



MONEY CALLS THE SHOTS

PHARMA'S RESPONSE TO THE COVID-19 VACCINES CRISIS

AMNESTY
INTERNATIONAL



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Cover photo: Covid-19 vaccine vials on a stack of US dollar and euro banknotes. © BPS

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INTRODUCTION



Stunt highlighting the lack of vaccine accessibility for people in low- and lower-middle-income countries, on the occasion of the G20 Summit in Rome, Friday 29 October 2021. © Amnesty International

The Covid-19 pandemic has handed extraordinary power to a tiny group of pharma companies.

After western governments refused to intervene in decision-making over the manufacturing and distribution of Covid-19 vaccines, the wellbeing of the whole world has come to rely on them.

But while these companies will be forever associated with the brilliance of their scientists, their chief executives, directors and largest investors will also be remembered for tragically failing to rise to the challenge of a once-in-a-century health and human rights crisis.

In September 2021, Amnesty International published *A Double Dose of Inequality: Pharma companies and the Covid-19 vaccines crisis*.¹ This assessed how the pharmaceutical industry was restricting

1. Amnesty International, "A double dose of inequality: pharmaceutical companies and the Covid-19 vaccines crisis", (Index: POL 40/4621/2021), September 2021, www.amnesty.org/en/documents/pol40/4621/2021/en/

fair access to their life-saving Covid-19 vaccines, and how states had failed to protect human rights globally through not requiring them to lift these restrictions. This report updates that assessment of these companies until the end of 2021. It also includes an assessment of two leading Chinese manufacturers.

The reality is that ten billion doses of Covid-19 vaccines were produced last year, more than enough to reach the 40% target of global vaccination by the end of 2021, which was set by the World Health Organization (WHO). Yet while this target was comfortably surpassed in wealthy states, just over 4% of the population living in low-income countries had been fully vaccinated by the end of the year.

The WHO is now calling for 70% of the population in each country to be vaccinated by the end of June of this year. But demand for boosters in upper-income countries is again diverting supply from other countries. More boosters are now being administered in high-income countries that have been administered in low-income countries, and millions of vaccine doses have been dumped after their expiry dates were reached.² In addition, a lack of predictability and clear supply timelines has contributed to undermining trust in national vaccination programmes in low-income countries.³

Amnesty International's analysis shows that of all vaccine developers, only Johnson & Johnson and AstraZeneca had more than 50% of their stock reach low- and lower-middle-income countries (with many of these doses provided as "donations" from upper-income countries, not as part of sales agreements). By contrast to the others, which all stand to make tens of billions of dollars from their vaccines, these two companies have also both committed to distributing them at no profit during the pandemic. But the world cannot rely on charity alone.

All of the vaccine developers, including AstraZeneca and Johnson & Johnson, have continued to block essential steps for increasing global production. They have monopolized technology and lobbied against the sharing of intellectual property. They opposed proposals to temporarily lift intellectual property rights, such as the World Trade Organization Trade Related Intellectual Property Rules (TRIPS) Waiver. All of the vaccine developers refused to widely share their technology and intellectual property through WHO-coordinated initiatives, such as the Covid-19 Technology Access Pool (C-TAP) or the mRNA-vaccine technology hubs.

The pharma companies say that lifting intellectual property protections would not achieve greater access to vaccines.⁴ But if they had shared intellectual property, technology and know-how with other manufacturers from the start of the crisis, things could be looking very different now.⁵

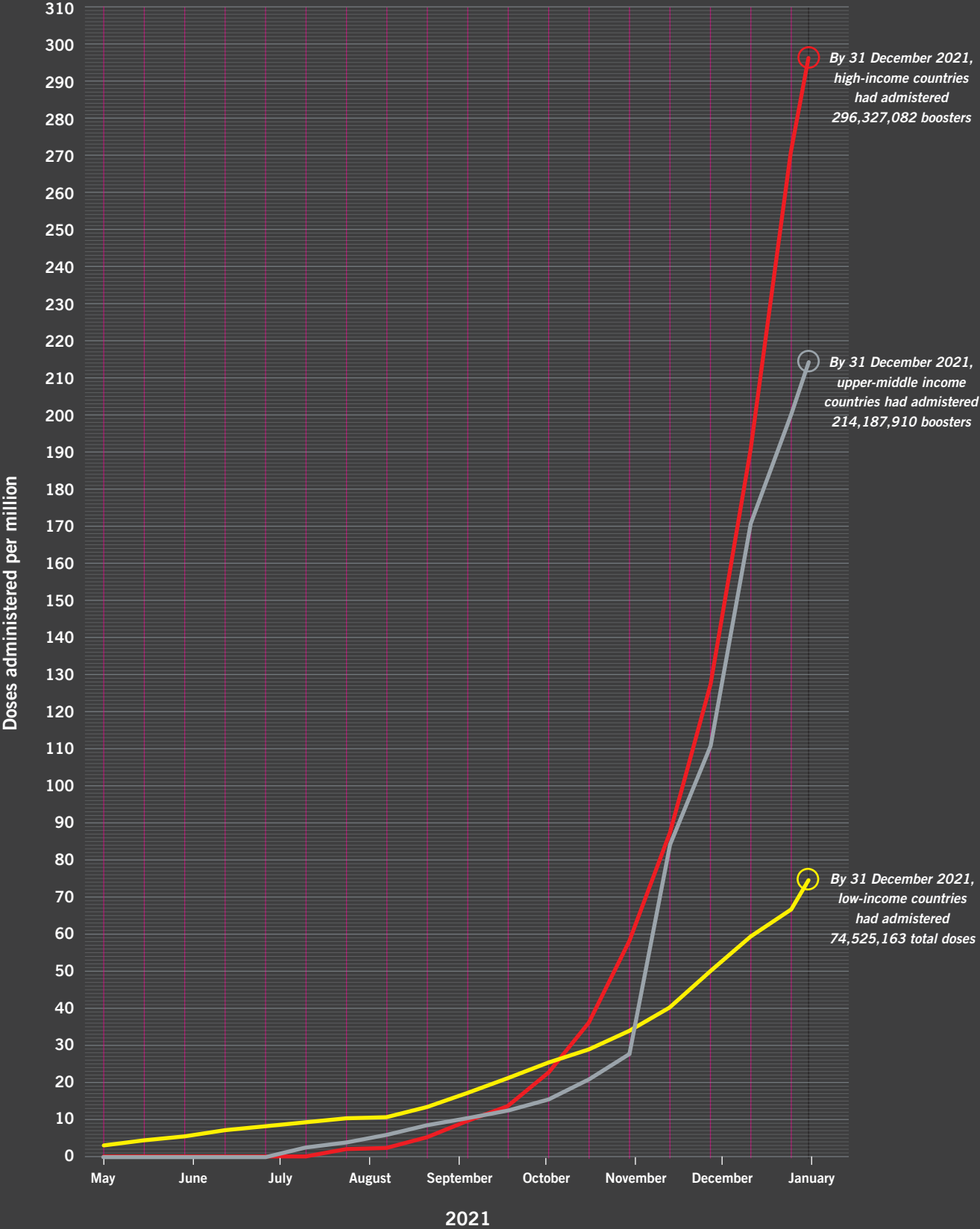
2. The Guardian, "Covid booster jabs in England to be thrown away as demand falls", 14 January 2022, www.theguardian.com/society/2022/jan/14/covid-booster-jabs-in-england-to-be-thrown-away-as-demand-falls; NBC News, "15 million Covid vaccine doses thrown away in the U.S. since March, new data shows", 1 September 2021, www.nbcnews.com/news/us-news/america-has-wasted-least-15-million-covid-vaccine-doses-march-n1278211; Financial Times, "Covid-19 vaccines burnt as shelf-life complicates global rollout", 1 June 2021, www.ft.com/content/8e1385cf-1569-4bf8-904e-fdc29367a758.

3. Amnesty International, East Africa: Global pharmaceutical firms must improve vaccine distribution across the region to save lives, 14 December 2021, www.amnesty.org/en/latest/news/2021/12/east-africa-global-pharmaceutical-firms-must-improve-vaccine-distribution/

4. Johnson & Johnson at IFPMA, International Federation of Pharmaceutical Manufacturers and Associations, "Global Biopharma CEO/Top Executives Covid-19 Media Briefing", 7 September 2021, Minute 53:40, www.ifpma.org/resource-centre/global-biopharma-ceo-top-executives-covid-19-media-briefing-7-september-2021-video/ Pfizer, www.pfizer.com/news/articles/why_pfizer_opposes_the_trips_intellectual_property_waiver_for_covid_19_vaccines

5. New York Times, "Here's why developing countries can make mRNA Covid vaccines", 22 October 2021, www.nytimes.com/interactive/2021/10/22/science/developing-country-covid-vaccines.html

Figure 1: High-income countries and upper-middle-income countries have administered more boosters since July than low-income countries' total doses in 2021



Source: Our World in Data

COMPANIES ASSESSED (LISTED IN ALPHABETICAL ORDER)⁶

AstraZeneca produced over 2.3 billion vaccines in 2021 and supplied 1.7% of these to low-income countries and 70% to lower-middle-income countries up to 31 December 2021,⁷ an increase on the previous assessment. But the company is still opposed to initiatives to share technology and intellectual property widely - such as the WHO's technology access pool - and has said that it will aim to profit from the vaccine in the future.⁸

Johnson & Johnson produced just over 300 million vaccines in 2021 and 20% of these have been delivered to low-income countries and 31% to lower-middle-income countries up to 31 December 2021.⁹ This is a significant increase on the previous assessment and a fair distribution of its vaccines, albeit often through state purchases that were redistributed to these countries. But similar to AstraZeneca, Johnson & Johnson announced that it plans to charge market prices for its vaccine, and is also against efforts to widely share intellectual property and technology, such as the WHO's technology access pool.¹⁰

Moderna produced over 670 million vaccines in 2021 and delivered only 2% of these to low-income countries and 23.5% to lower-middle-income countries up to 31 December 2021, a significant increase on the previous assessment, but still short of what is required.¹¹ Moderna has not cooperated with the mRNA technical transfer hub set up by the WHO and others in South Africa, a major barrier to full and fair access to the vaccine.

Pfizer/BioNTech produced over 2.4 billion vaccines in 2021. They delivered only 1% of these to low-income countries and 14% to lower-middle-income countries up to 31 December 2021, a slight increase on the previous assessment.¹² Pfizer/BioNTech have still not participated in C-TAP or cooperated with the mRNA technical transfer hub set up by the WHO and others in South Africa, a significant barrier to full and fair access to the Covid-19 vaccine.

Sinopharm produced over 2.25 billion doses in 2021, most of which were supplied domestically within China. The company delivered only 1.4% of its doses to low-income countries and 23.6% to lower-middle-income countries.¹³ Sinopharm has charged relatively high prices for its vaccines, has not joined C-TAP or issued open, non-exclusive production agreements.

Sinovac produced 2.45 billion doses in 2021, most of which were supplied domestically within China. It delivered less than 0.5% of its doses to low-income countries and 20.6% to lower-middle-income countries, like Sinopharm, skewing its distribution heavily to upper-middle-income countries, particularly China.¹⁴ Sinovac charges relatively high prices for its vaccines, compared to some other companies, has not joined C-TAP or issued open, non-exclusive production agreements.

6. Full company assessments are detailed later in the report. Figures on distribution are drawn from data provided by Airfinity, a life science information and analytics company, www.airfinity.com/

7. Airfinity, www.airfinity.com/

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

9. Airfinity, www.airfinity.com/

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

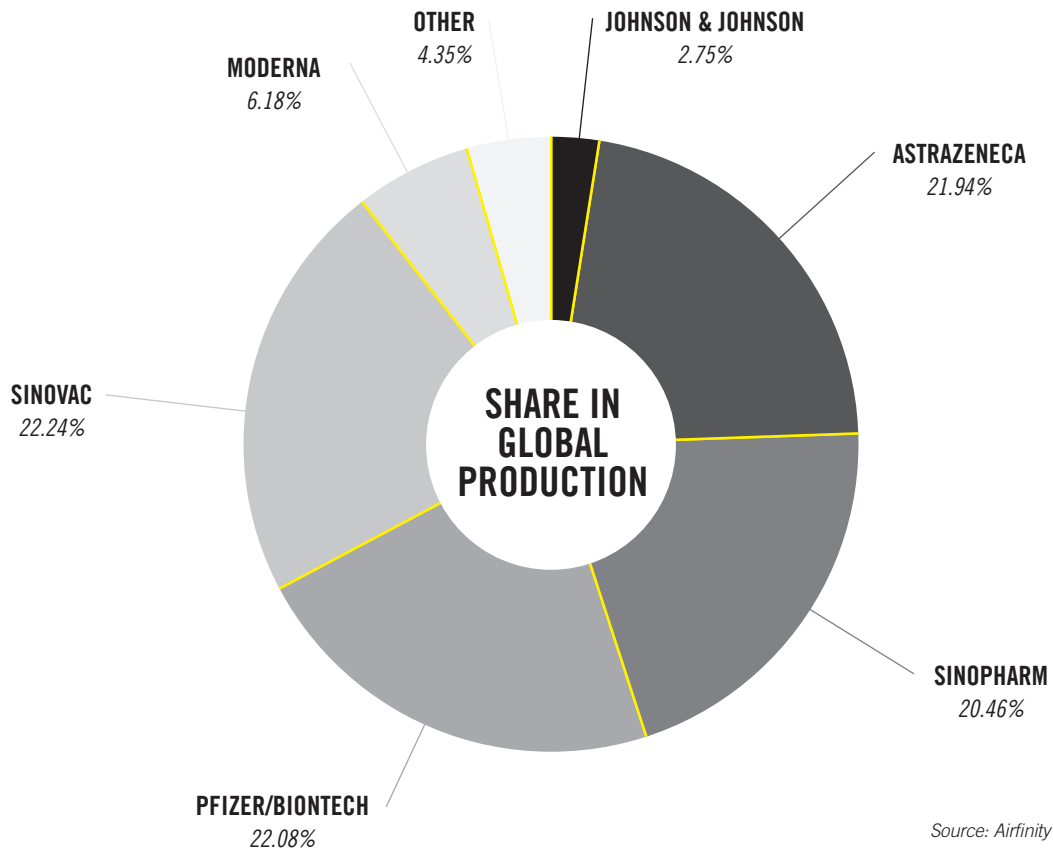
11. Airfinity, www.airfinity.com/

12. Airfinity, www.airfinity.com/

13. Airfinity, www.airfinity.com/

14. Airfinity, www.airfinity.com/

Figure 2: Share by company of global production by end 2021



Despite billions in public funding, these companies are continuing to put their own business interests before their human rights responsibilities. They are creating barriers to fair access to their Covid-19 vaccines through their decisions not to share intellectual property and technology. Pfizer, BioNTech and Moderna in particular are also impeding states' ability to ensure access to Covid-19 vaccines by privileging supply to wealthier countries, often at a significant profit. Sinovac's and Sinopharm's general lack of transparency presents a major obstacle to full and fair access to vaccines.

