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A Public Eye Report – March 2021

Big Pharma takes it all

How pharmaceutical corporations profiteer from their privileges – even in a global health crisis like COVID-19

Public Eye

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COVID-19, showcase of a perverted business model

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"No one is safe until everybody is safe", "leave no one behind" are mantras that have been oft repeated by state leaders and the World Health Organization (WHO) since the coronavirus pandemic turned our world upside down in spring, 2020. But today's reality is different: wealthier states with preferential access deals are already rolling out their vaccination campaigns while most middle- and low-income countries (LMICs) will have to wait months, if not years, to achieve herd immunity due to hoarding of the limited supplies of COVID-19 vaccines.

"More than 39 million doses of vaccine have now been administered in at least 49 higher-income countries. Just 25 doses have been given in one lowest-income country. Not 25 million; not 25 thousand; just 25." WHO's Director General Dr. Tedros at the 148th session of the Executive Board, 18.1.21[1]

This unequal and inequitable access is not the result of fate or insurmountable logistical challenges but of the opportunistic political choice of high-income countries (HICs), including Switzerland, to protect the current, monopoly-based business model of their pharmaceutical companies. This model curtails the options available to states to safeguard public health and protect the human right to health. It also leads to devastating economic and social consequences for individuals and communities. These impacts, while most devastating in LMICs, will also be felt in HICs if the pandemic cannot be controlled globally.

There was some hope early in the pandemic that the sudden onset of this global health crisis and the magnitude of demand for medical tools to combat the coronavirus would politically challenge the monopoly-driven business model, which is essentially a 'high-price, low-volume' approach. In an unusual move, HICs like Germany, France, Chile and Canada passed legislation to fast-track compulsory licensing procedures – even Israel issued one for the first time. World leaders called for future vac-

People relax after receiving their Pfizer-BioNTech vaccination at Salisbury Cathedral in Salisbury, England, in January 2021.

cines to be considered "global public goods". Governments adopted multilateral resolutions for universal, timely and equitable access to all COVID-19 health technologies, committing colossal amounts of public funding to accelerate their development and the scaling up of production. Even pharmaceutical companies issued reassuring statements promising unprecedented collaboration and committing themselves not to profiteer from this pandemic.

BUSINESS-AS-USUAL HAS PREVAILED

This report shows that most of these pledges have remained pure rhetoric. Big Pharma (see Box 1) has succeeded in preserving its sacrosanct intellectual property rights. These enable them to lock-up knowledge (even when it is the result of generous tax-payer money), decide on the scale of production (although it has been obvious since spring, 2020, that demand would outstrip supply) and set their own prices (even though public funds significantly de-risked the whole research endeavour). And they have done so with the full complicity of countries, such as Switzerland, that are home to large pharmaceutical companies.

Nowadays, many actors are vocal about the slow pace of the vaccination campaigns in Switzerland and other European countries. But this is the result of the political choice to keep their hands off corporate monopolies. HIC governments have chosen scarcity over sufficient supply. They have handed over the keys, no-strings attached, to big pharmaceutical firms with a long track-record of prioritising profit above people and public health. Patents, trade secrets and other exclusive rights are decisively limiting possibilities to manufacture at scale and enable excessive prices. HIC governments have caved in to the toxic combination of corporate and public pressure, and repeated mistakes of the past, for example the 2009 H1N1 influenza pandemic (swine flu). Nationalism, not solidarity, has prevailed and resulted in hoarding of vaccines and treatments. By refusing to share their exclusive rights and know-how, pharmaceutical firms have fuelled vaccine nationalism by instigating an atmosphere of scarcity.

According to recent estimates (1 March, 2021),[4] high-income (and some middle-income) countries have already snatched up more than 8.2 billion doses. Together with another 6.5 billion optional doses, total pre-orders amount to some 15 billion doses. This is more than all of the doses that leading vaccine manufacturers – i.e. those that already have a market approval or are in the last testing phase with a possibility to obtain it soon, including from China and Russia – said they could produce in 2021, based on their most optimistic manufacturing targets.[5] Many HICs have purchased enough to vaccinate their entire populations several times over (UK, Canada, USA, EU, Switzerland). Those MICs with manufacturing and/or clinical testing capacity (Brazil, India, South Africa) have also secured some direct deals, although not enough to cover their needs. However, low-income countries have been simply left out. They will have to rely on a global mechanism called COVAX for "Western" vaccines, which was established to provide poorer countries with vaccines for 20% of their population – if there are any doses left and if COVAX receives the necessary funds from member states to operate. Or they will have to rely on Chinese and Russian vaccine diplomacy.

