¹

Responding to Amnesty International’s inquiries about their due diligence in relation to the vaccine developers assessed, Baillie Gifford stated “We identified that global access to vaccines would be a major human rights risk given that ground-breaking innovation in healthcare is primarily taking place in high income countries. Therefore [...] we engaged with Moderna and BioNTech early on and during the pandemic to discuss what they would do to support global vaccine rollout.”³⁴² BlackRock said that it engages with pharmaceutical companies “on all aspects of their business” including “asking questions to understand their role in Covid-19 vaccines”. The company added that “access to medicine is a key ESG concern held by BlackRock”.³⁴³ UBS wrote that it sees pharmaceutical companies as having “an important role to play in addressing the access to medicine issue” and that it “engage[s] with pharmaceutical companies to directly address the issue of access to medicine and human rights”.³⁴⁴ However, neither Baillie Gifford, BlackRock, UBS nor any of the other top ten institutional investors, as identified by Amnesty International, were among the signatories of the public call by almost 150 investors in February 2021.

336. OECD, “Responsible business conduct for institutional investors: Key considerations for due diligence under the OECD Guidelines for Multinational Enterprises”, p. 33, mneguidelines.oecd.org/RBC-for-Institutional-Investors.pdf.

337. OECD, “Responsible business conduct for institutional investors: Key considerations for due diligence under the OECD Guidelines for Multinational Enterprises”, p. 35, mneguidelines.oecd.org/RBC-for-Institutional-Investors.pdf.

338. OECD, “Responsible business conduct for institutional investors: Key considerations for due diligence under the OECD Guidelines for Multinational Enterprises”, p. 35, mneguidelines.oecd.org/RBC-for-Institutional-Investors.pdf.

339. While some investors may not have operational control over their investee companies, the responsibility to try to prevent and mitigate adverse human rights impacts applies to all investors that invest in a company. According to the OECD, “The degree of leverage an investor has over the company causing the adverse impact is useful in considering what it can do to persuade that entity to take action, but is not relevant to considering whether the investor should carry out due diligence and effectively exercise any leverage it may have.” OECD, “Responsible business conduct for institutional investors: Key considerations for due diligence under the OECD Guidelines for Multinational Enterprises”, p. 38, mneguidelines.oecd.org/RBC-for-Institutional-Investors.pdf.

340. Of the top ten institutional investors overall, only three own shares in BioNTech, which are worth just 3.4% of the total shares in the company. Mapping based on data from Bloomberg Terminal, accessed 26 May 2021.

341. Access to Medicine Foundation, “Investors issue urgent call for “fair and equitable” global response to COVID-19”, 23 February 2021, accesstomedicinefoundation.org/news/investors-issue-urgent-call-for-fair-and-equitable-global-response-to-covid-19

342. Baillie Gifford & Co, Letter to Amnesty International, 10 September 2021, on file.

343. BlackRock, Email to Amnesty International, 10 September 2021, on file. BlackRock also referred Amnesty International to Investment Stewardship Vote Bulletin: Johnson & Johnson, www.blackrock.com/corporate/literature/press-release/blk-vote-bulletin-johnson-and-johnson-apr-2021.pdf; and Q3 2020 BlackRock Investment Stewardship Global Quarterly Stewardship Report October 2020, pp. 20-21 www.blackrock.com/corporate/literature/publication/blk-qrly-stewardship-report-q3-2020.pdf

344. UBS, Email to Amnesty International, 10 September 2021, on file.

5. CONCLUSIONS AND RECOMMENDATIONS

“A global pandemic of this scale and human cost, with no clear end in sight, requires a concerted, principled and courageous response [...] based on the bedrock human-rights based principles of international solidarity, cooperation and assistance.”

UN Human Rights Experts, 9 November 2020³⁴⁵

The current structure of the global public health system affords private actors a fundamental role in the development, manufacturing, and allocation of medicines. The protection of international intellectual property rights puts manufacturers of medicines in a position of immense power which allows them to decide whether and under what conditions other companies and countries can develop and manufacture life-saving Covid-19 vaccines. Vaccine developers – many extraordinarily profitable – must exercise that power in alignment with their human rights responsibilities.

Some pharmaceutical companies are putting profits first. They cannot continue to adopt a business-as-usual approach during a global health emergency when the health and lives of millions are at stake. Their approach – notwithstanding commitments by AstraZeneca and Johnson & Johnson to sell at cost price during the pandemic - has ultimately failed to address the global health crisis, and resulted in the concentration of intellectual property, knowledge, technology, profit and vaccines in the Global North, whilst the Covid-19 crisis worsens for the Global South.

Companies must not enforce existing intellectual property rights, and refrain from applying and enforcing new intellectual property rights. They must issue global, open and non-exclusive licences on their patents, know-how and other proprietary technologies or participate in C-TAP. They must share and fully transfer their knowledge and technology and train qualified manufacturers committed to contribute to the ramp-up of the production of Covid-19 vaccines. They should not seek to use their influence over governments to obstruct measures designed to facilitate intellectual property and technology sharing, such as the proposed TRIPS waiver. With regards to pricing, companies must

345. OHCHR, “Statement by UN Human Rights Experts Universal access to vaccines is essential for prevention and containment of COVID-19 around the world”, November 2020, www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26484&LangID=E

not put their economic interests before their human rights responsibilities; profit must not become an obstacle to states' capacity to ensure access to the vaccine. All companies must prioritize increasing availability of vaccines in poorer regions and countries by devoting a significant share of their 2021 production to the COVAX Facility and sustaining high levels of deliveries into COVAX throughout 2022. Transparency across all aspects of vaccine development and delivery is vital for optimizing supply and ensuring fair vaccine allocation.

In the long run, solely market-driven models will never deliver essential medicines fairly. Stronger laws and regulations – especially around accessibility and affordability – are needed for states and companies to deliver on their respective human rights obligations and responsibilities. States must ensure that intellectual property rights do not prevent any countries from upholding the right to health. This includes agreeing to 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. States must also assess and make any necessary adjustments to their intellectual property laws, policies, and practices to ensure that these do not form a barrier to access to health.

In July, a task force set up by the leaders of the WHO, WTO, IMF and World Bank set a target to vaccinate 40% of people in low- and lower-middle income countries by the end of 2021, to protect them and others from Covid-19. With 100 days until the end of the year, less than 10% of people in these countries are fully vaccinated, and tens of thousands of people are dying each week.

As the world reaches a critical phase of the pandemic, Amnesty International is launching a campaign calling on states and pharmaceutical companies to deliver 2 billion vaccines to 82 low- and lower-middle income countries over the next 100 days, in order to fully vaccinate an additional 1.2 billion. To reach this goal, companies and states need to adopt a radically different approach to vaccine allocation: companies must distribute 50% of their production to low- and lower-middle income countries, preferably through the COVAX Facility and other multilateral initiatives; states must urgently redistribute hundreds of millions of surplus vaccines currently in their stocks, favouring international and regional mechanisms such as COVAX. These measures alone could bridge the gap.

The challenge must not stop there. States and companies must ensure that deliveries continue to be equitable throughout 2022, that doses go where they are most needed and that low- and lower-middle income countries are fully vaccinated as quickly as possible. Action must also be taken to share the knowledge, technology and intellectual property needed to allow more manufacturers to produce vaccines, and facilitate equitable access to affordable vaccines for years to come.

RECOMMENDATIONS

Amnesty International is calling on vaccine developers to:

- Deliver 50% of their production of Covid-19 vaccines to low- and lower-middle income countries throughout the last 100 days of 2021, preferably through international and regional mechanisms such as COVAX, and ensure that deliveries continue to be equitable throughout 2022 and beyond.
- Carry out human rights due diligence to identify, prevent, mitigate and account for how they address potential and actual adverse human rights impacts in relation to their Covid-19 vaccines.
- Pursue vaccine allocation based on human rights considerations, such as the prevalence of the pandemic in a country, the functioning of a country's health care system, vaccination rate and non-discrimination.