With the exception of the state-owned Sinopharm, all of these companies are publicly listed, owned by and accountable to, their shareholders. These investors also have a responsibility to respect human rights. This means exercising the considerable leverage they have over the companies that they part own, and there is little evidence of them having done so.

Ultimately, this crisis is a crisis of leadership, one that has exposed the failure of governments to protect human rights globally. These have failed to take the necessary steps to prevent vaccine developers from impeding broader access to Covid-19 vaccines, support and resource C-TAP and promote open and non-exclusive licences that include knowledge and technology transfer. They should not have left it to the goodwill of the pharma industry to see us out of this crisis and must now act.

Figure 3: Share of population by vaccination status and country income group

Share of population which has...	High-income	Upper-middle-income	Lower-middle-income	Low-income
... received one dose ¹⁵	78.3%	76.2%	49.2%	8.5%
... been fully vaccinated ¹⁶	72.4%	70.2%	35.4%	4.2%
... received a booster dose ¹⁷	23.8%	8.44%	0.5%	-

Source: Our world in data, accessed 4 January 2022



An aerial view of residents queuing up to receive COVID-19 vaccines at Hefei Olympic Sports Center on 17 May 2021 in Hefei, Anhui Province of China. © VCG via Getty Images

15. This reflects both, people who have received the first dose of a two-dose vaccine and people who have full vaccination status following administration of a one-dose vaccination.

16. This represents the share of the total population that has been fully vaccinated against COVID-19, receiving all doses prescribed by the vaccination protocol.

17. Booster doses are doses administered beyond those prescribed by the original vaccination protocol — for example, a third dose of the Moderna vaccine, or a second dose of the Johnson & Johnson vaccine.

METHODOLOGY

This report updates Amnesty International's assessment of five leading vaccine manufacturers, AstraZeneca plc (AstraZeneca), BioNTech SE (BioNTech), Johnson & Johnson, Moderna, Inc. (Moderna), and Pfizer, Inc. (Pfizer). It also includes for the first time an assessment of the two largest Chinese vaccine producers, China National Pharmaceutical Group Co., Ltd. (Sinopharm) and Sinovac Biotech Ltd. (Sinovac). These were companies whose Covid-19 vaccines had been approved for emergency use by the WHO in September 2021, the beginning of the assessment period covered by this report. Other vaccines have since been listed by the WHO.¹⁸

Drawing on the UN Guiding Principles on Business and Human Rights (UN Guiding Principles) and other standards, this assessment examines 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. Three companies, AstraZeneca, Pfizer and BioNTech responded. Amnesty International reviewed the responses, which can be found in the annex, and took appropriate account of information provided in updating its findings.¹⁹

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 supply was drawn from Airfinity, a science information and analytics company. They reflect supply to the receiving country, whether directly from the vaccine developer or as donations from other countries. Some vaccine developers have shared data on their annual production and supply. Where this data is different from the supply data collected by Airfinity, both data sets are mentioned.

Amnesty International also wrote to the ten largest institutional investors in these companies to ask them about how they engage with the vaccine developers they invest in to prevent any impediment to access to Covid-19 vaccines. Four investors have responded with only one of those, Baillie Gifford, providing information on its due diligence process since September 2021 (see annex).



Mobile billboard calling on G20 leaders to address the issue of vaccine inequality at the G20 Summit in Rome, Friday 29 October 2021. © Amnesty International

18. WHO, "Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process", extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_23Dec2021.pdf, accessed 6 February 2022.

19. These companies, as well as Johnson and Johnson and Moderna, also previously wrote to Amnesty International, ahead of the publication of its report in September 2021.

THE HUMAN RIGHTS RESPONSIBILITIES OF COMPANIES

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.²⁰ 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 must develop and implement policies that aim to make quality Covid-19 vaccines available, accessible, and affordable. They must 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. Rather, they must extend access to vaccines.²¹ This applies, among other things, to their decisions on with whom they engage in contracts, pricing and allocation of their vaccines, as well how they handle their intellectual property rights, knowledge and technology.²²

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.²³

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.²⁴ 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.”²⁵

20. 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, OECD Guidelines for Multinational Enterprises, OECD, 2011, dx.doi.org/10.1787/9789264115415-en

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

22. Further guidance for vaccine developers was provided in the UN Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines in 2008. These state that businesses have a “human rights responsibility to extend access to medicines for all including disadvantaged individuals, communities and populations”. 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

23. 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), www.amnesty.org/download/Documents/POL3034092020ENGLISH.PDF

24. 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), www.amnesty.org/download/Documents/POL3034092020ENGLISH.PDF

25. 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=4slQ6QSmIBEDzFEovLCuW1AVC1NkPsgUedP1F1vfPMKseJUC1C1GfclakFK95v85g4Ik7k7QB18EdfqmCITMrvi1V0r1IHI0eN189AlrQB0R2hKpuBKCvHETpIGUieZd

While states should use the maximum of their available resources to secure the right to health,²⁶ 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.²⁷ This may include the sharing of research, knowledge, medical equipment and supplies.²⁸

Furthermore, as articulated in the UN Guiding Principles on Business and Human Rights, states have the obligation to step in and protect people from abuses in which business actors are involved.²⁹ This obligation extends extraterritorially, in that states have a duty to protect people's human rights from potential abuses by corporate actors over which they exercise regulatory control. In the context of the right to health, 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.

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 (COVAX) 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 only reached half that total by January 2022.³⁰

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.³¹

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.³²

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. To date, the waiver has not received the necessary support from governments.³³

26. CESCR, General Comment 25, para 47.

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

28. 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.

29. UN Guiding Principles, Principle 1.

30. Gavi, the Vaccine Alliance, "COVAX has so far shipped over 1 billion COVID-19 vaccines to 144 participants", 17 January 2022, www.gavi.org/covax-vaccine-roll-out

31. WHO, COVID-19 Technology Access Pool, www.who.int/initiatives/covid-19-technology-access-pool

32. 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

33. Amnesty International, Time for countries blocking TRIPS waiver to support lifting of restrictions, 1 October 2021, www.amnesty.org/en/latest/news/2021/10/covid-19-time-for-countries-blocking-trips-waiver-to-support-lifting-of-restrictions-2/

COMPANY ASSESSMENTS

The vaccine developers have, to different degrees, created obstacles to fair access to Covid-19 vaccines by not sharing intellectual property, technology and knowledge, by charging unfair prices and failing to divulge vital information about pricing, and by making vaccine allocation decisions based on their economic interests instead of health needs.

ASSESSMENT CRITERIA:

Intellectual Property and Knowledge Sharing

The extent to which companies have shared their intellectual property, codified and tacit knowledge, and technology through C-TAP or the mRNA technology transfer hub set up by the WHO and partners, or otherwise issued global, non-exclusive licences.

Refusal to share intellectual property and to transfer knowledge and technology necessary for the development of Covid-19 vaccines has hampered an early ramp up of global production while global demand surpassed global supply. Even as global supply is continuously growing, the lack of diversification of global production of Covid-19 vaccines poses a significant supply risk such as the interruption of supply following India's export ban in 2021. Diversified supply chains will also be necessary to respond to multiple variants.³⁴ In a situation in which governments depend on few companies to facilitate life-saving medication, intellectual property protections confer disproportionate power to vaccine developers, allowing them to put economic interests before public health needs.

Fair pricing

The extent to which companies publish their research and development costs, their average production costs and their profit margins, charge fair prices and do not seek to exploit the predicament of governments to gain excessive profits.

Vaccine developers' human rights responsibilities require that in their pricing decisions, they do not consider only their economic interests and economic viability, but also address the potential adverse impact of profit. Pricing plays a key role in determining access to Covid-19 vaccines because purchasing price directly impacts a state's ability to make Covid-19 vaccines available – to its own population as well as at a global level. Further, investments in highly priced vaccines reduce a state's capacity to finance other crucial avenues to fight the pandemic, for instance investing in hospitals.

34. Peter Singer, "Virus variants point to need to scale manufacturing", Al Jazeera, 26 March 2021, www.aljazeera.com/opinions/2021/3/26/virus-variants-point-to-need-to-scale.

Profit margins must remain reasonable in order not to amount to obstacles to access vaccines. In the context of the pandemic, they are not reasonable when there is a major disparity between the prices a company charges for its vaccines on the one hand and the vaccine's development, production and transport costs on the other.

Furthermore, transparency in pricing is vital for ensuring fair contract negotiations. Lack of transparency can lead to price gouging.

Fair Vaccine Allocation

The extent to which vaccine developers have allocated their annual production proportionally to population, differentiated according to income country groups, with the aim to reach the vaccination rate targets in each country as set by the WHO.³⁵

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. To ensure fair access to vaccines and distribution to every country in the world, vaccine developers must allocate their annual production with the aim to reach the vaccination rate targets in each country as set by the WHO, giving priority to those countries and regions currently left behind.



Employees at the Afrigen biotechnology company and Vaccine Hub facility, work in the manufacturing laboratory in Cape Town, on 5 October 2021. © AFP via Getty Images

35. WHO, "Strategy to Achieve Global Covid-19 Vaccination by mid 2022", 7 October 2021, cdn.who.int/media/docs/default-source/immunization/covid-19/strategy-to-achieve-global-covid-19-vaccination-by-mid-2022.pdf?sfvrsn=5a68433c_5

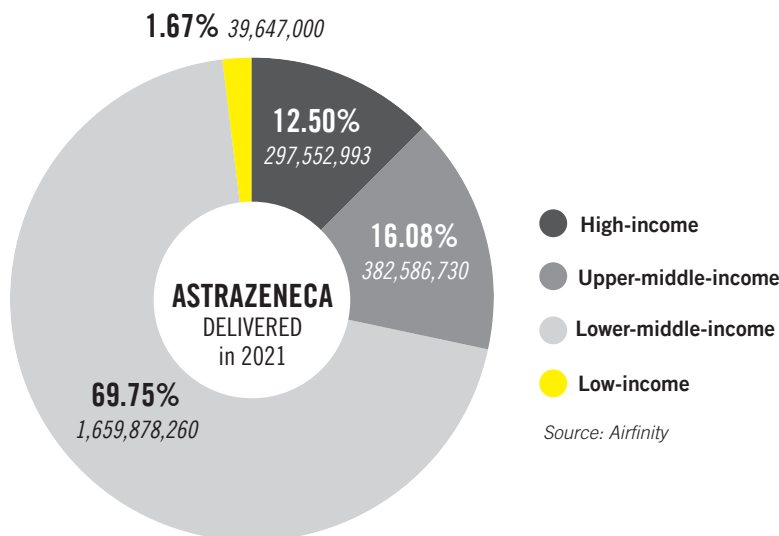
COMPANY ASSESSMENTS, PRESENTED IN ALPHABETICAL ORDER:

ASTRAZENECA

AstraZeneca is a British-Swedish pharmaceutical company that is manufacturing and distributing the coronavirus vaccine developed by the University of Oxford.³⁶ The company received US\$1.3 billion in funding for vaccine trials, manufacturing and distribution of vaccine doses from the US government and US\$96.7 million from the UK government for research and development.³⁷

AstraZeneca has published a human rights policy on its website.³⁸ 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.”³⁹ The company has pledged to supply its viral vector vaccine, “broadly and equitably at no profit during the pandemic.”⁴⁰ In its letter to Amnesty International, it stated that it “remains committed to providing broad and equitable global access to the vaccine.”

Vaccines delivered by country income group - percentage and number of doses



In its initial assessment of the company in September 2021, Amnesty International welcomed AstraZeneca’s not-for-profit approach to pricing, and its dose allocation which favours low- and lower-middle-income countries.⁴¹ But it found that the company’s reluctance to share intellectual property

36. Oxford University, “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. Company homepage is available at: www.astrazeneca.com.

37. 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; GovTribe, “Other Transaction IDV W15QKN2191003, Federal Contract IDV Award”, govtribe.com/award/federal-idv-award/othertransaction-idv-w15qkn2191003; GovTribe, Definitive Contract 75A50120C00114, Federal Contract Award, 2020, govtribe.com/award/federal-contract-award/definitive-contract-75a5120c00114org/10.1101/2021.04.08.21255103

38. 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

39. AstraZeneca, Human Rights Statement.

40. Email to Amnesty International, 8 June 2021.

41. Amnesty International, “A double dose of inequality”, pp. 34-38.




more widely and fully cooperate with the WHO’s knowledge-sharing initiatives remained barriers to fair access to the Covid-19 vaccine. Additionally, AstraZeneca’s lobbying activities which aimed to discourage countries from supporting the TRIPS waiver were also in conflict with its human rights responsibilities. Amnesty International also criticized AstraZeneca’s lack of transparency on actual costs of production, sources of external funding, prices charged in different countries, or contractual terms and conditions, and information about discounting, donations, and advance order guarantees.