Box 1

BIG PHARMA

Big Pharma is used as a term to denote large multinational pharmaceutical companies that constitute together a business group with powerful economic, political and social influence.[2] Smaller biotech companies play a crucial role in developing new health technologies. Often, Big Pharma does not itself engage in the lengthy and sometimes risky investments in developing such technologies, but simply buys smaller companies or their technologies, including the intellectual property rights, when they are ready to be manufactured and marketed at large and profitable scale.[3] This pattern has also been observed in the current pandemic, although more in the form of manufacturing partnerships in which Big Pharma has imposed its intellectual property policies.

Box 2

METHODOLOGY

This study is based on Public Eye's long-standing expertise in the pharmaceutical sector as well as published evidence gathered from a vast and rigorous selection of scientific articles, blogs, media reports, open letters, and press statements originating from many different actors published since January 2020 – in total some 2,700 publications. We are also grateful for the discussions and shared information with international civil society organisations advocating for access to medicines and the right to health.

Box 3

RESEARCH STATEMENT

Public Eye defends the human right to health and advocates for equal access to health care worldwide. It takes a critical look at the behaviour of pharmaceutical companies and holds governments accountable for their obligation to protect the human right to health. Access to essential medicines, including vaccines as a recognised public health instrument, is an integral part of the human right to health.[13] Equal access means that governments and citizens everywhere should have a choice about whether and which diagnostics, vaccines and treatments they wish to use. To have this choice, health technologies must be available and affordable.

PUBLIC FUNDING HAS BEEN ESSENTIAL

By choosing not to leverage the estimated €93 billion in government subsidies to *"drive the development of critical health technologies as global health commons"*,[6] HICs have wasted this historical opportunity to force the pharmaceutical industry to openly share their intellectual property and technical know-how. Worse still, Big Pharma and its host countries have opposed all political moves to fundamentally question the 'business-as-usual' approach, even though its well-known deficiencies have been amplified by this pandemic.

Making vaccines available less than one year after the start of the pandemic is undoubtedly a remarkable achievement. As a result, pharmaceutical companies are benefiting from a *"shot of redemption"*[7] and are hailed by some as saviours. But let us not forget that public funding has been essential to de-risking this existential endeavour. Public funding has covered large parts of the research and development (R&D) costs, increased manufacturing capacity and enabled advance market commitments. It has even discharged manufacturers from liability in the case of adverse events following market approval. Although considered less lucrative than the pricier longer-term treatments for chronic diseases like cancer, Big Pharma can nevertheless expect juicy profits for their COVID-19 vaccines. Market analysts have projected that the top five players are likely to divvy up about US$38.5 billion in sales, with the first-to-market companies reaping more than half of that.[8] Although sales volumes may decrease in future, the potential need (as it stands) for regular boosters and the post-pandemic reversion of currently non-profit to for-profit vaccines means that the market could still be worth well over US$10 billion a year.[9] Pfizer's expected revenue in 2021 will surpass its bestseller to-date, the pneumonia vaccine Prevnar13.[10] Moderna, virtually unknown 12 months ago, has seen its shares skyrocket by nearly 700 % in 2020 and is expected to rake in US$13.2 billion in COVID-19 vaccine revenue in 2021 alone – a staggering increase on the US$60 million it generated in sales in 2019.[11]

So are they vaccine heroes or profiteers? This report aims to show that, during this global health crisis of unprecedented scale, pharmaceutical companies have relied on many features of their traditional business model to game the system and maximise their profits, despite their public pledge not to do so.

At the beginning of the race to secure bilateral deals in June, 2020, the French newspaper Le Monde commented presciently, *"Pharma companies are selling promises, States are buying hope"*.[12] We need to update this to, *"Pharmaceutical companies and their host countries played their usual game – and people in LMICs are paying the price"*.

Box 4

GLOBAL MECHANISMS

COVID-19 Technology Access Pool (C-TAP): a voluntary pool in which intellectual property, know-how and other undisclosed data for COVID-19 health tools is shared for free or licensed on reasonable and affordable terms. Proposed by Costa Rica and launched by WHO, in partnership with the Government of Costa Rica and 40 member state co-sponsors, together with the Solidarity Call to Action in May 2020.[14]

The Access to COVID-19 Tools (ACT) Accelerator: brings together governments, scientists, businesses, civil society, philanthropists and global health organizations (the Bill & Melinda Gates Foundation, CEPI, FIND, Gavi, the Global Fund, Unitaid, Wellcome Trust, the WHO, and the World Bank), and is organized into four pillars of work: diagnostics, treatment, vaccines and strengthening of health systems. Launched at the end of April 2020.[15]

COVAX: the vaccine pillar of the ACT Accelerator. Launched by WHO, CEPI and GAVI in April 2020 for research into an effective vaccine for all countries. It supports the building of manufacturing capabilities and buying supply so that 2 billion doses can be fairly distributed by the end of 2021.[16]