- Engage with the purchasers of their Covid-19 vaccines and build in contractual flexibility regarding delivery terms to ensure that those most at risk globally get access to the vaccines in a timely manner, especially in cases of sudden Covid-19 outbreaks which require urgent responses.
- Share intellectual property by issuing open and non-exclusive licences or participating in C-TAP, and publicly disclosing all terms and conditions.
- Share their codified and tacit knowledge and technology and train qualified manufacturers committed to contribute to the ramp-up and diversification of the production of Covid-19 vaccines by participating in C-TAP and, where applicable, making use of technology transfer hubs established by the WHO.
- Price their vaccine doses so that profit does not constitute an obstacle to access to Covid-19 vaccines. At a minimum, supply vaccines at cost to low- and middle-income countries for at least the duration of the global health emergency.
- Publicly disclose their pricing and allocation policies in a timely and accessible fashion, including the actual costs of production, individual cost items, sources of external funding, prices charged in different countries under what contractual terms and conditions, and information about discounting, donations and advance order guarantees.
- Allow purchasing states to sell or donate any surplus of Covid-19 vaccine doses to other countries, including for donation via NGOs or the WHO, without a prior consent of the vaccine developer or any other obstacle such as indemnity clauses.
- Respect the spirit of the Doha Declaration on the TRIPS Agreement and Public Health (2001) by not opposing initiatives that increase access to Covid-19 health products, such as the proposed waiver to WTO TRIPS Agreement.
- Cease lobbying against initiatives seeking to increase manufacture and supply of Covid-19 vaccines and promote their fair distribution, such as the proposed TRIPS waiver and WHO technology sharing mechanisms.
- Engage in remediation of human rights harm in all instances in which they have caused, contributed to or are directly linked to the harm.

Amnesty International is calling on institutional investors owning or managing shares of vaccine developers to:

- Conduct comprehensive human rights due diligence on their investments and financial services. This includes:
 - a. Monitoring the human rights implications of the vaccine developers' Covid-19 vaccines on an ongoing basis, and taking immediate action to prevent any adverse impacts, mitigate any risks and remedy any harm that they identify.
 - b. Publicly disclosing the human rights due diligence they conduct and actions taken to prevent and remediate any harm and mitigate any risk in relation to the vaccine developers' Covid-19 vaccines.
 - c. Requiring publicly accessible annual reporting from the vaccine developers whose shares they hold or manage on their human rights due diligence, including accounting for how they are addressing or have addressed any adverse human rights impact in relation to their Covid-19 vaccines.
 - d. Ensuring that the vaccine developers whose shares they hold or manage implement their own due diligence process to identify, prevent, mitigate and account for the actual and potential human rights impacts linked to the development, production, trade and allocation of their Covid-19 vaccines.

And states to:

- Redistribute all surplus Covid-19 vaccine stocks to low- and lower-middle income countries over the last 100 days of 2021, preferably through international and regional mechanisms such as COVAX, and ensure that vaccine allocation continues to be equitable throughout 2022 and beyond.
- Put measures in place, including legislation, to prevent vaccine developers from impeding access to Covid-19 vaccines.
- Support and resource C-TAP and promote open and non-exclusive licences that include knowledge and technology transfer.
- Source Covid-19 vaccines through COVAX to allow fair vaccine allocation based on human rights considerations such as non-discrimination, prevalence of the pandemic in a country, the functioning of a country's health care system, and a country's vaccination rate.
- Put all necessary measures in place, and support countries in need, to ensure effective and fair vaccination roll-out upon receipt of vaccine doses.
- 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 waiver to WTO TRIPS Agreement and making use of the TRIPS flexibilities in a timely fashion.
- Make public funding for companies transparent and conditional on companies sharing intellectual property, knowledge and technology, joining global vaccine supply and technology sharing 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.
- Allow contractual flexibility for vaccine developers regarding delivery terms to ensure that those most at risk globally get access to the vaccines in a timely manner, in particular where sudden Covid-19 outbreaks require urgent responses.
- Publicly disclose terms and conditions of agreements with vaccines developers, including funding, advance purchasing, and purchasing agreements.
- Support efforts to reform intellectual property rights regimes to ensure universal access to essential, life-saving medicines.

ANNEX 1: HUMAN RIGHTS COMMITMENTS OF THE TOP TEN INSTITUTIONAL INVESTORS

Each of the top ten institutional investors has committed publicly to respecting human rights, while some have also made an explicit reference to the UN Guiding Principles and the requirement to conduct human rights due diligence, and where necessary engage with their investee companies. However, the scale of this commitment varies, with only small numbers explicitly referring to their engagement with companies whose shares they own or manage in relation to human rights concerns.

Vanguard Group Inc. has stated that it established a “formal procedure to identify and monitor portfolio companies whose direct involvement in crimes against humanity or patterns of egregious abuses of human rights would warrant engagement or potential divestment.”³⁴⁶ Though information on the procedure is limited, the procedure seems not to align with the UN Guiding Principles, which require business enterprises to address any human rights risks, not only those amounting to crimes against humanity or reflecting patterns of egregious human rights abuses. Further, measures to mitigate risks and prevent harm can be manifold and are not limited to divestment. They for instance include exerting leverage over the investee to ensure human rights compliance.

BlackRock Inc has a detailed human rights policy that explicitly refers to the UN Guiding Principles and the OECD.³⁴⁷ It states that it asks the companies that it invests in to “implement processes to identify, manage, and prevent adverse human rights impacts that are material to their business, and provide robust disclosures on these practices.” While this commitment to request human rights due diligence from investees, it does not fully align with the UN Guiding Principles which require companies to address any human rights risks, not only those which are material to the business. BlackRock also states its commitment to “engaging with companies on how they manage the human rights issues that are inherent in their businesses and monitor human rights practices on a best-efforts basis.”

State Street Corporation states that it is committed to “fair, ethical and responsible business practices” and that it “supports fundamental principles of human rights, such as those adopted in the United Nations Universal Declaration of Human Rights”.³⁴⁸ But its statement on human rights does not reference the UN Guiding Principles or provide any information about whether or how it engages with investees in relation to human rights risks.

Capital Group Cos Inc acknowledges the Universal Declaration of Human Rights and other international human rights standards and believes that “it is an essential obligation of our portfolio holdings to uphold these fundamental standards in their own operations and throughout their supply chains”.³⁴⁹ The investor further expects organisations to “conduct due diligence and monitoring of their supply chain.” Its human rights statement does not reference the UN Guiding Principles but does state that the company has “systematically incorporated” human rights into its investment processes. The company adds that “in our firmwide ESG monitoring and engagement programs, we seek to ensure that analysts are aware of potential violations and engaging with issuers on these topics.”

Wellington Management Group LLP does not have a human rights policy. It invites investees to work on their environmental, social and governance performance with the view for investees to “[r]educe the risk of being a target of shareholder activism”.³⁵⁰ In the “Adverse Sustainability Impacts Statement” of

346. Vanguard, Principles and Policies, about.vanguard.com/investment-stewardship/principles-policies/

347. Blackrock, “Our approach to engagement with companies on their human rights impacts”, www.blackrock.com/corporate/literature/publication/blk-commentary-engagement-on-human-rights.pdf

348. State Street, “Corporate Responsibility and ESG Policies”, www.statestreet.com/values/corporate-responsibility/corporate-policies.html

349. Capital Group, “ESG policy statement”, www.capitalgroup.com/advisor/pdf/shareholder/ITGEOT-001-643701.pdf

350. Wellington Management, “ESG insights for private companies”, [ESG insights for private companies —The critical role of ESG in private equity - US - Wellington Management.](https://www.wellington.com/insights/esg-insights-for-private-companies)

the Wellington Management Europe GmbH (“WME”), a member of Wellington Management, under the European Sustainable Finance Disclosure Regulation, WME states that Wellington Management will identify companies which have business practices which breaches any one of the ten Global Compact Principles.³⁵¹ These include a commitment to “support and respect the protection of internationally proclaimed human rights” and to “make sure that they are not complicit in human rights abuses”. In its 2020 Sustainability Report Wellington Management Group says it supports the UN Sustainable Development Goals, and says it is committed to “sustainable investing”. This includes a commitment to “engaging with companies to understand their strategy, financial and nonfinancial performance and risk, capital structure, social and environmental impact, and corporate governance and seek to guide and encourage change where appropriate.”³⁵²

Baillie Gifford has a clear policy on human rights, stating that it expects “all our holdings to respect internationally accepted human rights and labour rights throughout their business operations and value chain in line with the United Nations Guiding Principles for Business and Human Rights.”³⁵³ It does not explain further how it implements this commitment in its due diligence processes.

Bank of America Corp has a human rights statement in which the company commits to promote and protect human rights, and to conduct its business in a manner consistent with the Universal Declaration of Human Rights, the UN Guiding Principles on Business and Human Rights and the International Labor Organization’s Fundamental Conventions.³⁵⁴ It does not further elaborate how this commitment is operationalised in its due diligence processes.