Since the assessment, AstraZeneca has indicated that as the Covid-19 pandemic was entering its “endemic phase”, it would aim to profit from the vaccine in 2022. The company stated that it will adopt a “tiered pricing approach aligned to Gross National Income per capita” and, “will continue to supply the vaccine at no profit [...] to low-income countries.”⁴² This could limit access to vaccines in the future, if this results in the adoption of market-driven distribution models favouring higher paying customers as seen with other companies that are following a tiered pricing policy.⁴³

AstraZeneca has still not published its pricing policy or research, development and production costs making it impossible to assess its commitment to not-for-profit pricing. It reported just over US\$2.2 billion in sales from its Covid-19 vaccine up to the third quarter of 2021, which is substantially less than its rivals, Moderna and Pfizer, which are operating on a for-profit model.⁴⁴

According to Airfinity, AstraZeneca has produced over 2.3 billion vaccines in 2021 (2.5 billion vaccines according to information provided by the company)⁴⁵ and has supplied 70% of its vaccines to low- and lower-middle-income countries up to 31 December 2021, roughly the same as in the previous assessment. Doses delivered to low-income countries remain very low at 1.7%.⁴⁶ AstraZeneca was the first company to join COVAX but has still not joined C-TAP or offered non-exclusive licensing of its Covid-19 vaccine, maintaining barriers to fair access to the Covid-19 vaccine.

ASTRAZENECA ASSESSMENT⁴⁷

<i>Intellectual Property, Knowledge and Technology Sharing</i>			
<i>Fair and Transparent Pricing</i>			
<i>Vaccine Allocation</i>			

42. [AstraZeneca](#), Email to Amnesty International, 13 January 2022, on file.

43. See Moderna and Pfizer/BioNTech assessment.

44. AstraZeneca. “Year to date and Q3 2021 results”, 12 November 2021, www.astrazeneca.com/content/dam/az/PDF/2021/q3/Year-to-date_and_Q3_2021_results_announcement.pdf

45. AstraZeneca, Email to Amnesty International, 13 January 2022, on file.

46. Airfinity, www.airfinity.com/

47. Please find the assessment key on page 35.

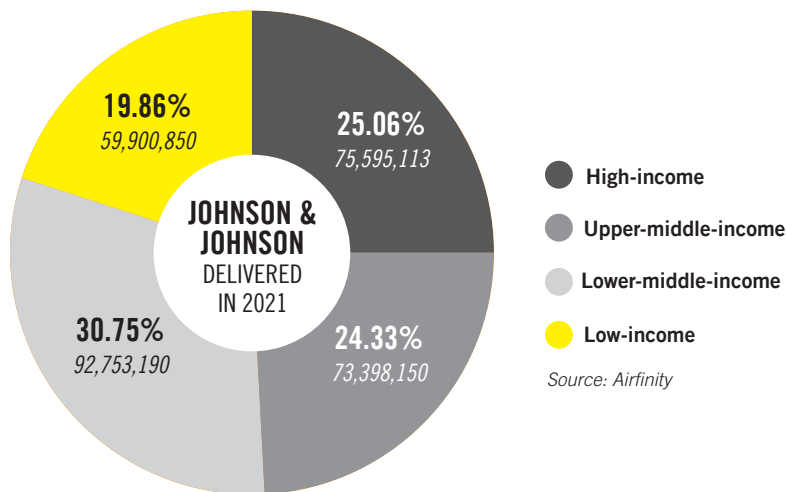
JOHNSON & JOHNSON

Johnson & Johnson is 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. According to the US 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).⁴⁸

Johnson & Johnson has published a human rights policy on its website.⁴⁹ The company says that its commitment to human rights is “guided” by the UN Guiding Principles and other international standards.⁵⁰

In contrast to other approved vaccines, the Janssen/Johnson & Johnson vaccine is single dose and 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.”⁵¹ Similar to AstraZeneca, the company also pledged to distribute its vaccine “on a not-for-profit basis for emergency pandemic use.”⁵²

Vaccines delivered by country income group - percentage and number of doses



48. 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-toproduce-millions-of-covid-19-invest/

49. 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

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

51. Johnson & Johnson, “Johnson & Johnson Announces Advance Purchase Agreement with the African Vaccine Acquisition Trust for the Company’s COVID-19 Vaccine Candidate” www.jnj.com/johnson-johnson-announces-advance-purchase-agreement-with-the-african-vaccine-acquisition-trust-for-the-companys-covid-19-vaccine-candidate

52. 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-usefirst-single-shot-vaccine-in-fight-against-global-pandemic

In its September 2021 assessment, Amnesty International welcomed Johnson & Johnson's commitment to offer its vaccine on a not-for-profit basis.⁵³ However, its reluctance to widely share intellectual property, knowledge, and technology, and the fact that 67.7% of its vaccine deliveries had gone to high-income countries had hampered rapid and fair access to vaccines around the globe. Amnesty International also criticized Johnson & Johnson's lack of transparency on actual costs of production, sources of external funding, prices charged in different countries, or contractual terms and conditions, and information about discounting, donations, and advance order guarantees.

Since then, Johnson & Johnson announced that it plans to charge market prices for its vaccine after gaining full approval for use in the USA (as opposed to the current emergency authorization).⁵⁴ This could limit global access to vaccines in the future, if this results in the adoption of market-driven distribution models favouring higher paying customers. Johnson & Johnson has not published its research, development and production costs or its pricing policy. Johnson & Johnson reported US\$766 million earnings for its Covid-19 vaccine in the first three quarters of 2021, substantially less than Moderna and Pfizer which operate on a for-profit basis.⁵⁵

Johnson & Johnson produced just over 300 million Covid-19 vaccines in 2021 and delivered 20% of these to low-income countries and 31% to lower-middle-income countries up to 31 December 2021.⁵⁶ This is a significant increase on the previous assessment, and reaching Amnesty International's 50% target for supplies to lower-income countries in 2021, albeit often through state purchases of vaccines that got redistributed to low- and lower-middle-income countries.⁵⁷ A higher share of Johnson & Johnson's production reached low-income countries than the other companies assessed, and at just under 60 million doses was also the highest in absolute terms.

Johnson & Johnson has also agreed to participate in Gavi, the Vaccine Alliance, and the member agencies of the Inter-Agency Standing Committee (IASC)'s COVAX Humanitarian Buffer, which aims to deliver Covid-19 vaccines to 167 million displaced people around the world. Johnson & Johnson, along with vaccine manufacturers Clover, Sinopharm and Sinovac – will waive indemnification requirements for humanitarian agencies delivering doses to these populations, removing the burden of risk for adverse events linked to the use of the companies' products from UN agencies and local NGOs.⁵⁸

However, since the September assessment, Johnson & Johnson has still not participated in the WHO's technology access pool or issued any non-exclusive licences for its vaccines.

The company did not reply to Amnesty International's letter requesting comment on this assessment.

53. Amnesty International, "A double dose of inequality", pp. 39-43.

54. In a third-quarter earnings call, the company's executive vice president Ashley McEvoy said that: "as we move into more of a booster market in later '22, potentially into 2023, we'd be looking at moving into more of a commercial market." The Motley fool, Johnson & Johnson (JNJ) Q3 2021 Earnings Call Transcript, Oct 19, 2021, 8:30 a.m. ET, www.fool.com/earnings/call-transcripts/2021/10/19/johnson-johnson-jnj-q3-2021-earnings-call-transcri/




55. United States Securities and Exchange Commission, Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended October 3, 2021 Johnson & Johnson FORM 10-Q, www.sec.gov/ix?doc=/Archives/edgar/data/200406/000020040621000070/jnj-20211003.htm; Johnson & Johnson, "Sales of key products/franchises", johnsonandjohnson.gcs-web.com/static-files/3544469e-12e1-4995-91ccc47496ffb09a

56. Airfinity, www.airfinity.com/

57. Airfinity, www.airfinity.com/

58. GAVI, Gavi and humanitarian agencies partner to deliver COVID-19 vaccines to the most vulnerable people in the world, 16 November 2021, www.gavi.org/news/media-room/gavi-and-humanitarian-agencies-partner-deliver-covid-19-vaccines-most-vulnerable

JOHNSON & JOHNSON ASSESSMENT⁵⁹

<i>Intellectual Property, Knowledge and Technology Sharing</i>			
<i>Fair and Transparent Pricing</i>			
<i>Vaccine Allocation</i>			

MODERNA

Moderna is a biotechnology company based in Cambridge, Massachusetts, in the USA. Founded in 2010, Moderna is a pioneer in developing mRNA technology.⁶⁰ It has received huge amounts of aid from the US government, which said in February 2021 that its total investment in Moderna, including “vaccine development, clinical trials, manufacturing and purchase” was approximately US\$5.75 billion.⁶¹

Moderna has published a human rights policy on its website which states that human rights are inherent in its “values and our commitments.”⁶² On 23 December 2020, Moderna published a document entitled “Moderna’s Commitment to Vaccines and Therapeutics Access.” This includes a commitment to “provide effective and affordable vaccines and therapeutics to all populations.”⁶³ But has made no commitment to distribute its vaccine equitably or at cost price, unlike AstraZeneca and Johnson & Johnson.

In September 2021, Amnesty International found Moderna had hindered full and fair access to its Covid-19 vaccine through several of its business decisions.⁶⁴ The company had by then delivered 88% of its Covid-19 vaccines produced in 2021 to high- and upper-middle-income countries. As it applies a tiered pricing system charging low-income countries comparably lower prices for vaccines while selling to high-income countries with a higher profit margin, it thus privileged profit over people. Moderna had pledged not to enforce its intellectual property rights during the pandemic, but it had not shared its manufacturing know-how or transferred its technology to other manufacturers via the WHO’s C-TAP or mRNA technology transfer hubs.⁶⁵

59. Please find the assessment key on page 35.

60. Moderna, About us, www.modernatx.com/about-us

61. 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

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

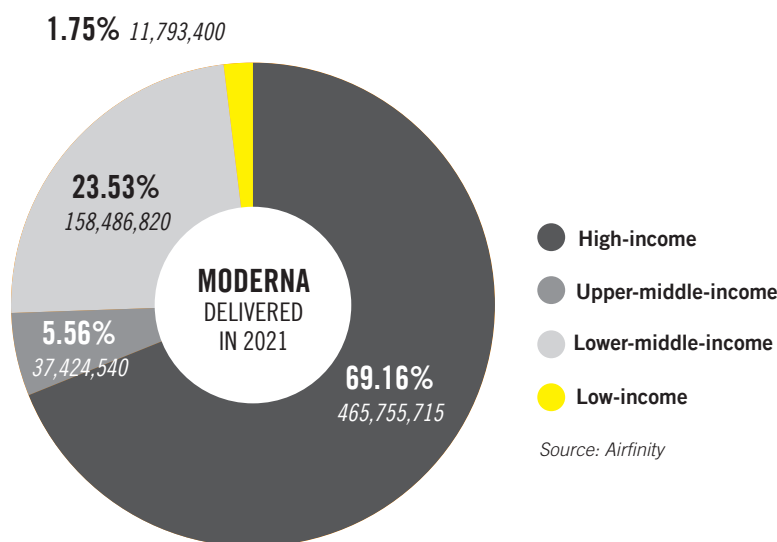
63. Moderna, “Moderna’s Commitment to Vaccines and Therapeutics Access”, 23 December 2020, investors.modernatx.com/newsreleases/news-release-details/modernas-commitment-vaccines-and-therapeutics-access

64. Amnesty International, “A double dose of inequality”, pp. 43-48

65. Amnesty International, “A double dose of inequality”, pp. 43-48.

Since then, Moderna has been embroiled in a dispute with the US National Institute of Allergy and Infectious Diseases over certain patent applications and their mutual role in the invention of the mRNA sequence at the core of Moderna's Covid-19 vaccine.⁶⁶ Co-ownership would allow the US government to use the patented invention, including granting licences.⁶⁷ This would solve the legal uncertainty a consortium of manufacturers in South Africa considering replicating Moderna's Covid-19 vaccine are struggling with,⁶⁸ given that Moderna has only committed not to enforce intellectual property rights "while the pandemic continues".⁶⁹ Moderna is also facing a request from Legal & General Investment Management America, Inc. for a report to shareholders "on whether and how Moderna's receipt of government financial support for development and manufacture of a vaccine for Covid-19 is being, or will be, taken into account when making decisions that affect access to such products, such as setting prices."⁷⁰

Vaccines delivered by country income group - percentage and number of doses



Moderna is still refusing to cooperate with C-TAP or the mRNA technical transfer hub set up by the WHO and others in South Africa,⁷¹ a significant barrier to full and fair access to the Covid-19 vaccine.

66. Reuters, "Moderna COVID-19 vaccine patent dispute headed to court, U.S. NIH head says", 11 November 2021, www.reuters.com/business/healthcare-pharmaceuticals/moderna-covid-19-vaccine-patent-dispute-headed-court-us-nih-head-says-2021-11-10/

67. United States Code, Title 35, § 262, www.law.cornell.edu/uscode/text/35/262

68. Washington Post, "Frustrated by vaccine inequity, a South African lab rushes to replicate Moderna's shot", 28 November 2021, www.washingtonpost.com/world/2021/11/28/frigen-south-africa-vaccine-moderna/; CBS News, "Moderna offers NIH co-ownership of COVID vaccine patent amid dispute with government", 15 November 2021, www.cbsnews.com/news/moderna-covid-vaccine-patent-dispute-national-institutes-health/.