Gavi Alliance (formerly the Global Alliance for Vaccines and Immunisation): a global health partnership of WHO, UNICEF, the World Bank and the Bill & Melinda Gates Foundation with donations from governments, private sector foundations and corporate partners.[17]

CEPI – Coalition for Epidemic Preparedness Innovations: founded in Davos by the governments of Norway and India, the Bill & Melinda Gates Foundation, Wellcome Trust, and the World Economic Forum to finance and coordinate the development of new vaccines for infectious disease epidemics. Accepts donations from public, private, philanthropic, and civil society organisations.[18]

2

Big Pharma's 10 strategies for cashing in

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In the pharmaceutical industry, patents and other exclusive rights are used by transnational corporations to impose and sustain their technological domination and to drive profits.[19] When profit-margin maximisation drives innovation, prices are pushed up, which leads to a two-tier medical system that excludes those who cannot afford to pay for new treatments. It also means that many essential medicines are never developed in the first place.[20]

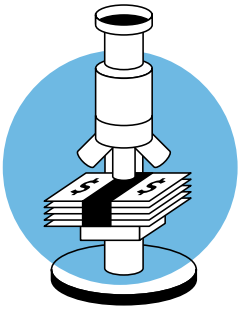
"The system is broken. (...) Patent and intellectual property exclusivities are the only cornerstone of the current model. Companies can ask the price they like. This will no longer do. We need to develop alternative business models." Edith Schippers (Dutch Minister of Health) and Liliane Ploumen (Dutch Minister for Foreign Trade and Development Cooperation) in The Lancet, November 2016[21]

Big Pharma's current business model relies on intellectual property rights (IPR) to secure market monopolies. These monopolies go far beyond allowing pharma companies to recoup their investments; they enable companies to make huge profits because they confer incredible market power that can potentially push medicine prices to exorbitant levels – well beyond the bar of US$100,000 per year for a cancer drug, even going as high as US$2 million for a single treatment.[22] The pharmaceutical industry is one of the most profitable across all sectors, expected to be worth US$1.4 trillion by the end of 2020.[23]

Pharmaceutical R&D is thus driven by corporate interests, not by health outcomes. This has created a system of excessive financial rewards to patent holders – mostly large pharmaceutical companies – while creating huge costs to society. The coronavirus crisis has acted as a magnifying lens and brought the inherent deficiencies of this business model into sharp focus. More than ever, this pandemic necessitates alternative models that reconcile technical innovation and equitable access.

In this report, we will present the 10 strategies, already highly effective prior to the pandemic, that have led to the scandalous response and inequities in terms of availability and access to COVID-19 pharmaceutical tools.

2.1 – DETERMINE R&D PRIORITIES BY POTENTIAL PROFITS ALONE



▶ **FACT(S)** In 2003, we witnessed the Severe Acute Respiratory Syndrom (SARS) global health crisis, caused by a coronavirus very similar to COVID-19. When the present pandemic hit, 17 years later, there was still still neither a vaccine vaccine prototype nor any treatment candidate ready to handle COVID-19.

▶ **EXPLANATION** In the current system, pharmaceutical companies determine their research & development (R&D) priorities by potential profit rather than public health needs.[24] Following this logic of profit-maximisation, Big Pharma develops drugs primarily for those who can pay, predominantly in HICs, rather than for neglected populations predominantly in LMICs.[25] In addition, drugs for chronic diseases, such as cancer or diabetes, that can be prescribed repeatedly and over long periods of time are far more profitable than antibiotics or vaccines against infectious diseases.[26]

▶ **CONSEQUENCE(S)** Until recently, there were increasingly fewer companies engaged in low-profit products such as vaccines. The global COVID-19 pandemic has suddenly presented them with potentially enormous profits.

"In a business driven by profit, vaccines have a problem. They're not very profitable — at least not without government subsidies. (...) In many parts of the world, established vaccines cost a few dollars per dose or less" Jay Hancock, Kaiser Health News[27]

Before COVID-19, the vaccine business was divided between four major players: Pfizer, Sanofi, GlaxoSmithKline (GSK), and Merck. None of these heavyweights showed much interest at the start of the pandemic, although all had the means to take up the COVID-19 challenge. Observers described *"an atmosphere of extreme reluctance"*[28] among the biggest pharma groups in the early weeks.

Their change of mind coincided with the commitment of billions of dollars of government money. *"While the commercial calculation to join the vaccine race was different for different companies, experts said two factors fundamentally heightened the allure: the sheer size of the pandemic and the unprecedented levels of public funding".*[29] In mid-March 2020, Big Pharma entered the race for the vaccine, mostly through partnerships with smaller biotech companies that were leading the way.