Morgan Stanley states that it acknowledges “the corporate responsibility to respect human rights articulated in the United Nations’ Guiding Principles on Business and Human Rights.”³⁵⁵ It also states that “[h]uman rights considerations are incorporated into our transaction due diligence process, our engagement with companies, our supplier expectations, and our own operations.” And that “[a]reas of potential heightened human rights risk undergo enhanced diligence and may be escalated to senior management.”³⁵⁶

Bank of New York Mellon states that it is “committed to the protection and preservation of human rights around the world” and that it applies “these principles to everyone we do business with inclusive of our employees, suppliers, clients, communities and other stakeholders.” The bank’s human rights statement does not, however, reference the UN Guiding Principles or other standards or detail further how it operationalises its commitment, in particular in its due diligence processes.³⁵⁷

UBS has also issued a human rights statement which makes references the UN Guiding Principles.³⁵⁸ UBS states that it has put a process in place which “helps us identify and manage potential adverse impacts to the environment and to human rights”. Further, the company is committed “to reporting on the focus areas of this statement.”

351. Wellington Management, “Adverse Sustainability Impacts Statement”, www.wellington.com/uploads/2021/03/9dc929eca7b3914ec0a7c10374d3eff0/wme-adverse-sustainability-impacts-statement-0321-new.pdf

352. Wellington Management, “Sustainability Report 2020”, p. 7, www.wellington.com/uploads/2021/04/a68b814ca927aac8aa73051091fc50f0/sustainability-report_2020.pdf

353. Baillie Gifford, “Governance and Sustainability Investment managers 2021 Principles and Guidelines”, p. 17, www.bailliegifford.com/jp/japan/professional-investor/literature-library/corporate-governance/governance-and-sustainability-principles-and-guidelines/

354. Bank of America, “Bank of America Human Rights Statement”, about.bankofamerica.com/assets/pdf/human-rights-statement.pdf

355. Morgan Stanley, “Statement on Human Rights”, www.morganstanley.com/about-us-governance/pdf/human_rights_statement.pdf

356. Morgan Stanley, “2020 Sustainability Report”, p. 45, www.morganstanley.com/pub/content/dam/msdotcom/sustainability/Morgan-Stanley_2020-Sustainability-Report_Final.pdf

357. Bank of New York Mellon, “Human Rights Statement”, www.bnymellon.com/us/en/about-us/esg-and-responsible-investment/enterprise-esg/human-rights-statement.html

358. UBS, “UBS Human Rights Statement”, www.ubs.com/global/en/ubs-society/our-documents/_jcr_content/mainpar/toplevelgrid/col1/tabteaser/tabteasersplit_61486/innergrid_1976054452_651975952/xcol3/teaser/linklist/link_1026286007_copy_1331309605.172204686_9filebGluay9wYXRoPS9jb250ZW50L2RhbS91YnMvZ2xvYmFsL3Vicy1zb2NpZXR5LzlwMjE3Vicy1odW1hbi1yaWdodHMtc3RhdGVtZ50LWVvLW1hci0yMDIxLnBkZg==/ubs-human-rights-statement-en-mar-2021.pdf

ANNEX 2: LETTERS FROM COMPANIES

RESPONSES FROM ASTRAZENECA, BIONTECH, JOHNSON & JOHNSON, MODERNA AND PFIZER

ASTRAZENECA

Tue 08/06/2021

Dear Mr Wilcken,

Thank you very much for your recent correspondence in relation to AstraZeneca's human rights responsibilities regarding access to health. We have a proud record in these areas and are pleased to be able to respond.

I can personally assure you that we take our commitment to global public health and corresponding human rights responsibilities extremely seriously. From the outset of the pandemic, we knew we had a responsibility to act given our capacity to make a real difference to people's lives and health. That is why, as indicated in your letter, we are committed to supplying our COVID-19 vaccine broadly and equitably at no profit during the pandemic in response to a global public health emergency. Our aim is to meet an urgent need and support healthcare systems and economies to recover. It is through this that we hope to improve the lives and health of people globally, an objective that is underpinned by our commitment to human rights.

Our firm belief is that no one is safe until we are all safe, and this is why AstraZeneca has supplied its vaccine to over 170 countries globally to date. We were also the first vaccine manufacturer to partner with COVAX, the multilateral global equitable access initiative, so far providing 96 percent of the 70m+ doses supplied to over 120 countries – the majority of which are low-and-middle income countries. We work closely with CEPI, GAVI, the World Health Organization and others to maximise distribution and equitable vaccine access.

Intellectual Property (IP) and Technology Transfer

IP is the key driver of innovation for the research-based pharmaceutical industry, which has enabled unprecedented collaboration between industry and governments to develop lifesaving medicines, including to speed up progress on COVID-19 vaccines and treatments.

Building on our experience as a leading COVID-19 vaccine manufacturer, we believe the most effective way to address the pandemic is for vaccine manufacturers with specialised expertise to support the timely transfer of technological capabilities and know-how where production can be set up or ramped up at scale, combined with a commitment to supply billions of doses at not-for-profit pricing. We believe this approach effectively supports increased global access.

For AstraZeneca, an IP waiver would be unlikely to increase our global vaccine production as a significant proportion of our supply chain is already in the geographic regions supposed to benefit from this change.

We are open to exploring viable options to further expand the production of our vaccine while we optimise the productivity of existing supply, as part of our ambition to provide our COVID-19 vaccine to people around the world and help end of the pandemic.

Licensing Agreements and Due Diligence

AstraZeneca has risen to the challenge of creating a vaccine that is widely available around the world, so far securing supply capacity for billions of doses of the vaccine. In just one year, we have built a global supply network with more than a dozen parallel supply chains and more than 20 partners over 15 countries to deliver on our commitment to broad, timely and equitable access and accelerate vaccine production.

In building our supply chains, we have shared IP and know-how with capable and established vaccine manufacturing organisations to scale up supply. We have signed four sub-licensing agreements, with those organisations managing the allocation of their vaccine supply. This includes partnerships in low-and-middle income countries, such as the Serum Institute in India (SII), through which we have supplied 90% of the COVID-19 vaccines in India. Our approach has been to leverage local manufacturing where possible to balance speed of supply against our no profit pledge, while upholding the highest quality standards.

Pricing Policy and COVISHIELD™

At the start of the pandemic we made a commitment to make the vaccine available to as many countries as possible at no profit to support broad and equitable access around the world. However, given the complexity of global supply chains, cost of the vaccine can vary depending on supply chain, location and volumes requested by countries. This explains price differentiations between different countries. In addition to the manufacturing costs, AstraZeneca is incurring costs globally that include clinical development, regulatory, distribution, pharmacovigilance and other expenses.

ASTRAZENECA

COVISHIELD™ (manufactured by SII) and COVID-19 Vaccine AstraZeneca (manufactured by AstraZeneca) are the same vaccine developed by University of Oxford. COVISHIELD is priced according to our global no profit commitment, as is the case across our entire supply network, with local variables dictating cost.

As you will appreciate, our entire focus right now is on playing our part in ending the current pandemic and helping in our shared objective of vaccinating the world. We are not yet in a position to be discussing any plans in relation to future agreements.

We hope this information gives you a strong sense of our deep commitment to equitable vaccine distribution, protection of ethics and human rights as part of our shared public health responsibility. As always, we will be guided by our core values as a healthcare leader on what we believe is the right thing to do.

I want to thank you for your engagement and leadership in ensuring human rights accountability throughout the pharmaceutical industry at such a critical time. There has never been a more important time to ensure global accountability and widespread commitment to the sanctity of human rights. We strive to improve the lives of people all over the world, and are pleased to have an opportunity to play our part to support global recovery.

We hope this can be part of an ongoing dialogue as we work towards our shared ambitions on these important areas.

Yours sincerely,



Vice President, Global Corporate Affairs

09.09.2021

Statement on Amnesty International publication on vaccine developers' human rights responsibilities in relation to the Covid-19 vaccine rollout

As a COVID-19 vaccine manufacturer we see it as our responsibility to support the worldwide supply of the Pfizer/BioNTech vaccine by continuously increasing our manufacturing capacities. We recognize and agree with the need for supply of vaccine doses to low and lower-middle income countries. To date, Pfizer and BioNTech have shipped more than 1.4 billion COVID-19 vaccine doses to more than 100 countries or territories in every region of the world. The companies are firmly committed to working towards equitable and affordable access for COVID-19 vaccines for all people around the world, actively working with global governments as well as global health partners with the aim to provide 2 billion doses to low- and middle-income countries in 2021 and 2022 – 1 billion each year. This includes an agreement to supply 500 million doses to the U.S. Government at a not-for-profit price, that the government will, in turn, donate to the African Union and the COVAX 92 Advanced Market Commitment (AMC) countries, as well as a direct supply agreement with the COVAX facility for 40 million doses. We are fully committed to supplying our vaccine to people around the world in all countries and across all income levels. We all know that no one will be safe until everyone is safe.