69. Moderna, "Statement on Intellectual Property", 8 October 2020, investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2020/Statement-by-Moderna-on-Intellectual-Property-Matters-during-the-COVID-19-Pandemic/default.aspx

70. SEC, Moderna, Inc.; Rule 14a-8 no-action letter, 17 December 2021, www.sec.gov/divisions/corpfin/cf-noaction/14a-8/2021/lgimamoderna121721-14a8-incoming.pdf

71. Washington Post, "Frustrated by vaccine inequity, a South African lab rushes to replicate Moderna's shot", 28 November 2021, www.washingtonpost.com/world/2021/11/28/frigen-south-africa-vaccine-moderna/; CBS News, "Moderna offers NIH co-ownership of COVID vaccine patent amid dispute with government", 15 November 2021, www.cbsnews.com/news/moderna-covid-vaccine-patent-dispute-national-institutes-health/

According to estimates based on research by Public Citizen, the Moderna vaccine could cost under US\$3 per dose to manufacture at large scale,⁷² meaning prices could be up to 10 times of the potential production costs.⁷³ In November, Moderna reported sales of between US\$15 and US\$18 billion for 2021.⁷⁴

According to Airfinity, Moderna has produced over 670 million doses of its vaccine. Of those, it supplied 2% to low-income countries and 23.5 % vaccines to lower-middle-income countries up to 31 December 2021, a significant increase on the 11.8% figure in the previous assessment, but still far short of what is required.⁷⁵

The company did not reply to Amnesty International’s letter requesting comment on this assessment.

MODERNA ASSESSMENT⁷⁶

<i>Intellectual Property, Knowledge and Technology Sharing</i>			
<i>Fair and Transparent Pricing</i>			
<i>Vaccine Allocation</i>			

72. Public Citizen, “How to Make Enough Vaccine for the World in One Year”, 26 May 2021, hmkus3lurbh3lbtg254fzode-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/vaccinemonopolies-make-cost-vaccinating-world-against-covid-least-5-times-more

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

74. Moderna, “Moderna reports third quarter fiscal year 2021 financial results and provides business updates”, 4 November 2021, investors.modernatx.com/news/news-details/2021/Moderna-Reports-Third-Quarter-Fiscal-Year-2021-Financial-Results-and-Provides-Business-Updates-11-04-2021/default.aspx

75. Airfinity, www.airfinity.com/

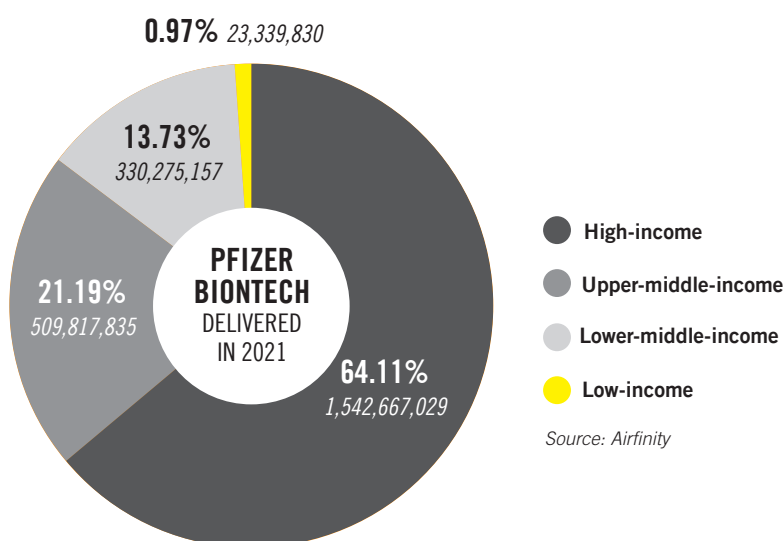
76. Please find the assessment key on page 21.

PFIZER/BIONTECH⁷⁷

Pfizer is a US-based multinational pharmaceutical company headquartered in New York, which has partnered with vaccine developer BioNTech, based in Mainz, Germany. Pfizer has indirectly benefited from advance sales and the public funding of its partner,⁷⁸ BioNTech which has received a US\$443 (€375million) grant from the German Federal Ministry of Education and Research to Support Covid-19 Vaccine Programme.⁷⁹

Pfizer has published a human rights policy on its website and has committed to “respect internationally recognized human rights throughout our operations.”⁸⁰ In a letter to Amnesty International, CEO Dr Albert Bourla stated that “the right to health is the most salient human rights issue for Pfizer.”⁸¹

Vaccines delivered by country income group - percentage and number of doses



In September 2021, Amnesty International found that Pfizer/BioNTech had hampered rapid and fair access to Covid-19 vaccines.⁸² The companies had not shared their manufacturing know-how or transferred their technology to other manufacturers via the WHO’s C-TAP or mRNA technology transfer hubs. Pfizer/BioNTech had put profit over people’s health by privileging delivery to high-income countries. By September, they had delivered 79.9% of their production to high-income countries and only 2% to lower-middle-income countries.

77. Pfizer and BioNTech work jointly to manufacture and distribute their Covid-19 vaccine worldwide, with exception of China.

78. BioNTech stated that it has been the sole grantee in an email to Amnesty, 14 January 2022, on file.

79. 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-eu375mfundinggerman-federal-ministry; On advance orders see summary in Supplementary appendix to Wouters OJ, Kenneth C Shadlen, Maximilian Salcher-Konrad, et al. “Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment”, *Lancet* 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)

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

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

82. Amnesty International, “A double dose of inequality”, pp. 51-56.

Pfizer/BioNTech have still refused to join C-TAP or cooperated with the mRNA technical transfer hub set up by the WHO and others in South Africa,⁸³ a significant barrier to full and fair access to the Covid-19 vaccine.

Pfizer has taken a different approach when entering into a voluntary licence agreement for the antiviral treatment candidate, Paxlovid, with the Medicines Patent Pool, a United Nations-backed public health organization.⁸⁴ The agreement allows the generic production of its new oral Covid-19 antiviral treatment, to be sold and used in certain low- and middle-income countries that represent roughly 50% of the world's population.⁸⁵ While a step forward, the deal still excludes billions of people who are not living in countries covered by the agreement, such as middle-income countries Brazil, Peru, Iraq, Kazakhstan and Lebanon, in which the generic drugs cannot be sold.⁸⁶ BioNTech has stated that it is planning to construct manufacturing facilities on the African Continent and in Asia "that will only produce mRNA-based vaccines for the respective regions".⁸⁷

Pfizer/BioNTech have not published its pricing policy or disclosed its research, development or production costs. Pfizer stated that they are following a tiered pricing approach,⁸⁸ offering vaccines to low-income countries at cost, while adding increasing profit margins to upper-middle-income and high-income countries.⁸⁹ On that basis, if Pfizer/BioNTech sold the African Union vaccines at cost for US\$6.75 each, the companies have made over 400% profit on each dose they sold to Taiwan at a price of US\$35.⁹⁰ Likewise, from the deal with the European Union, covering up to 1.8 billion doses, Pfizer/BioNTech may have made profits of up to US\$29.5 billion.⁹¹

An estimate of the production costs of Pfizer/BioNTech's Covid-19 vaccine carried out by the NGO Public Citizen which Pfizer has disputed,⁹² suggests that costs are much lower, leading to even higher profits.⁹³ Over the year, Pfizer/BioNTech have increased the prices for their vaccine,⁹⁴ while continuously upgrading their earnings outlook for 2021. Pfizer expects up to US\$36 billion earnings

83. Washington Post, "Frustrated by vaccine inequity, a South African lab rushes to replicate Moderna's shot", 28 November 2021, www.washingtonpost.com/world/2021/11/28/frigen-south-africa-vaccine-moderna/; CBS News, "Moderna offers NIH co-ownership of COVID vaccine patent amid dispute with government", 15 November 2021, www.cbsnews.com/news/moderna-covid-vaccine-patent-dispute-national-institutes-health/.

84. Medicine Patent Pool, Pfizer and The Medicines Patent Pool (MPP) Sign Licensing Agreement for COVID-19 Oral Antiviral Treatment Candidate to Expand Access in Low- and Middle-Income Countries, 16 November 2021, medicinespatentpool.org/news-publications-post/pfizer-and-the-medicines-patent-pool-mpp-sign-licensing-agreement-for-covid-19-oral-antiviral-treatment-candidate-to-expand-access-in-low-and-middle-income-countries

85. A compulsory license has been requested to allow supply of Paxlovid in the Dominican Republic which is not listed in the agreement. For further information see: Knowledge Ecology International, www.keionline.org/37066

86. Amnesty International, "Amnesty International's reaction to Pfizer's license agreement for Paxlovid with the Medicines Patent Pool", 18 November 2021, (Index : POL 40/5010/2021, www.amnesty.org/en/wp-content/uploads/2021/11/POL4050102021ENGLISH.pdf)

87. BioNTech, Email to Amnesty, 14 January 2022, on file.

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

89. Pfizer, "An open letter from Pfizer Chairman and CEO to colleagues", 7 May 2021, https://www.pfizer.com/news/hot-topics/why_pfizer_opposes_the_trips_intellectual_property_waiver_for_covid_19_vaccines

90. These prices have been reported by Knowledge Portalia, "Reported Price/Dose for Covid-19 Vaccine Candidates", www.knowledgeportalia.org/covid19-vaccine-arrangements, accessed 14 December 2021.

91. The EU is reported to have secured 1.8 billion vaccine doses at 23.15US\$ a dose in April 2021. Applying an at-cost price of 6.75 US\$ based on the price the African Union is paying for its doses, Pfizer/BioNTech makes 16.40 US\$ profit per dose, or 29.5 billion US\$ for the total of doses covered by the agreement.

92. 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.

93. Public Citizen estimates that the production of 8 billion doses of Pfizer/BioNTech's Covid-19 vaccine costs US\$9.34 Billion, thus about US\$1.18 per dose. For further detail see: How to Make Enough Vaccine for the World in One Year - Public Citizen.

94. Nasdaq, "Pfizer, Moderna Raise Vaccine Prices For EU", 2 August 2021, www.nasdaq.com/articles/pfizer-moderna-raise-vaccine-prices-for-eu-2021-08-02

from the Covid-19 vaccine alone in 2021, amounting to about 85% of its total revenue for the year.⁹⁵ Its partner, BioNTech has reported that it expects revenues of up to US\$18.5 billion in 2021.⁹⁶

Pfizer has stated that with BioNTech, they have produced over 2.6 billion vaccine doses in 2021.⁹⁷ According to Airfinity, they have delivered only 1% Covid-19 vaccine doses to low-income countries and 14% vaccines to lower-middle-income countries up to 31 December 2021, a significant increase on the 2.1% figure to low- and lower-middle-income countries in the previous assessment,⁹⁸ but still failing to meet their human rights responsibilities.

Both, Pfizer and BioNTech have made misleading statements about how they allocate their vaccines; they amalgamated low, lower-middle, and upper-middle countries - over 84% of the global population - into one group and referred to them as “low- and middle-income”.⁹⁹ Within this very broad category, the majority of Pfizer/BioNTech’s doses – more than 21 % of total supply - have in fact been going to upper-middle-income countries. Of the total Pfizer/BioNTech vaccine production, 64% have still been supplied to high-income countries. In a letter to Amnesty International in November, the company admitted that at that time only 154 million doses - less than 8 percent of its total – had in fact reached 42 low- and lower-middle-income countries. Pfizer also acknowledged that it had distributed less than 10 percent of these (i.e. 15.4 million) to low-income countries.¹⁰⁰

However, it has also denied being at fault for selling most its stock to wealthier countries, stating that “early on the majority of our first doses were reserved by the high-income countries because middle- and low-income countries had placed orders first with other vaccine makers, either because of the uncertainty of mRNA technology or because they were pursuing other options.”¹⁰¹

PFIZER/BIONTECH ASSESSMENT¹⁰²

Intellectual Property, Knowledge and Technology Sharing			
Fair and Transparent Pricing			
Vaccine Allocation			

95. Pfizer, Quarterly Report, 3 October 2021, Form 10-Q, s28.q4cdn.com/781576035/files/doc_financials/2021/q3/Pfizer-10-Q.pdf.

96. BioNTech, “BioNTech Announces Third Quarter 2021 Financial Results and Corporate Update”, 9 November 2021, eur02.safelinks.protection.outlook.com/GetUrlReputation

97. Airfinity, www.airfinity.com/

98. BioNTech, Statement in response to Amnesty International letter, 14 January 2022, in annex.; Pfizer, Letter to Amnesty International, 15 June, 2021, on file; Newsweek, “Pfizer CEO Says Low-Income Nations Will Receive 1Bn COVID Vaccine Doses by Year’s End”, 26 September, 2021, www.msn.com/en-us/news/world/pfizerceo-says-low-income-nations-will-receive-1bn-covid-vaccine-doses-by-years-end/ar-AAOQQle. For more information see: Amnesty International, “Despite the rhetoric, Pfizer’s failures continue to fuel human rights Covid-19 crisis”, POL 40/4969/2021, 11 November 2021, www.amnesty.org/en/documents/POL40/4969/2021/en/.

99. Amnesty International, “Despite the rhetoric, Pfizer’s failures continue to fuel human rights Covid-19 crisis”,

100. 11 November 2021, www.amnesty.org/en/wp-content/uploads/2021/11/POL4049692021ENGLISH.pdf

101. Pfizer letter to Amnesty International, 14 January 2022.

102. Please find the assessment key on page 35.

SINOPHARM

China National Pharmaceutical Group Co., Ltd. (Sinopharm) is a state-owned group of companies.¹⁰³ In May 2021, the World Health Organization approved for emergency use a vaccine that was developed by Beijing Bio-Institute of Biological Products Co Ltd, which is a subsidiary of China National Biotec Group, which in turn is owned by Sinopharm.¹⁰⁴ According to Airfinity, by the end of 2021 Sinopharm had manufactured over 2.25 billion doses, making it the third largest producer behind AstraZeneca and Sinovac.¹⁰⁵

Sinopharm does not have a human rights policy.¹⁰⁶ The company says it applies the corporate philosophy of “All for Health, Health for All”, though it is unclear what measures the company has taken in this regard.¹⁰⁷

By any measure, and certainly compared to the other companies assessed in this report, Sinopharm has made very little information about its operations and policies related to its Covid-19 vaccine business available to the public. As it is a state-owned company and not publicly listed, Sinopharm is not required to disclose any information, as is the case with the other vaccine manufacturers assessed in this report, including Sinovac. Since 1 Jan 2021, the company has only published one press release on its Covid-19 vaccine, and an interview with its chairperson.¹⁰⁸

Sinopharm has provided no information about subsidies or support it may have received from the Chinese government for Covid-19 vaccine development. It has also provided no information about its vaccine pricing policy. According to available data, the company has charged between US\$9-35 per dose to foreign governments.¹⁰⁹ According to a state-owned media source, Sinopharm charges the Chinese government, 200 Yuan or US\$31 per dose.¹¹⁰

Most of Sinopharm’s manufacturing takes place in China, but it has also reached agreements with six foreign manufacturers, in Bangladesh, Hungary, Indonesia, Morocco, Serbia and the United Arab Emirates.¹¹¹ Sinopharm has not taken a public position on proposals to waive intellectual property protections for vaccines during the pandemic.¹¹²

Sinopharm has not issued open, non-exclusive production agreements or signed up to participating in C-TAP or one of the technology transfer hubs established by the WHO, potentially creating barriers to fair access to the Covid-19 vaccine.

Sinopharm produced just over 2.25 billion doses in 2021, most of which were supplied domestically within China. The company delivered 1.4% of its doses to low-income countries and 23.6% to lower-middle-income countries, short of what is required for a fair global distribution of its vaccines.¹¹³

In July 2021, Sinopharm has agreed to supply vaccines to the COVAX Humanitarian Buffer, which aims to deliver Covid-19 vaccines to 167 million displaced people around the world.¹¹⁴

103. Sinopharm, www.sinopharm.com/en/1156.html

104. WHO, “WHO lists additional Covid-19 vaccine for emergency use and issues interim policy recommendations”, 7 May 2021, www.who.int/news/item/07-05-2021-who-lists-additional-covid-19-vaccine-for-emergency-use-and-issues-interim-policy-recommendations

105. Airfinity, Vaccine Production, science.airfinity.com/supply-and-production/production/by-vaccine

106. Sinopharm, About Us: Social Responsibility, www.sinopharm.com/en/1315.html

107. Sinopharm, Annual Report 2020, P9, media-sinopharm.todayir.com/2021042308080224799730699_en.pdf

108. Sinopharm, “China grants conditional market approval for Sinopharm CNBG’s COVID-19 Vaccine”, 2 January 2021, www.sinopharm.com/en/s/1395-4689-38862.html; “Chinese Covid-19 Vaccine Efficacy Better than Expected; Interview with Mr. Liu Jingzhen, Chairman of Sinopharm”, 16 January 2021, www.sinopharm.com/en/s/1395-4689-38923.html

109. Knowledge Portal, Chinese COVID-19 Vaccines, www.knowledgeportalia.org/vaccines-china

110. Global Times, “Government to pay 200 yuan per dose of Chinese COVID-19 inactivated vaccines”, 16 December 2020, www.globaltimes.cn/content/1210093.shtml

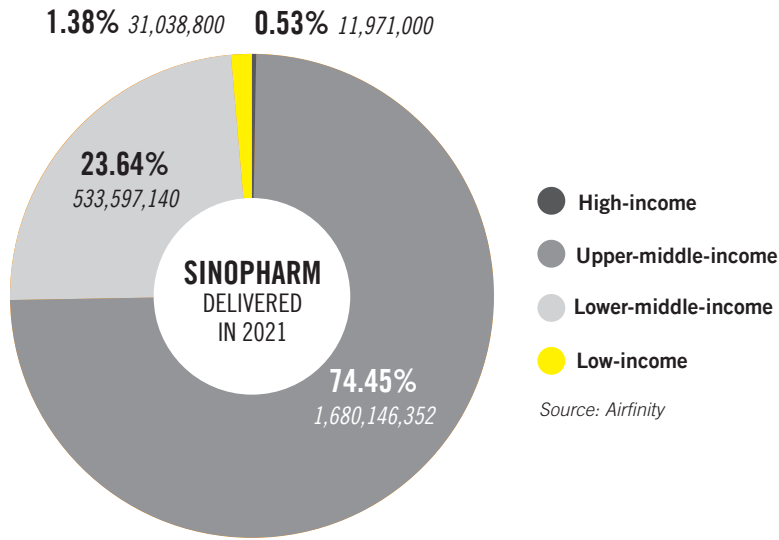
111. Knowledge Portal, Chinese COVID-19 Vaccines, www.knowledgeportalia.org/vaccines-china

112. Although the Chinese state has publicly supported the proposals to relax intellectual property rules put forward by India and South Africa to the WTO Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) Council for Trade-Related Aspects of Intellectual Property Rights, ‘Minutes of Meeting: Held in the Centre William Rappard on 15–16 October and 10 December 2020’ (IP/C/M/96/Add.1, 16 February 2021) para. 977, docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/M96A1.pdf&Open=True

113. Airfinity, www.airfinity.com/

114. GAVI, Gavi and humanitarian agencies partner to deliver COVID-19 vaccines to the most vulnerable people in the world, 16 November 2021, www.gavi.org/news/media-room/gavi-and-humanitarian-agencies-partner-deliver-covid-19-vaccines-most-vulnerable

Vaccines delivered by country income group - percentage and number of doses



Sinopharm does not have a human rights policy and does not reference core international business and human rights standards on its website. It charges relatively high prices for its vaccines, compared to some other companies, and does not have a published pricing policy or information on actual costs of production, individual cost items, sources of external funding, prices charged in different countries, or contractual terms and conditions. By the end of 2021, Sinopharm had delivered just 1.4% of its 2.25 billion doses to low-income countries and 23.6% to lower-middle-income countries, short of what is required for a fair distribution of its vaccines. Sinopharm has distributed vaccine supplies through COVAX, but has not joined C-TAP or issued open, non-exclusive production agreements.

The company did not reply to Amnesty International’s letter requesting comment on this assessment.

SINOPHARM ASSESSMENT¹¹⁵

<i>Intellectual Property, Knowledge and Technology Sharing</i>			
<i>Fair and Transparent Pricing</i>	—	—	—
<i>Vaccine Allocation</i>			

115. Please find the assessment key on page 35. The assessment of fair pricing was not possible due to the lack of accessible information.

SINOVAC

Sinovac Biotech Ltd. (Sinovac) is a Beijing-based vaccine developer and manufacturer.¹¹⁶ It is not a state-owned company. While its management and most of its business activities are in China, Sinovac has an international corporate structure: it is incorporated in the Caribbean island of Antigua and its shares are listed on the US exchange, the Nasdaq.¹¹⁷ The subsidiary that makes its Covid-19 vaccine, Sinovac Life Sciences Co., Ltd, is partly owned by another Chinese pharma company, called Sino Biopharmaceutical Ltd., which is listed on the Hong Kong stock exchange and incorporated in the Cayman Islands.¹¹⁸

In June 2021, the WHO approved for emergency use Sinovac's vaccine, known as CoronaVac.¹¹⁹ By late December 2021, the company said it had supplied more than 2.5 billion doses around the world, which is likely to be more than any other manufacturer.¹²⁰

Sinovac does not have a published human rights policy. Its website makes no reference to human rights but expresses the company's vague commitment to using "practical actions to contribute to the cause of public health, fulfil our responsibilities, and work together for a healthier world for all.

Compared to the western vaccine manufacturers, Sinovac has put relatively little information about its operations or policies in the public domain. While it has published press releases on the roll-out of its vaccine, these have provided little or no information about the agreements it has reached to supply China or other countries.¹²¹

Sinovac's shares are listed on the Nasdaq. It is therefore required to report information by the US financial regulator, the Securities and Exchange Commission (SEC). However, the SEC suspended trading in Sinovac's shares in 2019 following a dispute between shareholders over an attempted takeover.¹²²

Neither the Chinese government nor Sinovac has provided a comprehensive statement detailing the total amount of public funding or other support that the company has received to develop and manufacture its vaccine.

Sinovac has only published limited information about its financial situation in 2021. But it has previously stated it had received some state aid. In 2020, it reported receiving \$14.2 million in government grants, both to cover some research and development costs, as well as for costs relating to "property, plant and equipment."¹²³ It did not provide any other details or explain whether these were linked to its Covid-19 vaccine or not. In April 2020, the company said that it had received a low-interest rate loan of \$8.5 million from a state bank, and access to more than 70,000 square metres of land in Beijing for a new manufacturing plant, according to media reports.¹²⁴

Most importantly perhaps, the Chinese government has granted the subsidiary that makes Sinovac's vaccine with a preferential tax status.¹²⁵ From 2020-2022 the company will only have to pay a

116. Sinovac, *Company Profile*, www.sinovac.com/investor/show.php?id=177&lang=en

117. Sinovac, *Annual Report*, 2020, p72, www.sec.gov/ix?doc=/Archives/edgar/data/0001084201/000156459021020156/sva-20f_20201231.htm

118. Sino Biopharm, "Sino Biopharm holds 15.03 percent in the subsidiary", *Interim 2021 Annual Report*, p12, www.sinobiopharm.com/userfiles/files/E21082528-Sino%20Bio-IR.pdf

119. Sinovac, World Health Organization Authorizes SINOVAC's CoronaVac® for Emergency Use, 2 June 2021, www.sinovac.com/news/shownews.php?id=1245&lang=en

120. Airfinity weekly report, 17 December 2021, p36; according to Airfinity's own data, Sinovac has shipped just over 2.45 billion doses, the highest number of all Covid-19 vaccine developers, Airfinity, Production by vaccine, accessed 10 January 2022, science.airfinity.com/supply-and-production/production/by-vaccine

121. Sinovac, "Press Releases", www.sinovac.com/news/news.php?class2=154&lang=en

122. SEC, "Charges Activist Investors for Participation in Undisclosed Plan to Replace the Board of China-Based Biopharmaceutical Company", Administrative Proceeding, File No. 3-19799, 13 May 2020 www.sec.gov/enforce/34-88864-s

123. Sinovac, *Annual Report*, 2020, p48, www.sec.gov/ix?doc=/Archives/edgar/data/0001084201/000156459021020156/sva-20f_20201231.htm

124. Reuters, "China's Sinovac gains land and loans to speed up work on coronavirus vaccine", 23 April, 2020, www.reuters.com/article/health-coronavirus-china-sinovac-biotech/chinas-sinovac-gains-land-and-loans-to-speed-up-work-on-coronavirus-vaccine-idUSL5N2CB0C9

125. Sinovac, *Annual Report*, 2020, p52, www.sec.gov/ix?doc=/Archives/edgar/data/0001084201/000156459021020156/sva-20f_20201231.htm

corporate tax rate of 15 percent, as opposed to the standard rate of 25 percent, the company disclosed. This preferential rate could be worth billions of dollars to the company.

Sinovac has not provided information on its pricing policy, but unlike AstraZeneca and Johnson & Johnson has not made commitments to operate on a not-for-profit basis during the pandemic. The company reported that its profits for the first half of 2021 were US\$10.3 billion, compared to only US\$58.2 million the previous year.¹²⁶ According to available data, the company charges foreign governments between US\$10-22 dollars per dose.¹²⁷ According to a state-owned media source, Sinovac charges the Chinese government, 200 Yuan or US\$31 per dose.

Sinovac's manufacturing is largely centred on China, but it has signed agreements with manufacturers in seven other countries, with an estimated total production amounting to more than 1550 million doses.¹²⁸ These countries are Algeria, Brazil, Egypt, Indonesia, Malaysia and Sri Lanka.

Sinovac has not taken a public position on proposals to waive intellectual property protections for vaccines during the pandemic, but it has previously expressed its support for such protections. In its most recent annual report, Sinovac reported that, "our success depends, in part, on our ability to protect our proprietary technologies. We try to protect the technology that we consider important to our business by filing patent applications and relying on trade secret and pharmaceutical regulatory protection, including our existing and potential vaccines."¹²⁹

Sinovac has not issued open, non-exclusive production agreements or signed up to participating in C-TAP, creating barriers to fair access to the Covid-19 vaccine.

According to data provided by Airfinity, by the end of 2021 Sinovac had produced 2.45 billion vaccine doses and delivered 79% of them to high and upper-middle-income countries, with 20.6% to lower-middle-income countries and less than 0.5% to low-income countries.¹³⁰ While the bulk of Sinovac's doses have been supplied domestically within China, more than 646 million doses of the Sinovac vaccines have been purchased by 31 countries, regions or organizations around the world. Of these, only 2 million were purchased by a low-income country (Tajikistan), and 105 million by lower-middle-income.