However, patents are not the limiting factor for the production or supply of our vaccine. They would not increase the global production and supply of vaccine doses in the short and middle term. Experts have already pointed out, that the set-up and validation of new manufacturing sites usually takes up to one year. Furthermore, there are many important factors separate from patent considerations that are involved in producing an mRNA vaccine to ensure its quality, safety and efficacy. The manufacturing process of mRNA is a complex process developed over more than a decade. All steps must be precisely defined and executed accurately. It takes experienced personnel. It takes raw materials that need to be sourced and qualified for use. It takes established processes for preparing the vaccine which need to be followed meticulously. If any of these requirements is not met, the quality, safety and efficacy of the vaccine cannot be ensured by the manufacturer nor the innovator. This could put the health of the vaccinees at risk. Also, there is the risk that some of the limited and important raw materials are not used in an efficient manner thereby reducing the amount of vaccine doses that can be produced in already established manufacturing networks.

We have conducted numerous technology transfers to dramatically increase production of our vaccine while ensuring the highest quality standards. This is why we are already working closely with partners under licensing and manufacturing agreements to further establish a global GMP-certified manufacturing network which meets all requirements to manufacture safe and effective vaccines. Together with Pfizer, we have entered into additional contracts with more than 150 vendors specifically supporting the development and production of our vaccine. We also plan to incorporate Biovac's Cape Town (SA) facility for fill & finish into the vaccine supply chain by the end of 2021 to support supply on the african continent. We have also signed a letter of intent with Brazilian biopharmaceutical company Eurofarma Laboratórios to perform manufacturing activities within Pfizer's and BioNTech's global COVID-19 vaccine supply chain and manufacturing network for distribution within Latin America. Pfizer's and BioNTech's global COVID-19 vaccine supply chain and manufacturing network, which will now span four continents and include more than 20 manufacturing facilities. BioNTech has already started the evaluation of manufacturing capabilities, following the Company's announcement of its aim to develop a well-tolerated and highly effective Malaria vaccine and to implement

BIONTECH



sustainable end-to-end vaccine supply solutions on the African continent. The decision to evaluate manufacturing solutions in Rwanda and Senegal follows the guidance of the African Union, the Africa Centres for Disease Control and Prevention (Africa CDC) and the African Medical Agency under formation. The prospective locations of the necessary manufacturing sites are expected to co-locate with the World Health Organization's (WHO) upcoming Vaccine Hubs. These efforts will be aligned with the Team Europe Initiative on manufacturing and access to vaccines, medicines and medical technologies (MAV+) led by the European Commission in collaboration with the EU Member States.

We believe that the continued expansion of manufacturing capabilities leveraging GMP-certified sites and experienced manufacturers will help to end this pandemic by ensuring worldwide supply with safe and effective vaccines. In order to achieve this, governments, manufacturers as well as international and national organizations will have to jointly support the supply of low and lower middle income countries from the already existing manufacturing sites and help to identify new certified sites. This applies for manufacturing capacities and supply agreements but also for improving the infrastructure and logistics for the supply.

Together with Pfizer, we are also working with various organizations to support the supply of vaccines to populations worldwide. And we will continue to provide low or lower middle income countries with our vaccine at a not-for-profit price.

JOHNSON & JOHNSON

14 September 2021

Johnson & Johnson responded to Amnesty International's request for comment by email on 14 September 2021 by commenting directly on Amnesty International's letter. The following provides an overview of Johnson & Johnson's main comments.

IN RELATION TO JOHNSON & JOHNSON'S HUMAN RIGHTS POLICY

- "Beyond issues of IP and pricing transparency, we have developed and delivered our vaccine in accordance with human rights in other respects as well. For example: we conducted our COVID-19 vaccine trials in lower-income settings and recruited a diverse set of trial participants; and we helped advocate for the implementation of the world's first vaccine injury compensation mechanism for eligible individuals in 92 Low- and Lower-Middle-Income Countries."

IN RELATION TO INACTION ON INTELLECTUAL PROPERTY AND TECHNOLOGY SHARING:

- "To the contrary, J&J has been far from inactive with our IP – we have used it to foster innovation and scale manufacturing in the most effective and efficient way to produce the vaccine and address the human right to health. Producing vaccines involves complex manufacturing processes. Globally, there is a limited number of manufacturers with sites capable of producing the high quality and safe vaccines necessary to address this pandemic. In an effort to identify qualified partners, J&J assessed nearly 100 different production sites resulting in 12 partnerships across four continents. Examples include our collaborations with Aspen Pharmacare (South Africa), Biological E. (India), Merck (U.S.) and Sanofi Pasteur (France). Each of these partnerships include a tech transfer component; a manufacturing license to our technology and the sharing of manufacturing know-how to enable the safe and high-quality production of our vaccine and to activate our manufacturing on a global scale as soon as possible. We do not believe that circumventing IP, or the forced sharing of IP, would produce additional manufacturing sites capable of producing safe and effective vaccines and would hinder the ability of companies to enter into the partnerships necessary to scale up vaccine supply. IP has not been a barrier but rather has been a key facilitator of our COVID response at every step of the way."
- "J&J has established 12 manufacturing and supply partnerships across four continents, each of our manufacturing partnerships is based on a voluntary technology transfer from Johnson & Johnson to its partners. These transfers include a manufacturing license to our technology and the sharing of manufacturing know-how to enable the safe, swift and highest-quality production of our vaccine on a global scale. We have also initiated discussions with Aspen Pharmacare to further expand COVID-19 vaccine production, including a potential commercial license, and we are continuing to assess additional manufacturing opportunities in various regions"

ON TRANSPARENCY OF CONTRACTUAL TERMS AND CONDITIONS OF PURCHASE AGREEMENTS

- "We have permitted a redacted version of our APA with the European Commission to be published: https://ec.europa.eu/info/sites/default/files/ji_apa_202005071550.pdf"



200 Technology Square • Cambridge, MA 02139
Phone 617-714-6500 • Fax 617-583-1998

June 8, 2021

Mr. Patrick Wilcken
Head of Business, Security and Human Rights
Amnesty International
Peter Beneson House
1 Easton Street
London WC1X 0DW
United Kingdom

Sent by email to [REDACTED]

Dear Mr. Wilcken:

I write in response to your letter of May 26, 2021 addressed to Stéphane Bancel, Chief Executive Officer of Moderna, Inc. We share your deep concern with the humanitarian and public health crisis posed by the COVID-19 pandemic, particularly in low- and middle-income countries, and we agree that it is vitally important to rapidly increase global access to safe, effective vaccines by expanding the production of our COVID-19 vaccine. I hope that the explanations below will help address the questions that you posed in your letter.

Background

I believe it is important to provide some background on the technology and manufacturing processes that are used to produce Moderna's COVID-19 vaccine. Our company was only founded a decade ago, and our COVID-19 vaccine is our first commercial product. Since our founding, our mission has been to improve patients' lives by creating a new generation of transformative medicines based on messenger RNA ("mRNA").

For our first decade, Moderna focused on research and development. We designed our strategy and operations to unlock the potential of mRNA over a long time horizon. We raised billions of dollars in capital and built and invested in our technology platform, which creates mRNA sequences that cells recognize as if they were produced in the body. We have announced twenty-four therapeutic and vaccine development programs to date. These programs span a wide range of conditions, including infectious diseases, immunoncology, rare diseases, autoimmune diseases, and cardiovascular diseases.

This decade of research taught us valuable lessons about designing mRNA medicines, including vaccines. We learned how to manufacture and formulate mRNA that can be safely injected into people and induce an appropriate immune response. We also gained experience producing over 100 batches of mRNA for use in human clinical trials.

When COVID-19 emerged, Moderna was able to develop our vaccine quickly because we leveraged our prior research, experience, and mRNA platform. We progressed from genetic sequencing to a vaccine ready for human testing in just 63 days. After clinical trials, on December 18, 2020, the U.S. Food & Drug Administration authorized the emergency use



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of our COVID-19 vaccine. This was the first time any Moderna product has been authorized for use outside of clinical testing.