China has purchased a further 8.5 million doses and donated to 22 countries.¹³¹ In July 2021, Gavi, the Vaccine Alliance, signed purchase agreements with both Sinovac and Sinopharm to provide 500 million doses to the COVAX facility, but the majority of these have not yet been delivered.¹³²

Sinovac has agreed to participate in Gavi, the Vaccine Alliance, and the member agencies of the Inter-Agency Standing Committee (IASC)'s COVAX Humanitarian Buffer, which aims to deliver Covid-19 vaccines to 167 million displaced people around the world. Sinovac, along with vaccine manufacturers Clover, Johnson & Johnson and Sinopharm – will waive indemnification requirements for humanitarian agencies delivering doses to these populations, removing the burden of risk for adverse events linked to the use of the companies' products from UN agencies and local NGOs.¹³³

126. SEC, Sinovac Reports Unaudited First Half of 2021 Financial Results, www.sec.gov/Archives/edgar/data/1084201/000110465921154709/tm2136598d1_ex99-1.htm

127. Chinese COVID-19 Vaccines, Knowledge Portal, www.knowledgeportal.org/vaccines-china

128. Chinese COVID-19 Vaccines, Knowledge Portal, www.knowledgeportal.org/vaccines-china

129. Sinovac, *Annual Report*, 2020, p24.

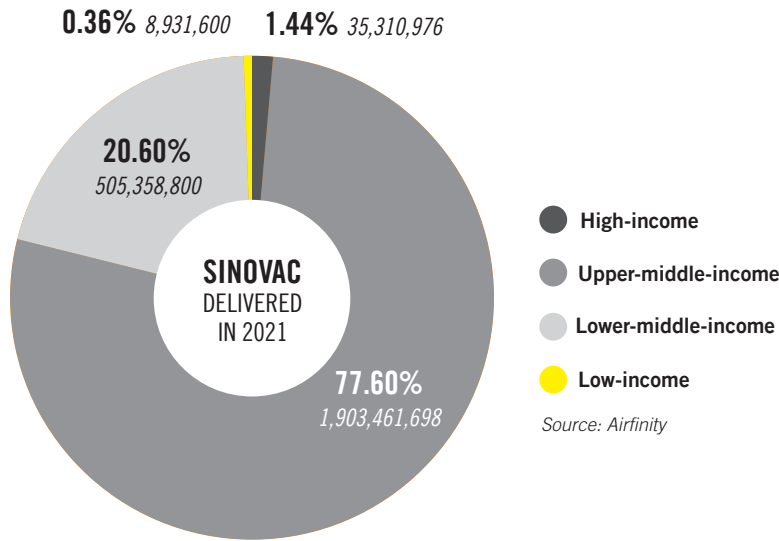
130. Airfinity, Data provided on 7 January 2022, on file, www.airfinity.com/

131. Knowledge Portal, Chinese COVID-19 Vaccines, www.knowledgeportal.org/vaccines-china

132. GAVI, "Gavi signs agreements with Sinopharm and Sinovac for immediate supply to COVAX," 12 July, www.gavi.org/news/media-room/gavi-signs-agreements-sinopharm-and-sinovac-immediate-supply-covax

133. GAVI, Gavi and humanitarian agencies partner to deliver COVID-19 vaccines to the most vulnerable people in the world, 16 November 2021, www.gavi.org/news/media-room/gavi-and-humanitarian-agencies-partner-deliver-covid-19-vaccines-most-vulnerable

Vaccines delivered by country income group - percentage and number of doses



SUMMARY

Sinovac does not have a human rights policy and does not reference core international business and human rights standards on its website. It charges relatively high prices for its vaccines, compared to some other companies, and does not have a published pricing policy or information on actual costs of production, individual cost items, sources of external funding, prices charged in different countries, or contractual terms and conditions. Sinovac has pledged vaccine supplies to COVAX, but has not joined C-TAP or issued open, non-exclusive production agreements. Sinovac’s deliveries are skewed towards higher-income countries: 79% of its vaccines have been delivered to higher-income countries, with 20.6% to lower-middle-income countries, and less than 0.5% to low-income countries.

The company did not reply to Amnesty International’s letter requesting comment on this assessment.

SINOVAC ASSESSMENT¹³⁴

<i>Intellectual Property, Knowledge and Technology Sharing</i>			←
<i>Fair and Transparent Pricing</i>	—	—	—
<i>Vaccine Allocation</i>			

134. Please find the assessment key on page 35. The assessment of fair pricing was not possible due to the lack of accessible information.

RESPONSIBILITIES OF INVESTORS

The responsibility to respect human rights and to prevent harm applies not just to the vaccine developers themselves but also to the companies that invest in them, including both asset managers and asset owners.¹³⁵ 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.¹³⁶ Once an investor has identified potential or actual adverse impacts, they should engage with their investee company and exert their leverage to mitigate these adverse impacts.¹³⁷ They should also insist that their investees conduct their own human rights due diligence.¹³⁸

In its report in September 2021, Amnesty International mapped the ten largest institutional investors in AstraZeneca, Johnson & Johnson, Moderna, Novavax, Pfizer and BioNTech.¹³⁹ These were mainly US-based asset managers and banks, with combined holdings worth more than US\$250 billion. They are (in order of total size of holding across the western vaccine developers): Vanguard Group Inc., Blackrock Inc., State Street Corp., Capital Group Cos Inc., Wellington Management Group LLP, Baillie Gifford, Bank of America Corp, Morgan Stanley, Bank of New York Mellon and UBS.

The single largest, Vanguard Group Inc., held shares worth a total of more than US\$66 billion in AstraZeneca, Johnson & Johnson, Moderna, Novavax and Pfizer. At that time, BlackRock Inc had more than US\$62 billion invested in them. The size of their combined holdings, as well as their total portfolios across the whole sector, give them a significant role in these companies and potential influence in their business decisions. Combined, these investors owned 22.7% of AstraZeneca's shares, 27.9% of Johnson & Johnson's, 24.6% of Moderna's, 17.3% of Novavax's, and 32.7% of Pfizer's.¹⁴⁰

135. 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."

136. 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.

137. 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.

138. 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

139. Amnesty International, "A double dose of inequality: pharmaceutical companies and the Covid-19 vaccine crisis", (Index: POL 40/4621/2021), September 2021, pp. 59, www.amnesty.org/en/wp-content/uploads/2021/09/POL4046212021ENGLISH.pdf

140. All data from Bloomberg, 26 May 2021.

Yet despite the undoubted influence that these huge shareholdings gave them, none of these investors had publicly exerted leverage over their investee or disclosed such engagement with the aim to encourage vaccine developers to fully respect their human rights responsibilities.¹⁴¹

Little has changed since Amnesty International last received communication from these investors in September. Amnesty International again approached these ten investors in January 2021 to find out whether they had engaged with their investees on their actual and potential adverse impact on fair access to their Covid-19 vaccines.

Only four investors responded, of which only Baillie Gifford provided information on their due diligence process since September 2021.¹⁴² The investor stated that it had met with BioNTech and Moderna, and discussed in particular with Moderna the role it says it is playing to achieve the WHO's global vaccination target.. "We are encouraged by the steps Moderna is taking towards expanding equitable access to its vaccines, such as prioritising COVAX contracts and low- and middle-income countries (LMICs) [...]." It further said that the company prefers "to promote change through active ownership and direct engagement with management rather than public activism through the media in the first instance."

BlackRock referred to a previous letter to Amnesty International in which it said it engages with pharmaceutical companies "on all aspects of their business" including "asking questions to understand their role in Covid-19 vaccines".¹⁴³ UBS equally referred to its previous communication in which it 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."¹⁴⁴

But none of these companies have taken steps similar to an initiative led by other investors. In January 2022, in preparation of forthcoming Annual General Meetings, 65 institutional investors, including Nomura, Investec and Achmea Investment Management sent an open letter to the boards of AstraZeneca, Johnson & Johnson, Moderna and Pfizer, asking them to integrate the WHO vaccination targets and recommendations into the companies' business strategies. They called for tying the executives' remuneration to the achievement of fair access to Covid-19 vaccines.¹⁴⁵

Similarly, in November 2021, other investors filed a shareholder resolution alongside Oxfam and the Interfaith Center on Corporate Responsibility. This requested that Pfizer and Moderna look into the feasibility of transferring vaccine technology and know-how to increase global production.¹⁴⁶

Regrettably, those investors with the largest stake in the vaccine manufacturers have done little, or nothing, to ensure that their investments do not result in human rights harm, putting profits before people.¹⁴⁷

141. Amnesty International, "A double dose of inequality: pharmaceutical companies and the Covid-19 vaccine crisis", (Index: POL 40/4621/2021), September 2021, pp. 59, www.amnesty.org/en/wp-content/uploads/2021/09/POL4046212021ENGLISH.pdf

142. Baillie Gifford, Letter to Amnesty International, 31 January 2021, on file.

143. 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-qrtly-stewardship-report-q3-2020.pdf

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

145. Achmea Investment Managers, Letter to Boards, www.achmeainvestmentmanagement.nl/-/media/files/institutioneel/nieuws/letter-executive-remuneration-pharma-4-1-2022.ashx

146. Oxfam America, "Shareholder resolutions push Pfizer, Moderna, and Johnson & Johnson to address COVID vaccine inequality", 4 November 2021, www.oxfamamerica.org/press/press-releases/shareholder-resolutions-push-pfizer-moderna-and-johnson-johnson-to-address-covid-vaccine-inequality/.

147. Peter Singer, Investors Must Tackle Vaccine Inequity, Jackson Hole Economics, 24 January 2022, jheconomics.com/investors-must-tackle-vaccine-inequity/

CONCLUSION AND RECOMMENDATIONS

In 2022, the prospective global production of Covid-19 vaccines should be sufficient to meet global needs. Nevertheless, for too many people around the world access may still be denied or come too late if vaccine makers, and their investors, continue to make business decisions without fulfilling their human rights responsibilities. All the companies assessed are creating obstacles to fair access to Covid-19 vaccines, and therefore are contributing to an unprecedented global human rights crisis.

People living in low-income countries are being left behind. While distribution bottlenecks in many countries certainly do exist, a lack of predictable and sufficient supply remains a key factor in low vaccination rates.

The companies must act urgently, in cooperation with states, to prioritize supply to those countries and areas where vaccination targets have not yet been reached and are most needed. States must 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. They must put all necessary measures in place, and support countries in need, to ensure effective and fair vaccination roll-out upon receipt of vaccine doses. There is a particular responsibility on those states where the vaccine developers are based or operating from, including Germany, the UK and US, as well as China.

As the Covid-19 global health emergency continues to evolve with no end in sight, pharmaceutical companies must radically change their approach to dose allocation, pricing and the sharing of intellectual property and technology, putting human rights before profits. Only through fair distribution and pricing, and open sharing of technology and intellectual property can vaccine developers truly fulfill their human rights responsibilities.

Regrettably, Covid-19 and the lack of accountability of pharmaceutical companies have exposed the gaps in our norms and standards to ensure that corporate actors meet their human rights responsibilities. The UN Guiding Principles outline the human rights responsibilities for corporates under international law. But Covid-19 has exposed how, in practice, few companies genuinely respect them. This is not good enough. Urgent efforts are needed to establish meaningful and enforceable rules at national and international levels to ensure accountability for corporate actors, including those in the pharma industry.

As we enter the third year of the pandemic, it is vital that **the vaccine developers** take action now. They must:

- Take immediate urgent measures to ensure fair supply of their Covid-19 vaccines to low- and lower-middle-income countries, prioritizing in particular access to vaccines in low-income countries in order to reach the WHO's target of 70% vaccination rate by July 2022.

- 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. To ensure this, commit a significant share of their annual production to the COVAX Facility, including via state donations.
- 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 lower-middle-income countries for at least the duration of the global health emergency.
- Assign oversight and responsibility for complying with the company's human rights responsibility to extend fair access to Covid-19 vaccines to all relevant senior management and assign board level responsibilities, including through linking it to executive pay.

The **institutional investors** that hold or manage shares in these vaccine developers also have human rights responsibilities. They need to use the considerable leverage that they have over these companies, to pressure them to remove obstacles to fair access to Covid-19 vaccines, and to promote accountability and transparency. They must:

- Conduct comprehensive human rights due diligence on their investments and financial services. This includes monitoring the human rights impacts 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, for instance by:
 - Issuing public statements calling on the companies they invest in to take the steps outlined above.
 - Insisting that management structures ensure compliance with human rights responsibilities, including through linking this to executive pay.
 - 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.

Finally, Amnesty International is calling on **states to**:

- Redistribute surplus Covid-19 vaccine stocks to low- and lower-middle-income countries, preferably through international and regional mechanisms such as COVAX, and ensure that vaccine allocation becomes equitable throughout 2022 and beyond. Likewise, put all necessary measures in place, and support other countries to carry out effective and fair vaccination roll-out upon receipt of vaccine doses.
- Put all possible measures and policies in place, including legislation, to expand global production of Covid-19 vaccines and prevent vaccine developers from impeding broader access to Covid-19 vaccines.

- Support and resource C-TAP and promote open and non-exclusive licences that include knowledge and technology transfer.
- Support efforts to reform intellectual property rights regimes to ensure universal access to essential, life-saving medicines and 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.
- Publicly disclose terms and conditions of agreements with vaccines developers, including funding, advance purchasing, and purchasing agreements and make public funding for companies transparent and conditional on them 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.
- Adopt and implement enforceable mandatory human rights due diligence obligations for business enterprises, including institutional investors, to prevent human rights harms and mitigate human rights risks through their operations and business relationships and within their value chains.



Interactive offering dedicated in memory of victims who lost the battle against COVID-19 was installed in Plaza Tolsá, Mexico City.
© Luis Barron / Eyepix Group/Barcroft Media via Getty Images

Figure 4 : Overview of company assets

COMPANY	IP, KNOWLEDGE AND TECHNOLOGY SHARING	FAIR AND TRANSPARENT PRICING	VACCINE ALLOCATION
ASTRAZENECA	AstraZeneca has not joined C-TAP nor offered non-exclusive licensing of its Covid-19 vaccine, thus maintaining barriers to fair access to the Covid-19 vaccine.	AstraZeneca is following an at cost- pricing policy so far, but has not disclosed information about its research, development or production costs.	AstraZeneca is supplying over 50% of its vaccines to lower-income countries.
JOHNSON AND JOHNSON	Johnson & Johnson has not joined C-TAP nor offered non-exclusive licensing of its Covid-19 vaccine, thus maintaining barriers to fair access to the Covid-19 vaccine.	Johnson & Johnson is following an at cost-pricing policy so far, but has not disclosed information about its research, development or production costs.	Johnson & Johnson is supplying over 50% of its vaccines to lower-income countries.
MODERNA	Moderna has not joined C-TAP nor offered non-exclusive licensing of its Covid-19 vaccine, thus maintaining barriers to fair access to the Covid-19 vaccine.	Moderna has not published its pricing policies or disclosed their research, development and production costs. The company charges disproportionately high prices gaining excessive profits.	Moderna has allocated 25.5% of its supply to lower-income countries.
PFIZER/ BIONTECH	Pfizer/BioNTech have not joined C-TAP nor offered non-exclusive licensing of its Covid-19 vaccine, thus maintaining barriers to fair access to the Covid-19 vaccine.	Pfizer/BioNTech have not published their pricing policies or disclosed their research, development and production costs. They charge disproportionately high prices gaining excessive profits.	Pfizer/BioNTech has allocated 15% of its supply to lower-income countries.
SINOPHARM	Sinopharm has not joined C-TAP nor offered non-exclusive licensing of its Covid-19 vaccine, thus maintaining barriers to fair access to the Covid-19 vaccine.	Sinopharm has not published its pricing policies or disclosed their research, development and production costs.	Sinopharm has allocated 25% of its supply to lower-income countries.
SINOVAC	Sinovac has not joined C-TAP nor offered non-exclusive licensing of its Covid-19 vaccine, thus maintaining barriers to fair access to the Covid-19 vaccine.	Sinovac has not published its pricing policies or disclosed their research, development and production costs.	Sinovac has allocated 21% of its supply to lower-income countries.

Explanatory note:

IP/Knowledge Sharing

- has obstructed sharing;
- has partially shared;
- has fully shared.

Pricing:

- not published, disproportionately high pricing;
- apparently fair pricing/not transparent;
- fair pricing/transparent

Allocation:

- below 25% to lower-income countries;
- between 25 and 50% to lower-income countries;
- above 50% to lower-income countries.

ANNEX 1: LETTERS FROM COMPANIES

RESPONSES FROM ASTRAZENECA, BIONTECH, PFIZER AND FROM INVESTOR BAILLIE GIFFORD

ASTRAZENECA¹⁴⁸

Statement (13 January 2022)

Intellectual Property (IP) and Technology Transfers

- Vaccines are highly specialised, complex biological products which are subject to rigorous testing and quality standards and processes during their development. Our approach has been to share our technology and know-how with more than 20 experienced vaccine manufacturing organisations (including four sub licence partners) in countries where production can be ramped up at scale.
- We believe this offers a more effective way of scaling up production and supporting innovation, and our model has enabled us to supply 2.5 billion doses to 170 countries around the world. Over two thirds of the doses have gone to low and lower middle income countries.
- Waiving IP rights completely would not solve the challenge of rapidly scaling up manufacturing to meet unprecedented global demand. IP is not the limiting factor but the time it takes to transfer the technical knowledge, skills and expertise to produce the vaccine, as well as the lack of specialised producers that can quickly set up the industrial capacity to make a safe and effective vaccine at the scale required.

Equitable access

- AstraZeneca remains committed to providing broad and equitable global access to the vaccine. Since the start of the pandemic, we have supplied over 2.5 billion doses at no profit to AstraZeneca. As previously confirmed, we have begun to move to an affordable pricing model - we are adopting a tiered pricing approach aligned to Gross National Income (GNI) per capita, which is a widely recognised and implemented model used by developers of medicines and vaccines, and we will continue to supply the vaccine at no profit for AstraZeneca to low-income countries.

Supporting donations

- To date we have facilitated the donation of over 200 million vaccine doses worldwide to 132 countries of which over 122 million have been facilitated via COVAX.
- AstraZeneca was the first manufacturer to support donations via COVAX.

148. AstraZeneca, Email to Amnesty International, 13 January 2022, on file.

BioNTech responded to Amnesty International's request for comment by email on 14 September 2021 by commenting directly on Amnesty International's letter as well as sending a short statement. The following provides an overview of BioNTech's main comments to the letter:

- Pfizer has not benefited from a US\$443 (€375million) grant from the German Federal Ministry of Education and Research to Support Covid-19 Vaccine Programme. The grant was solely given to BioNTech and used for Germany-based activity.
- Out of the 2.6 bn doses delivered in 2021, 1 bn went towards low- and middle-income countries.
- BioNTech is setting up manufacturing facilities on the African Continent and Asia that will only produce mRNA-based vaccines for the respective regions. Construction is planned to start 2022.

Statement

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 2bn doses 150 countries and territories around 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. Out of the 2.6 bn doses delivered in 2021, 1bn doses were delivered to low- and middle-income countries. 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. The first doses of our vaccine to reach the African continent through the COVAX Facility arrived in Rwanda 8 month ago. 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.

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. 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 is planning to establish sustainable end-to-end manufacturing on the African continent for the supply of the African Union with mRNA-based vaccine, following the Company's announcement of its aim to develop a well-tolerated and highly effective Malaria vaccine. Construction of the first mRNA manufacturing facility in Africa is planned to be initiated in mid-2022. The first manufacturing facility will become a node in a decentralized and robust African end-to-end manufacturing network. The decision to evaluate manufacturing solutions in several African countries 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.

Please also note, that we are not commenting or disclosing any details of contracts, inc. financials, that have been signed with governmental authorities.

149. BioNTech, Email to Amnesty International, 14 January 2022, on file.



January 14, 2022



Ref: Right to reply to upcoming Amnesty International Publication

Mr. Wilcken,

Thank you for the opportunity to comment on the material from your forthcoming publication. We are pleased to share updates about our access efforts since your previous report was published in September 2021.

Since then, we have continued to make progress on our existing commitments to COVID-19 vaccine and made big strides on antiviral access. We have invested significant time and resources to meet our responsibility to respect the right to health in the challenging global context of the pandemic.

In line with our commitment to open communication, we are happy to continue clarifying our position and to sharing some additional information with you, as our COVID response has continued to evolve since our last exchange. Please note that we cannot comment about the assessment of our partner BioNTech or the references to other companies' policies.

Like you, we continue to be extremely concerned about the toll that COVID-19 is taking on the lives and well-being of people all over the world. This is why we have put all the power of our company behind the objective of contributing to ending this pandemic.

We share below some key updates and our ongoing progress under three core themes underpinning the right to health in the COVID context: 1) Intellectual Property, Knowledge and Technology Sharing; 2) Fair and Transparent Pricing; and 3) Vaccine Allocation.

1) Intellectual Property, Knowledge and Technology Sharing

Pfizer shares the goal of the international health and human rights communities of facilitating access to medicines for patients and we support implementation of the Doha Declaration, which recognizes countries' right to protect public health, while also acknowledging that IP protection is important for the development of new medicines. We remain committed to working directly with governments and other stakeholders, including to help ensure the COVID vaccine and our oral antiviral treatment, Paxlovid™ (nirmatrelvir [PF-07321332] tablets; ritonavir tablets), is accessible and affordable for those who need them. We recognize the unique level of economic development and social challenges of Least Developed Countries (LDCs), as defined by the United Nations Committee for Development Policy, and therefore Pfizer has a general [policy of patent non-enforcement in LDCs](#).

However, experience has demonstrated that the challenges to ensuring equitable distribution of the COVID-19 vaccine stem not from the IP system but rather from systemic and policy

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challenges such as tight supplies for vaccine manufacturing, export controls and other trade barriers affecting both vaccine manufacturing supplies and final product (which also affected products in our non-COVID lifesaving portfolio), and distribution infrastructure limitations that determine country readiness, including cold chain capacity, availability of syringes and diluents, vaccine hesitancy, etc. Weakening or waiving IP rights would not address these real-world challenges in the short term, nor will it contribute to better future pandemic preparedness and response.

Intellectual property as an enabler for access

We are fully aligned with the overarching imperative of increasing overall supply to achieve equitable access. Since the beginning of our COVID vaccine development program, we have focused our efforts and resources in ways that maximize our supply so we can support the global need. Because of the urgent need to vaccinate more people, we are continuously exploring innovative ways to increase the number of doses we're able to supply – which includes expanding our existing facilities, adding more suppliers, and bringing on additional Pfizer/BioNTech sites and contract manufacturers around the world to produce the vaccine.

Pfizer and BioNTech's global COVID-19 vaccine supply chain and manufacturing network now spans four continents and includes more than 20 manufacturing facilities, including contract manufacturing agreements that Pfizer has in place to further accelerate access around the world. Last July we announced a [landmark agreement with The Biovac Institute in South Africa](#) to manufacture the Pfizer-BioNTech COVID-19 vaccine exclusively for the 55 member states that make up the African Union, and in August, Pfizer and BioNTech also announced the signing of a [letter of intent with Eurofarma Laboratórios SA](#), a Brazilian biopharmaceutical company, to manufacture our COVID-19 vaccine for distribution within Latin America.

Such efforts are facilitated by the IP framework that protects the innovation and allows for secure transfer of technical knowledge. We will continue to explore and pursue opportunities to bring new partners into our supply chain network to further accelerate access to the COVID vaccine.

To further explain our position, it is important to understand that vaccine manufacturing is a biological production. It is extraordinarily complex under any circumstances, and even more so during a pandemic. The steps involved in a technology transfer include – but are not limited to – on-site development, equipment installation, engineering and process qualification tests, and regulatory approvals. The timeline for technology transfers is dependent on the extent of work needed during the transfer. On an average a fill/finish technology transfer (where product is filled into vials/syringes and packaged for delivery) takes anywhere from 18 months to three years from project kickoff to the qualification tests in which the new facility demonstrates that it can consistently execute a well-controlled process and make quality product (also known as performance qualification (PPQ) execution).

Expanding vaccine manufacturing to organizations without a proven track record and without the necessary skills, experience, or expertise to reliably source and manufacture vaccines could result in failures, which would put pressure on raw resources, potentially diverting them away from manufacturers who are producing COVID-19 vaccines and other essential vaccines to protect against a wide range of diseases. Lapses in quality could result in loss of trust in our processes or our ability to deliver a high-quality vaccine.

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IP enabling access to our COVID-19 oral antiviral treatment, Paxlovid™ (nirmatrelvir [PF-07321332] tablets; ritonavir tablets)

We believe that antivirals can play an important role in treating or preventing COVID-19, complementing vaccines and other therapeutic and social interventions. This is why we have been working diligently to actively leverage our deep heritage in anti-infective development, as well as our research, scale, and capital resources, to create targeted treatments that may help those who contract the virus around the world. We know that these efforts will only be truly impactful if they can reach those most in need.

Aligned with our belief that the current innovation system is an enabler of access, Pfizer and the Medicines Patent Pool (MPP) recently [announced](#) a voluntary licensing agreement for Pfizer's COVID-19 oral antiviral treatment in low- and middle-income countries. Licensing antiviral intellectual property to the MPP potentially helps to enable Pfizer's oral antiviral, to reach low-income and lower-middle-income countries as well as some upper-middle income countries, accounting for approximately 53% of the world's population, if authorized or approved in those countries. Pfizer will not receive royalties on sales in low-income countries and will further waive royalties on sales in all countries covered by the agreement while COVID-19 remains classified as a Public Health Emergency of International Concern by the World Health Organization.

Our access strategy aims at delivering safe and effective antiviral therapeutics as soon as possible and at an affordable price. In addition to our agreement with the MPP, during the pandemic Pfizer will offer our oral antiviral therapy, if authorized or approved, through a tiered pricing approach based on the income level of each country to promote equity of access across the globe. High and upper-middle income countries will pay more than lower income countries, which will pay a not-for-profit price.

Pfizer continues to invest to support the manufacturing and distribution of PAXLOVID, including exploring potential contract manufacturing options. As a result of these efforts, Pfizer is raising its production projections from 80 million to 120 million courses of treatment by the end of 2022. We have initiated bilateral outreach to countries in all regions around the world, as well as to supranational organizations, to help ensure no one is left behind.

We have also been leveraging lessons learned from the development and distribution of the COVID vaccine—including challenges faced by manufacturers, governments and the broader global community—to inform a strengthened approach to ensuring access.

2) Fair and Transparent Pricing

Not-for-profit pricing for low income and lower-middle income countries

We recognize that pricing is a key aspect of access and the right to health in practice. Early in our development program (June 2020), we decided to offer our COVID vaccine through tiered pricing. During the pandemic we chose to charge governments a price that help them ensure that there is little to no out-of-pocket costs for their populations based on the principles of volume, advanced commitment, equity and affordability. And recognizing that equity doesn't mean we give everyone the same, but rather we give more help to 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.

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. The funds received by Pfizer through advance purchase agreements

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are payments for vaccine doses that governments are acquiring. Therefore, these payments do not constitute government subsidies for the development and production of the vaccine.

3) Vaccine Allocation

From day one of our COVID vaccine development program, our outreach has been broad and inclusive to help ensure equitable access. In parallel, we approached all governments where Pfizer has a presence and global health organizations, including COVAX.