Producing a vial of our vaccine is a multiple-stage process. First, we have to create large batches of the drug substance: mRNA encapsulated in a lipid nanoparticle. This first stage is itself a multistep process that requires the availability of raw materials and consumable supplies. The second and third major stages of the production process are filling vials with the drug substance, and then inspecting, testing, and packaging the filled vials for delivery. At any given time, millions of doses of our vaccine will be at different stages of this process.

The pace and volume of our production process has increased exponentially since we began making our vaccine, for several reasons. First, over time, the buildup of the product and other necessary supplies at each stage generally allows subsequent stages to operate more efficiently. Second, the pace also increases as the process gets refined and the highly skilled and experienced personnel operating that process gain greater familiarity with it. Third, as discussed below, we have been able to gradually onboard additional partners to expand our capacity.

Obviously, greater scale and speed cannot come at the expense of safety and quality. Ensuring both requires careful planning and specialized knowledge sharing between Moderna and its contract partners. As such, conducting technology transfers and ramping up new production lines requires significant time from a limited pool of experienced personnel with the requisite expertise.

Notwithstanding these challenges, to date, Moderna has produced and shipped well over 100 million doses of our vaccine, and we currently forecast producing between 800 million to 1 billion doses in 2021.

Expanding Global Vaccine Access

As we have said in recent public statements—both during our Annual Meeting of Shareholders and during our first quarter earnings call—we do not believe that a waiver of the protections under the World Trade Organization (“WTO”) Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) or the contribution of our intellectual property to the World Health Organization’s (“WHO”) COVID-19 Technology Access Pool (“C-TAP”) are effective ways of rapidly expanding access to COVID-19 vaccines. That said, we have undertaken several measures that we believe *will* meaningfully increase access to vaccines as quickly as possible, as further described below.

Supplying Up To 500 Million Doses To COVAX

On May 3, 2021, we announced that we have entered an agreement to supply up to 500 million doses of our vaccine to COVAX, including an initial 34 million doses to be delivered in the fourth quarter of 2021.¹ The agreement covers the 92 Gavi COVAX Advance Market

¹ Moderna, Press Release: *Moderna Announces Supply Agreement with Gavi for up to 500 Million Doses of COVID-19 Vaccine Moderna for COVAX To Help End COVID-19 Pandemic in Lowest Income Countries* (May 3, 2021), <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-supply-agreement-gavi-500-million-doses-covid>.



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Commitment low- and middle-income countries, and gives Gavi, the Vaccine Alliance, the option to procure 466 million additional doses in 2022. This agreement came just days after the WHO issued an Emergency Use Listing for Moderna's vaccine, a prerequisite to reaching agreement to supply COVAX. All doses are offered at Moderna's lowest tiered price.

While most of our efforts to provide our vaccine to low- and middle-income countries have been focused on COVAX, we have also entered into supply agreements with other nations, such as the Philippines, Colombia and Botswana for separate supply. We are in active discussions for supply with the Indian government and additional countries around the world.

Forming Partnerships to Increase Manufacturing Capacity

Moderna has entered into voluntary licensing arrangements to manufacture its vaccine and expand supply around the world. In the United States, Moderna's vaccine is produced both at its own Norwood, Massachusetts facility and at a facility in Portsmouth, New Hampshire operated by our contract manufacturing partner, Lonza Ltd. Moderna has also formed partnerships for the "fill-finish" stages of the process in the United States. That work is done by partners Catalent (in Bloomington, Indiana), Baxter BioPharma Solutions (in Bloomington, Indiana), and Sanofi (in Ridgefield, New Jersey), and we recently announced an intent to further expand this capacity by working with Thermo Fisher Scientific.

Moderna has also entered into partnerships to produce, fill, and finish its vaccine outside the United States. For nearly a year, Moderna has worked with Lonza to produce our vaccine at Lonza's facility in Switzerland. We recently partnered with Laboratorios Farmacéuticos Rovi in Spain for both the manufacturing and fill-finish process. We have also partnered with Recipharm in France for the fill-finish process.

We are committed to pursuing additional partnerships around the world to expedite production and delivery of our vaccine and we are continuing to seek out such agreements. Moderna is engaged in active conversations with governments and private companies in middle- and low-income countries about partnerships to expand the manufacturing process in those countries.

Building Capacity to Produce Up to 3 Billion Doses in 2022

We are also building production capacity here in the United States. On May 4, we announced the expansion of our Norwood, Massachusetts facility, which will more than double its space and transform it from a production and lab space to an industrial technology center. We will increase production and lab space from approximately 300,000 square feet to approximately 650,000 square feet through renovation of existing space and acquisition of a 240,000 square foot building located on the same campus. This expansion will support a 50% increase in production of our vaccine in Norwood.

This investment is part of a broader effort, announced a few weeks ago, to make new funding commitments to increase supply at our owned and partnered manufacturing facilities. We expect these investments and planned partnerships will increase global 2022



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capacity to **up to 3 billion doses of our vaccine**.² At the same time, we raised our 2021 manufacturing supply forecast to between 800 million to 1 billion doses.

When completed, the investments will also result in an increase in safety stock of raw materials and finished product used to deliver committed volumes. The company will begin making investments at its owned and partnered manufacturing facilities in 2021, with increased production from these investments expected to ramp up in late 2021 and early 2022.

We have also explored establishing a manufacturing presence in Africa to solve for unmet needs under current vaccine production capacity on the continent.

Addressing Logistical Obstacles Through Science

Moderna is also expanding global access by researching methods to extend vaccine shelf life and reduce the need for temperature-specific storage. These efforts are vital to broadening vaccine distribution in remote areas and developing nations. We recently announced data indicating that the current formulation of our vaccine could support a 3-month refrigerated (2-8°C) shelf life in alternative formats to facilitate easier distribution to doctor's offices and other smaller settings. Our vaccine is also the only authorized mRNA vaccine that does not require on-site dilution.

We also recently announced that we are working on a next generation vaccine candidate that we believe will extend refrigerated shelf life even further. Moderna's investments in its mRNA platform enabled development of this next generation vaccine candidate. It is a potential refrigerator-stable vaccine that could facilitate distribution and administration in a wider range of settings, including in developing countries.

Making a Voluntary Pledge on Intellectual Property

Finally, as you noted in your letter, on October 6, 2020—over eight months ago—Moderna voluntarily pledged not to enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic.³ Our statement noted that Moderna is a pioneer in the development of mRNA vaccines and therapeutics and that, with the support of our investors, we have invested billions of dollars into research and development to make mRNA medicines a reality. We recognized, as a company committed to innovation, that intellectual property rights play an important role in encouraging investment in research.

² Moderna, Press Release: *Moderna Announces Additional Investments to Increase Global Supply for COVID-19 Vaccine to up to 3 Billion Doses in 2022* (April 29, 2021), <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-additional-investments-increase-global-supply>. The total amount will depend upon the mix between our authorized vaccine at its current dose level and potentially lower doses of our variant booster candidates and pediatric vaccines, if authorized.

³ Moderna, Press Release: *Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic* (October 8, 2020), <https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19>.



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We noted that our portfolio of intellectual property is an important asset that will protect and enhance our ability to continue to invest in innovative medicines.

Notwithstanding that, we explained that Moderna “feel[s] a special obligation under the current circumstances to use our resources to bring this pandemic to an end as quickly as possible.” We pledged that “while the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic.” We also stated that “to eliminate any perceived IP barriers to vaccine development during the pandemic period, upon request we are also willing to license our intellectual property for COVID-19 vaccines to others for the post pandemic period.”

Barriers to Vaccine Access

Your letter asks us why we have not contributed our intellectual property to the WHO’s C-TAP. We believe that the best way to expand access to vaccines is by working with proven partners who are capable of producing our vaccine safely and effectively. With respect to mRNA vaccines, our view is that the complexity of the manufacturing process and the need to maintain rigorous safety and quality standards impose real constraints on the rate at which we can increase global supply. These practical constraints require cooperative, collaborative partnerships to overcome. As a result, it takes time and requires human expertise to ramp up new manufacturing lines.

There are additional barriers. Limits on raw materials and consumables, along with other supply chain issues, constrain the pace of production. Logistical challenges—such as the lack of cold storage and transportation and infrastructure problems—pose significant challenges to widespread distribution. Finally, local regulatory requirements and trade hurdles (including tariffs, export restrictions, customs procedures) serve as additional barriers to the effort to quickly vaccinate the global population.