Early on the majority of our first doses were reserved by the high-income countries because middle- and low-income countries had placed orders first with other vaccine makers, either because of the uncertainty of mRNA technology or because they were pursuing other options. Because of some of the challenges faced by other vaccine producers, many of these countries later came back to us and we worked to rapidly establish agreements and allocate doses as quickly as possible. Our contractual obligations on vaccine allocations have been determined by this sequence of events.

We recognize and are concerned by the relative lower pace with which vaccines ended up reaching low-income countries, however, it is important to also acknowledge that approximately two thirds of the 1.3 billion people living in poverty are in the middle-income countries. Our efforts to substantially increase Pfizer/BioNTech vaccine shipments through the end of 2021, had a particular focus on low- and lower-middle-income countries that are further from global targets.

We are happy to share that as of January 9, we have supplied more than 2.66 billion doses of the Pfizer-BioNTech COVID-19 vaccine to 167 countries in every region of the world. Of these, more 1 billion doses were delivered to 99 low- and middle-income countries by end-2021, with more than 40% going to 56 low- and lower-middle income countries. Specifically,

- We are a proud partner to COVAX, with an agreement to supply 40M doses in alignment with their allocation strategy for the Pfizer-BioNTech vaccine.
- In July 2021 we signed a milestone agreement with the US Government to provide 1 billion vaccines doses that they would subsequently donate to COVAX's AMC 92 and African Union Countries in 2021 and 2022. The first shipment from the US Government agreement reached Rwanda on August 18, 2021. As of January 9, 2022, more than 205 million doses have been delivered to 65 low-and-lower-middle income countries as part of this program¹.
- Similarly, we are also supporting the European Commission and participating member states in their efforts to provide donations to countries in need through COVAX. Pfizer/BioNTech, the European Commission and COVAX have established a framework that enables EC member states to donate doses from their allocations to low- and lower-middle-income countries in need through COVAX, with France acting as the coordinating member state for donations. The first donation under this framework, which occurred in late October, was the donation of doses from France to Rwanda. As of January 9, 2022, more than 16 million doses have been donated by EU nations to countries in need.

Because of all these ongoing initiatives and our continued efforts to boost vaccine manufacturing, in 2021 we pledged to supply 2 billion doses to low-and middle-income countries

¹ More information about status of vaccine deliveries via this donation program can be accessed via [USAID's website](#).

through 2022 – 1 billion each year. Our current allocation to low- and middle-income countries from all supply pathways² which includes also bilateral agreements and the initiatives mentioned above, surpassed this pledge in 2021.

Capacity and resources to strengthen vaccine access for LMICs

What's more, as we scale up manufacturing volume, we are simultaneously identifying parallel ways to ensure that low-and-middle-income countries have better access to vaccines and—crucially—capacity to dispense the vaccines to their populations. We recognise the dire need for vaccines in low-income country populations. We continue to see reliable vaccine deliveries to those countries as a central part of Pfizer's COVID-19 response and are continually working to improve the efficacy and speed of delivery to their vulnerable populations.

We've worked to leverage our expertise to both expand and improve the supply network and storage and handling requirements of the COVID vaccine itself – to meet the needs of our global network. We produced over 3 billion doses in 2021– more than double our original 1.3 billion-dose estimate, of which more than 1 billion went to low- and middle-income countries, as mentioned above. Pfizer expects to manufacture 4 billion doses in 2022.

Many elements have been critical to achieving this increase, including bringing on additional Pfizer and BioNTech facilities and external suppliers, expanding the supply of raw materials, and enhancing the manufacturing process itself. We have reduced our COVID-19 vaccine manufacturing timeline from approximately 110 days – from start to vial-ready – to an average of 60 days, an almost 50% improvement.

We have continued to invest and have made changes to the formulation of the current vaccine to make it more stable and easier to use, important elements impacting accessibility in low- and middle-income countries. The shelf life has been extended to 9 months and the vaccine can now be stored in a standard refrigerator for up to 31 days after being removed from our innovative thermal shipper.

But we know that global vaccination targets can be achieved, and people's rights to health fulfilled, only with support from *all* global health stakeholders, including vaccine manufacturers. Such partnership is of utmost importance to ensure country readiness and absorption of vaccines, as these are the access challenges requiring the most attention today.

Distributing these types of products rapidly and at national scale has no precedent in modern public health, and close coordination across all stakeholders is critical to the success of vaccination campaigns. Some of the country readiness challenges we are facing today include acceptance by the country's regulatory body, confirmation that the country can meet product handling requirements, the availability of sufficient ultra-cold-chain (UCC) and/or traditional cold chain capacity for both the vaccine and diluent, basic supplies such as syringes, and the development of a delivery strategy to reach target populations. Without cold chain support countries are not able to accept high volumes of vaccine that allow for robust vaccination campaigns. And without service delivery and sufficient workforce capacity, vaccines in country will not result in vaccinations.

These elements demonstrate that to achieve equitable access, it is not just increasing the volume of vaccines that will bring an end to the pandemic, but collaboratively strengthening

² Our current supply pathways include direct supply agreements with country governments, supply agreements with supranational organizations like COVAX and the European Union, partnerships with wealthy nations to donate doses to countries in need and humanitarian donations to vulnerable populations

healthcare infrastructure, enhancing country readiness, and addressing landscape challenges in order to enable people to receive these vaccinations.

When travel bans triggered due to Omicron towards end-2021, we were on pace to ship 43 million doses to the 8 southern African countries on the travel ban lists. For 5 of the 8 countries, Pfizer was asked by their respective governments over the past several months to delay or pause shipments due to issues related to country readiness.

This shows why greater investment in readiness efforts in many lower income countries will still be necessary to ensure that vaccines shipped effectively reach populations. The COVAX Facility and its international health partners have played a key role to support country readiness for vaccines, and Pfizer is committed to providing our expertise and resources to strengthen healthcare systems where greater support may be needed.

Therefore, Pfizer is partnering with global health stakeholders, including COVAX, to analyze supply chain capabilities in low-income countries to understand where the private sector can lend expertise and support the delivery of any COVID-19 vaccine - including dry ice supply, transportation, and best practice sharing. As a few key examples:

- Pfizer and the UPS Foundation are committed to accelerating the equitable distribution of COVID-19 vaccinations. The UPS Foundation is donating freezers to countries that need assistance with building out their ultra-cold chain capacity, and Pfizer provides guidance and experience in product supply. Our partnership leverages innovation in the healthcare cold chain to truly move our world forward by safely, securely and quickly delivering highly sensitive, critically needed vaccines to areas where they are needed most.
- As part of a four-year [partnership with Zipline](#), Pfizer is supporting an innovative pilot initiative in Ghana, focused on delivering vaccines requiring cold-chain storage to hard-to-reach areas using drones. The initial success of the project suggests that the program could be quickly expanded to deliver doses of COVID-19 vaccines to remote regions across the world where Zipline operates.
- Pfizer has signed an MOU with Global Environment and Technology Foundation to collaborate with Project Last Mile. The partnership is focused on aligning the supply chain expertise and technical capabilities of Coca-Cola, a company whose supply chain is characterized as one of the widest reaching in the world, with technical expertise from Pfizer on vaccine handling, storage and administration in order to improve the availability of vaccines in developing countries, and, in particular, to those residing in and around the last mile of the medical supply chain in Africa.

We are also drawing on our lessons learned from the last two years to address existing challenges with vaccine delivery. For example, internally we are exploring new strategies to improve the global COVID-19 vaccine delivery system, from supply chain through distribution, and better country readiness challenges.

Addressing access complexities from trade & regulatory policies

Export restrictions, regulatory needs, and border measures have all had an impact in our ability to manufacture and distribute vaccines. As we bring additional partners into our supply chain, the risk that trade bottlenecks will delay vaccine distribution increases significantly. Export restrictions for COVID-19 vaccines created cost and uncertainty and introduced additional

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access challenges for low and lower middle-income countries participating in the COVAX Facility.

Initiatives to reduce or eliminate export restrictions, today and in future, will be critical. The Trade and Health Initiative (TAHI) sponsored by over 50 WTO members is a welcome step in that direction. Similarly, a strong partnership between industry and regulatory agencies is helping to expedite the delivery of lifesaving medicines and vaccines to patients.

Pfizer has [worked](#) closely with the leaders of the World Trade Organization, World Health Organization, World Bank, and International Monetary Fund to identify very concrete steps that these organizations, in partnership with member governments, can take to address these challenges in the near term³. We are committed to continue supporting this endeavour.

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 COVID-19 poses to people, particularly in the most vulnerable geographies, and among the most vulnerable groups of society, and adapt our response. We hope the details provided above give a sense of the many angles we are covering in our efforts to ensure equitable access and to fulfill our human rights responsibilities.

At the same time, we recognize that deep-seated challenges to achieve the right to health cannot be solved working alone, particularly during an unprecedented pandemic. For this reason, we continue to invest our time and resources working in partnership with governments, international organizations, patient organizations and local healthcare systems so that we can, together, tackle systemic challenges.

We are committed to continue evolving and improving our response to this pandemic where we can, and we strongly welcome the opportunity to engage with others, including your organization, to share challenges, lessons learned and to raise awareness of the need for robust collaborative solutions to improve equitable healthcare access globally. We hope you will consider our clarifications above as you finalize your report.

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

Best regards,



³ See [global race infographic e.pdf \(wto.org\)](#)

Baillie Gifford & Co
Calton Square, 1 Greenside Row, Edinburgh EH1 3AN
Tel. 44 (0)131 275 2000 Fax 44 (0)131 275 3999
www.baillieghifford.com



31 January 2022

Dear Mr Dummett,

Thank you for contacting us. We value further engagements with civil society organisations such as yours and appreciate the work that you are doing.

As a guide to our overall approach to investment stewardship, we would like to draw your attention to our previous letter (dated 10 September 2021). This letter also details our reasons for investing in companies, like Moderna and BioNTech, which are bringing innovative vaccines and treatments to the world. We would highlight that we invest in both companies not simply because they are attractive investments for our clients, but because we believe in supporting a new generation of companies that are tackling the world's biggest health challenges.

Have you engaged with your investees specifically addressing their actual and potential adverse impact on access to Covid-19 vaccines?

Regular engagement is an integral part of our investment and ownership responsibilities, and we have discussed a range of social matters with each company, especially related to the pandemic. Our clients trust us to oversee and manage their investments for the long term. Stewardship of their holdings is a core part of this commitment and we prefer to promote change through active ownership and direct engagement with management rather than public activism through the media in the first instance. We publicly disclose on our website all our voting decisions and company engagement on a quarterly basis.

Since our letter in September 2021, we have met Moderna several times to explore and discuss the role it is playing in the achievement of the [WHO's Strategy to Achieve Global Covid-19 Vaccination by mid-2022](#). We are encouraged by the steps Moderna is taking towards expanding equitable access to its vaccines, such as prioritising COVAX contracts and low- and middle-income countries (LMICs) contracts following manufacturing delays, and facilitating the redirection of doses from high-income countries for distribution by COVAX.

Almost 40% of BioNTech's vaccines have been delivered to LMICs. We met with BioNTech's Chair of the Supervisory Board and the Chief Strategy Officer in January and discussed how it is

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

improving vaccine distribution in LMICs and advocated for the company to bring in greater diversity of talented professionals at a senior level to help with this mission.

We are also encouraged that both Moderna and BioNTech are developing manufacturing capabilities on the African continent to help improve access to current and future mRNA vaccines and treatments. This will be a major undertaking because vaccine production requires a significant long-term investment in distribution and infrastructure, the education, hiring and training of many people, and continual research and development. Baillie Gifford supports this long-term programme which will expand the biotechnology market in Africa, enable further independence of its pandemic preparedness capabilities, and ultimately improve health security across the continent.

Which measures have you taken to mitigate the risk and prevent harm?

We continue to engage with these companies on their approach to design, manufacture and distribute vaccines to help end the Covid-19 pandemic. In our meetings with Moderna, we have expressed support for the WHO's vaccine targets and reiterated that the company should continue working with relevant organisations to help achieve these. We have been assured that there will be more transparency and public announcements from Moderna about plans to expand vaccine access.

The current situation remains challenging and access to vaccines globally is an important goal. We continue to support companies in their efforts to achieve it. In the last year within our team, we have been joined by a former member of UNICEF. She has experience on the delivery of public health initiatives across LMICs at the strategic level. Her insight and experience are helping us to better engage with vaccine manufacturers and understand the challenges faced in making this happen more quickly. She is increasing our ability as investors to help guide companies, especially where we have significant ownership stakes.

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

With kind regards,






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 info@amnesty.org

 +44 (0)20 7413 5500

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MONEY CALLS THE SHOTS

PHARMA'S RESPONSE TO 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. In September 2021, Amnesty International published *A Double Dose of Inequality: Pharma companies and the covid-19 crisis*, which assessed the extent to which the pharmaceutical industry was restricting fair access to their life-saving Covid-19 vaccines.

This report updates that assessment of five leading vaccine manufacturers, AstraZeneca plc, BioNTech SE, Johnson & Johnson, Moderna Inc., and Pfizer Inc. It also includes for the first time an assessment of the two largest Chinese vaccine producers, China National Pharmaceutical Group Co., Ltd. (Sinopharm) and Sinovac Biotech Ltd. (Sinovac).

The report finds that access to Covid-19 vaccines remains skewed and that business decisions by vaccine developers are creating obstacles to states' ability to ensure fair access for all. All of the assessed vaccine developers are – to different degrees – failing to meet their human rights responsibilities. Regrettably, Covid-19 and the lack of accountability of pharmaceutical companies have exposed the gaps in our norms and standards to ensure that corporate actors meet their human rights responsibilities. Vaccine developers are monopolizing intellectual property and knowledge and some are supplying predominantly high-income countries putting economic interests before people.