Additional Intellectual Property and Technology Transfer Issues

As described above, Moderna has taken major steps to ensure that intellectual property rights are not a barrier to expanding global vaccine access. We have entered into voluntary licensing arrangements, conducted technology transfers, and formed manufacturing partnerships to expand production of our vaccine. We are committed to seeking additional partnerships. We have also voluntarily pledged not to enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic, and we have said that we are willing to license our intellectual property for COVID-19 vaccines to others for the post-pandemic period.

As discussed above, technology transfers require significant time from a limited pool of experienced personnel with the requisite expertise. We are focused on transferring technology to chosen partners around the world—partners that we are confident can produce our vaccine with the utmost commitment to safety and quality. We are prioritizing bringing these manufacturing capabilities and production lines online as quickly as possible. Trying to engage in additional technology transfers could put at risk the delivery of our



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current and upcoming production lines and could have negative efficiency, safety, and quality consequences.

We believe that the steps outlined above are the most effective way of expanding the supply of mRNA vaccines in 2021 and 2022. We are not aware of idle mRNA manufacturing capacity. Nor are we aware of companies who have developed manufacturing, purification, and medical processes that would allow them to rapidly run clinical trials and then produce a meaningful supply of mRNA vaccine. As a result, we are focused on the efforts described above to expand global vaccine access, as well as the development of vaccine boosters targeting emerging variants. From a policy perspective, we also believe that weakening intellectual property protections could impede future innovation by making it harder to fund research and development into high-risk, high-reward innovations over a long time horizon.

* * *

At Moderna, we share your concern with the humanitarian and public health crisis posed by the COVID-19 pandemic, particularly in low- and middle-income countries. We agree that it is vitally important to rapidly increase global access to safe, effective vaccines. We are committed to continuing our efforts to expand global vaccine access.

Thank you. We appreciate your willingness to engage constructively on this issue.

Sincerely,

SVP Government Engagement



Dr. Albert Bourla
Chairman of the Board
Chief Executive Officer

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June 15, 2021

Mr. Patrick Wilcken
Deputy Programme Director
Head of Business, Security, and Human Rights
International Secretariat
Amnesty International
1 Easton Street
London WC1X 0DW
United Kingdom

Dear Mr. Wilcken,

Thank you for your letter. We welcome the discussion on human rights and agree on its utmost importance to the healthcare sector. We know there is a lot of interest in every aspect of our work in relation to access to the COVID-19 vaccine and are grateful for all feedback. Before I answer your specific questions, I want to provide more context about our approach to addressing this pandemic.

Pfizer's purpose – *Breakthroughs that change patients' lives* – is the driver of everything we do. Equity, among our four Company values¹, determines how we deliver on our purpose and, in consequence, profoundly guides the ways in which we work to fulfill our responsibility to the global community.

You have likely seen in our public statements that our approach to the development of this vaccine was grounded in the hope that the vaccine would be available to every patient, country and community that seeks access.

Our COVID-19 efforts did not happen in isolation. Over the past four years, Pfizer has been engaged in a review of the UN Guiding Principles on Business and Human Rights and what they mean for our business. After assessing with internal and external stakeholders, we concluded that we needed to firmly state that the right to health is the most salient human rights issue for Pfizer, and that more work was needed to demonstrate the steps the company is taking to bring a human rights-based approach to our work. This resulted in revising our [human rights policy statement](#).

¹ The four values that guide Pfizer's culture are Equity, Joy, Excellence and Courage.

With the most vulnerable in mind, we opted for a multi-pronged approach to enable access to our COVID-19 Vaccine:

First, we chose to use a tiered pricing approach that was set based on the income level of each country which allowed Governments to distribute our vaccine to their citizens for free;

Second, we partnered with global health stakeholders to help strengthen healthcare systems where greater support may be needed to deploy COVID-19 vaccines; and,

Third, we continued investing in innovation to enable access, advancing research into the needs of specific populations and of the evolution of the disease.

Access

As the pandemic continues, our priority remains the same: *fair and equitable distribution of our COVID-19 vaccine*. To do this, we continue supporting Governments that choose to procure our vaccine by ensuring there is enough supply of vaccines for the government's needs. We have announced that we will manufacture to the world 3 billion doses in 2021, and we anticipate producing 4 billion doses in 2022. These doses are not for the rich or poor, not for the north or south. These are doses for ALL.

Although today most of the approximately 450 million doses we have shipped have gone to high income countries for a variety of reasons (including the time of their regulatory approvals and operational readiness), we actively took action, including me personally, reaching out to Heads of State by letter, phone, and even text, to urge them to reserve doses, to address the risk this imbalance represented to people in lower income countries because the supply was limited. In many cases, Governments had decided to prioritize vaccines from other manufacturers either because mRNA technology was untested at that time, or because they were offered local production options. Some didn't even approve our vaccine. Unfortunately, other vaccine producers were not able to meet their supply commitments for varying technical reasons. Most of the countries that did not choose us initially came back, and thanks to our phenomenal supply ramp up, we have started signing supply agreements with them. Pfizer also engaged with COVAX since the early phase of the pandemic, and we have put in place extensive support to minimize any barrier to countries receiving our vaccine.

Thanks to all these efforts, we now expect the supply balance to weigh in favor of middle- and low-income countries in the second half of 2021, and to have virtually enough supply in 2022 for all governments that choose to procure our vaccine.

Recently, we pledged to provide 2 billion doses of our COVID-19 vaccine to middle- and low-income countries over the next 18 months. We expect to provide 1 billion of these doses to low- and middle-income countries this year. And we pledged to deliver another 1 billion doses to these countries in 2022. Upon finalization of all agreements, we expect 40% of our planned supply to go to low- and middle -income countries.

On June 10, Pfizer and BioNTech [announced](#) plans to provide the U.S. government, at a not-for-profit price, 500 million doses of the companies' COVID-19 vaccine, 200 million doses in 2021 and 300 million doses in the first half of 2022, to further support the multilateral efforts to address the surge of infection in many parts of the world and to help end the pandemic. The government will, in turn, donate the Pfizer-BioNTech vaccine doses to low- and lower middle-income countries and organizations that support them. Doses will be donated to approximately 100 low- and lower middle-income countries, including those in the African Union via the COVAX Facility.

Under a previous agreement, Pfizer-BioNTech had allocated doses through COVAX to countries in every region of the world, including Rwanda, Cape Verde, Tunisia, West Bank/Gaza Strip, Angola, Botswana, Colombia, Peru, El Salvador, Bolivia, South Korea, Philippines, Maldives, Pakistan, Laos, Bangladesh, Bhutan, Moldova, Georgia, Ukraine, Bosnia & Herzegovina, Mongolia and Kosovo.

In the next round of COVAX allocations, Pfizer/BioNTech doses will have been allocated to nearly 50 diverse countries and territories through June 2021, and we continue to engage with COVAX in discussions on how to get more doses to more people.

Pricing model

In response to your question about Pfizer's pricing model, please note that we established pricing principles for the COVID-19 vaccine which are consistent with Pfizer's commitment to the right to health, our values, and our mission to bring *breakthroughs that change patients' lives*. These are extraordinary times, and our pricing reflects that. During the pandemic we priced our vaccine consistent with the urgent global health emergency we are facing to help ensure widespread vaccination for all countries that supply our vaccine. Our pricing enables governments to offer the vaccine at little to no out-of-pocket costs for their populations.

And recognizing that equity doesn't mean we give everyone the same, but rather we give more for those in higher need, we set a lower price for middle-income than high-income countries, and we are providing the vaccine to low-income and lower-middle-income countries at a not-for-profit price.

Volume of doses ordered, advance commitments, and equity considerations are key drivers in our government contract pricing. We have a tiered pricing approach that enables poorer countries to pay less, and we also take into account advance commitments and the number of doses contracted.

Pfizer believes it has, and will continue to, engage in transparent and appropriate pricing consistent with Pfizer's commitment to the right to health, our values, and our mission to bring breakthroughs that change patients' lives.

Pfizer's development and manufacturing costs relating to the COVID vaccine have been entirely self-funded. To date, Pfizer has already invested \$2 billion in the development of the vaccine. We have invested at risk, and are prepared to continue to bear the costs of development and manufacturing in an effort to advance a solution to this pandemic.

The agreements Pfizer has entered with Governments are for supply of vaccine to their people, not for vaccine development. We have invested from our own resources/flow of revenues at risk, and are prepared to continue to bear the costs of development and manufacturing to advance a solution to this pandemic.

Vaccines offer value to both patients and the public health and are complex to develop, manufacture and distribute. For example, our COVID-19 vaccine involves the use of over 280 materials that come from 86 suppliers in 19 different countries. Post the pandemic, we will utilize a market and value-based pricing approach.

Intellectual property

In response to your question about the TRIPS waiver and related lobbying efforts, the IP system is an essential facilitator to the availability of the vaccine and not an impediment or risk, and remains a critical enabler of the future research that will be necessary to end the pandemic. It took not only unprecedented courage and dedication, but also significant investments, at-risk, to bring diagnostics, treatments and now finally vaccines to tackle COVID-19.

The incentives provided by the intellectual property system enabled Pfizer to build the expertise and infrastructure that allowed us to quickly mobilize and devote the resources, technical knowledge and know-how required to combat the pandemic—and it also facilitated the advancement of cutting-edge technologies such as mRNA vaccines. It has enabled an unprecedented number of collaborations between biopharmaceutical innovators and governments, universities, and other research partners to speed up progress on finding solutions to end the pandemic, as demonstrated by our partnership with BioNTech. Under our agreement with BioNTech, the IP directed to the mRNA COVID-19 vaccine is primarily owned by BioNTech.

The TRIPS Agreement, which sets down minimum standards for many forms of intellectual property rights, is critical to lock in the IP protections that will be needed to incentivize innovation and facilitate partnerships, especially as we seek to find solutions for special populations (e.g., children) and overcome new variants of the virus. Not only would waiving those commitments send the wrong message to future innovators in the next pandemic, it could make it harder to resolve the current one, particularly if companies begin to buy up scarce inputs in the hopes of manufacturing a vaccine using technology developed by others. Greater demand pressures on inputs from new market entrants will make it harder, not easier, to manufacture vaccines in the near term.

As indicated in our [Environmental, Social & Governance Report](#), responsible use of our intellectual property (IP), enables us to engage in collaborations and partnerships that have the potential to speed up progress on the most pressing unmet medical needs, including COVID-19. We are proud of our long-standing commitment to keeping patients and societal benefit at the center of our IP practice.

Last month we, along with 25 members of the biopharmaceutical industry, launched the ["IP Principles for Advancing Cures and Therapies" \(IP PACT\)](#)--a groundbreaking, unified declaration of 10 key intellectual property principles that guide our companies' approach to IP—with patients as our North Star.

Recognizing the unique level of economic development and social challenges of Least Developed Countries, as defined by the United Nations Committee for Development Policy, Pfizer has a general policy of [patent non-enforcement in LDCs](#).

In response to your question regarding the *COVID-19 Technology Access Pool*, I can say that we have always said that no one company, vaccine or treatment would be enough to combat this pandemic, and that we need to harness the potential of the full biotechnology ecosystem. That is why, in March of last year, we committed to sharing our scientific tools and insights, development expertise, and manufacturing capacity in our 5-Point Plan. We also stood in solidarity with industry leaders and pledged to protect scientific integrity, building on our rich history in vaccine research and development. In that spirit, Pfizer welcomes voluntary initiatives that add to the pool of resources and options available to promote equitable access to COVID-19 therapies and vaccines, and we remain committed to constructive dialogue with all parties. We will continue to consider all reasonable options and mechanisms, as needed, to ensure that the vaccine and any potential therapies to help address the pandemic are accessible to those who need it.

In response to your questions about licensing agreements, knowledge and technology sharing, and due diligence of other solutions to expand manufacturing of COVID-19 vaccines, I can say the development, manufacturing, distribution and storage of complex innovative products, including the mRNA technology, requires globally-optimized supply chains and we are actively focused on production arrangements to support a robust and reliable global supply chain. We are one of the few companies that still develop and manufacture vaccines on a large scale. For biologics, sterile injectables and vaccines, we have approximately 17,000 colleagues in 23 manufacturing facilities in 11 countries.

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Pfizer is also one of the largest producers of generic sterile injectable products for the US market. We do the vast majority of our sterile filling internally for our branded and generics business, but we do use a great network of outside suppliers that do more specialized sterile filling for us.

Early on, we determined that the best way to manufacture this vaccine at significant scale quickly, and in compliance with all quality standards, would be to activate our extensive manufacturing network in Europe and the US, which includes relying on the thousands of highly skilled workers. At this point, we are favoring global contract manufacturers with broad regulatory approvals and significant available capacity over local contract manufacturers in individual markets. Localizing vaccines requires time consuming processes, as well as a significant commitment of technical and personnel resources, resources that would have to be pulled away from the current production of the vaccine. Therefore, Pfizer currently is focusing our efforts and resources in a way that maximizes our overall supply so we can better support the global needs. While we pursue our current strategy, we also continue to evaluate whether and where localization may be appropriate.

We have undertaken significant efforts to scale up capacity and enhance efficiency. For example, we have added suppliers as well as contract manufacturers, made process improvements to our existing production lines, and we are also making continuous improvements in our sites. We expanded the supply of raw material from existing suppliers and brought on new suppliers. We doubled our batch sizes in order to minimize time between batches and increased the yield per batch. Our efforts to date have paid off: We have increased projected 2021 global production from 1.3 billion doses, to more than 2.5 billion doses. Planning for the future, Pfizer continues to evaluate new manufacturing partners with appropriate manufacturing expertise, technical capabilities, trained personnel, qualified facilities and scientific expertise. All members of our supply chain are expected to operate their businesses in a responsible and ethical manner, respecting human rights, as outlined in Pfizer's Supplier Code of Conduct.

There is enormous collaboration to overcome existing obstacles already taking place. Manufacturers with the appropriate expertise, technical capabilities, and facilities have entered into partnerships and licensing agreements to speed up the production and distribution of vaccines. For example, Thermo-Fisher, Sanofi, and Novartis are supporting the Pfizer-BioNTech efforts to increase the supply of our COVID-19 vaccine, which includes expanding our manufacturing facilities, and adding more suppliers and contract manufacturers to our supply chain.

Continued innovation to enable access

We continue to study the safety and efficacy of the vaccine. Specifically, we continue advancing the science and knowledge about the impact of our COVID-19 vaccine in [specific populations](#), such as pregnant women and children. We have obtained approval for [new storage options](#) to help address distribution challenges, and we are delivering on our commitment to advance our research program for a COVID-19 Antiviral treatment, which is in development.

And beyond efforts around our COVID-19 vaccine, since the beginning of the pandemic, we have been working with governments and international non-governmental organizations to provide relief and support where it is needed through [donations of much needed medications](#) and by working to support front line health workers in [vulnerable communities](#).

We are committed to positive health outcomes for people everywhere and continue working to continuously improve wherever we can.

PFIZER

To conclude, we recognize and are concerned by the complex evolution of the pandemic and how it continues to have severe impacts on individuals, families and communities. We continue to regularly evaluate the risks it poses to people, particularly in the most vulnerable geographies, and among the most vulnerable groups of society. No single organization or Company can solve the equity challenge alone.

We are committed to continue evolving and improving our response to this pandemic where we can. For this, we welcome the opportunity to engage with all stakeholders and to listen to external perspectives, such as yours. We value the opportunity to reflect on what we have already achieved, and our lessons learned, and will be continuing this conversation internally in line with our commitment to continuous improvement.

We remain fully focused on getting high-quality, safe and effective vaccines to patients all over the world as quickly as possible and to helping end this deadly pandemic.

Your sincerely,



Dr. Albert Bourla, D.V.M., Ph.D.
Chairman of the Board Chief Executive officer

ANNEX 3: LETTERS FROM INSTITUTIONAL INVESTORS

RESPONSES FROM BAILLIE GIFFORD, BLACKROCK AND UBS

BAILLIE GIFFORD

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Patrick Wilcken
Head of Business, Security and Human Rights
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10 September 2021

Ref: TC POL
30/2021.029

Dear Mr Wilcken,

Thank you for contacting us. We value our engagements with civil society organisations and appreciate the work that you are doing to promote further research and discussion on such important topics.

Baillie Gifford focuses on long-term, active investment management. We emphasise 'bottom-up' research on individual companies, which also applies to our work on governance, environmental and social factors, and sustainability.

We agree that companies, including the institutional investors that form most of our client base, have a responsibility to respect all human rights wherever they operate in the world and throughout their operations. Our active long-term investment management style allows us to act in a manner which is supportive for society through the allocation of capital to companies driving positive change. This also allows us to influence the behaviour of decision-makers, so they take action to address important issues affecting society. We try to set a positive example as an investor, as an employer and within our own communities, to uphold and promote the highest standards of service and professional behaviours.

Our investment cases for Moderna and BioNTech were not a reaction to COVID-19 but based on the m-RNA technology that should allow these companies to address unmet needs in the healthcare sector. We identified them as transformational companies with the ability to create better patient outcomes. Moderna's true potential lies in its scalable approach to drug development, which means the success of the COVID-19 vaccine could be repeated across other areas such as flu, Zika, HIV, and cancer. In addition, we analysed their capabilities to democratise access to their solutions and engaged extensively with both firms to understand mission and motivation.

Regular engagement is an important part of our investment and ownership responsibilities, so we have engaged with each company on a range of social matters over the last 24 months, especially related to the pandemic.

A list of the partners' names is available at the above address.
Authorised and regulated by the Financial Conduct Authority.

Globally, access to vaccines is shaped by political, economic, social and health-sector related matters. In this context, with Moderna, we have had in-depth discussions on intellectual property, market shaping and pricing of vaccines. This includes identifying its role to facilitate access to vaccines in low and middle-income countries (LMICs). Moderna provides a three-tiered pricing scheme, with the lowest tiered pricing offered to LMICs, including sales to COVAX. Importantly, Moderna does not withhold intellectual property - it has publicly declared it will not enforce any of its patents against those making vaccines for the duration of the pandemic.

We have also engaged regularly with BioNTech and believe the company to be deeply committed to healthcare equality. This is evidenced, for instance, by the joint commitment with partner Pfizer to donate two billion doses to LMICs (announced in May), and plans to establish vaccine production facilities in Rwanda and Senegal to support supply for the Member States of the African Union (announced last week).

On your two questions, see our answers below.

Have you undertaken any due diligence in relation to your investee's potential adverse human rights impacts on access to COVID-19 vaccines?

In the case of Moderna and BioNTech, we aimed to identify companies which are developing technologies that meaningfully improve health outcomes for large segments of the global population. We did rigorous research with targeted questions – to assess the global problems each company could solve, whether the company has a differentiated culture, and evidence that the company genuinely cares about customers and patients.

During the research phase, if a company fails to answer these questions satisfactorily, then we will not have conviction to include it in the portfolio. Therefore, human rights and other behaviours or activities were considered as part of the investment research process for Moderna and BioNTech – as we do for all companies we evaluate.

Because we hold companies for five to ten years or more, we can reassess issues that arise throughout the period of investing. As stated earlier, access to COVID-19 vaccines were part of extensive and ongoing engagement with these companies.

What human rights risks have you identified and what measures have you taken to mitigate the risk and prevent harm?

We identified that global access to vaccines would be a major human rights risk given that groundbreaking innovation in healthcare is primarily taking place in high income countries. Therefore, as highlighted earlier, we engaged with Moderna and BioNTech early on and during the pandemic to discuss what they would do to support global vaccine rollout.

With COVID-19, never before have we seen such fast-paced disease, medical research or policy development. This extraordinary scenario has required everyone to react quickly and decisively, especially considering access to vaccines, diagnostics, and therapeutics. Therefore, Baillie Gifford identified the need to explore broader options and support the scientific fight against COVID-19 and future pandemics. For example, in 2020, we provided considerable funding to STOPCOVID, a rapid interception experimental medicine programme for COVID-19 respiratory failure. It is spearheaded

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by the Centre for Inflammation Research in the Queen's Medical Research Institute at the Edinburgh BioQuarter and Baillie Gifford provided a five-year funding commitment.

It is our responsibility to support companies, engage and work with them to mitigate risks, as a long-term, committed equity investor. That said, in the evolving pandemic scenario, it would be unrealistic to think that there isn't room for improvement within every decision. We welcome an open conversation with your organisation - to engage and learn from one another.

Therefore, I'd like to end by inviting you to ask us more questions and clarifications, if needed. We would also like to use this opportunity to initiate a constructive dialogue between us and Amnesty International, to explore how we can further collaborate and improve, with a common goal to accelerate health equality around the world.

With kind regards,



Investment Manager
Baillie Gifford & Co

BLACKROCK

Statement, attributable to a BlackRock spokesperson

10 September 2021

“We engage with pharmaceutical companies on all aspects of their business. This includes asking questions to understand their role in Covid-19 vaccines. Access to medicine is a key ESG concern held by BlackRock and a broad array of other shareholders. It is one of the material sustainability topics under SASB standards.”

As an example for our engagement, please have a look at the Vote Bulletin on Johnson & Johnson we issued in April this year. It describes a closely related issue.

<https://www.blackrock.com/corporate/literature/press-release/blk-vote-bulletin-johnson-and-johnson-apr-2021.pdf>

In addition, another publication worth looking at is our Investment Stewardship team’s Q3 2020 report, which includes a case study of engagements BlackRock had with three biotech companies that had received government support through Operation Warp Speed.

<https://www.blackrock.com/corporate/literature/publication/blk-qrtly-stewardship-report-q3-2020.pdf> (see pp. 20-21)

Finally, we wanted to point you to our [commentary on Engagement on Human Rights](#) (which you already cite in the excerpt you shared with you) that says:

“(…) We ask companies to implement processes to identify, manage, and prevent adverse human rights impacts that are material to their business, and provide robust disclosures on these practices. (...) We are committed to engaging with companies on how they manage the human rights issues that are inherent in their businesses and monitor human rights practices on a best-efforts basis. (...) While we engage with companies, and where appropriate vote against management, we lack authority to direct companies to address weaknesses in their business practices. Rather, the responsibility for managing human rights issues – and all business practices – lies with boards and management of companies and the governments that regulate them. (...)”

###

Dear Patrick,

10 September, 2021

Thank you very much for giving us the opportunity to comment on your work.

UBS has reportable positions in a large number of companies worldwide in which it does not have any strategic interest. Often UBS holds these positions on behalf of clients. The diverse positions in a particular company are collated across business units and reported to the company once the total position has crossed (or fallen below) the applicable notification threshold.

We believe that pharmaceutical companies have an important role to play in addressing the access to medicine issue. Hence, we signed the Access to Medicine Index Investor Statement a few years ago and have also actively participated in their collaborate engagement program, where we engage large pharmaceutical companies to highlight leadership and good practice as well as gaps and challenges.

Beyond this involvement in collaborative engagements, we also engage with pharmaceutical companies to directly address the issue of access to medicine and human rights specifically. As part of our integration and stewardship practices, we assess and engage on companies' human rights performance, which encompasses pharmaceuticals companies' practices concerning access to medicines, including their practices on distributing COVID-19 vaccines.

Additionally, in 2020, UBS employees and clients raised more than 15 million US dollars for the UBS Optimus Foundation COVID-19 Response Fund, which was matched by a 15 million US dollar donation by UBS. The UBS COVID-19 Response Fund enables low- and middle-income economies to have speedier access to vaccines, partnering with Gavi, the Vaccine Alliance, long-time experts in vaccinating the world's children against deadly and debilitating infectious diseases. Via COVAX, the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator, Gavi is leading the global effort to secure a response to COVID-19 that is effective and fair.

Kind regards,

[Redacted signature]



UBS Business Solutions AG
Group Sustainability and Impact

[Redacted address line]

Office of Sustainability
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A DOUBLE DOSE OF INEQUALITY

PHARMA COMPANIES AND THE COVID-19 VACCINES CRISIS

The rapid development of effective Covid-19 vaccines in 2020 gave hope to the world in the darkest days of the deadly pandemic. However, the vaccine roll-out has been massively skewed towards wealthy nations. While rich states have hoarded vaccines, companies have also played a decisive role in restricting fair access to a life-saving health product. This report focuses on six leading vaccine developers, AstraZeneca, BioNTech, Johnson & Johnson, Moderna, Novavax and Pfizer, assessing each company's human rights policy, pricing structure, records on intellectual property, knowledge and technology sharing, allocation of available vaccine doses and transparency. The report finds that vaccine developers have monopolized intellectual property and blocked technology transfers. Some companies have charged high prices for their vaccines, sold predominantly to rich countries, and stand to make enormous profits - despite receiving billions in public funding. While the vaccine developers claim to respect human rights, all of them - to differing degrees - have failed to meet their responsibilities.