Swiss pharmaceutical giants were noticeable by their absence. At the front line during the H1N1 influenza (swine flu) pandemic, Novartis had since got out of the unprofitable vaccine business. Roche, one of the global top five pharmaceutical companies and a world leader in diagnostics, had never been in the vaccine business. The two companies placed their bets on repurposing some of their older immune-modulating drugs to reduce complications in serious COVID-19 cases, which all failed in successive clinical trials (with the possible exception of Roche's Actemra, see Box 15 p. 35). In early 2021, however, Novartis sold its remaining vaccine production plant in Marburg (Germany) and announced an agreement with BioNTech to contribute with manufacturing capacities.

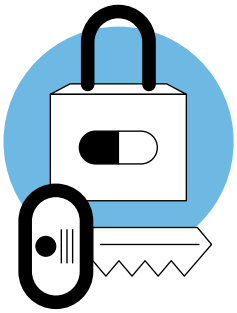
Could the pharma industry have done differently? Absolutely. The coronavirus was already on the public health authority radar. A vaccine prototype to protect against the SARS coronavirus strain had been developed in 2016 at the University of Texas, but no pharmaceutical company showed interest in funding the conclusion of the full set of clinical trials.[30] The Oxford University's Jenner Institute had also failed to secure funding to continue its work on a vaccine against the MERS (Middle-East Respiratory Syndrome), caused by a coronavirus with many similarities to that of COVID-19.[31] Despite the US National Institutes of Health outlay of nearly US$700 million on coronavirus R&D following the SARS outbreak, there were only 6 active coronavirus clinical trials in 2019 involving larger pharmaceutical companies.[32] The outlook was apparently not profitable enough. For the same reason, in 2017, the European Federation of Pharmaceutical Industries (EFPIA) rejected a European Commission proposal for a fully sponsored project with the pharmaceutical industry to fast-track vaccines against coronavirus.[33]

Just as the pharmaceutical industry depends on publicly-funded research to develop its commercial products, so the reverse is true in the current ecosystem: academic R&D efforts or projects led by start-up companies have little chance of

reaching the finish line without larger pharmaceutical firms bank-rolling the demanding regulatory requirements such as large clinical trials. Big Pharma is perfectly aware of this; its strategy is to wait until the bids and potential profits are high enough to get involved.

The efforts and pace at which COVID-19 vaccines have been developed are positive, and show that when there is a corporate will, there is a way. However, the highly competitive race for COVID-19 vaccines started only once billions in public funding was thrown at the sector. The structural problem remains that Big Pharma determines its R&D priorities based on potential profits. This endangers public health by leaving the world ill-prepared to face future pandemics, fight antibiotic resistance and develop effective treatments for neglected tropical diseases.

2.2 – ABUSE PATENTS TO LOCK UP KNOWLEDGE, INFLATE PRICES AND LIMIT SUPPLY



▶**FACT(S)** By spring 2020, it was already obvious that limits to the capacity to produce patented vaccines would create significant bottlenecks in supplying all countries in need. However, despite warnings from public health experts and massive subsidies, HICs deemed pharma monopolies as politically inviolable, leading to global scarcity, panic hoarding and the inequitable global distribution of COVID-19 vaccines.

▶**EXPLANATION** Governments grant patents for inventions that are novel, non-obvious and useful. The patent should compensate individuals or companies for the investment required to develop the invention while also benefitting society. Patent holders can prevent others from making, using, importing, or selling their invention. Other exclusive rights, such as trade secrets (know-how) and data protection, also prevent others from making or using the invention. All of these intellectual property rights (IPR) are enshrined in the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), adopted in 1995.

In terms of public health, this system has resulted in the gradual globalisation of flawed and socially unsustainable incentives that leave unprofitable health needs unmet.[34] It also creates huge challenges to accessing existing treatments because pharmaceutical companies abuse their monopoly power to price drugs at a level many people cannot afford. This is particularly disastrous in LMICs, where people pay out-of-pocket rather than through insurances or social security.[35] But HICs are also increasingly

There is an overwhelming demand for medical tools in a global pandemic. No single company, no matter how large, is able to meet it. In April 2020, Johnson & Johnson, GlaxoSmithKline (GSK), and Sanofi admitted that they do not have sufficient manufacturing capacity should their vaccines be approved.[40] *"Let's say the GSK-Sanofi approach succeeds, that alone will not be enough to supply 20 % of the world's population within one year. Several of the large-scale solutions have to come into play if we want to cater for the world's population over a period of one to two years. One company alone is not enough".*[41] In June, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) estimated a global capacity to manufacture vaccines of 5 billion doses[42] – a figure recently confirmed by IFPMA's director Thomas Cueni.[43] If all countries want to provide vaccines for their population, at least 15 billion doses will be needed, as each vaccination generally requires two doses.

Patents and other exclusive rights were immediately and widely recognized as fundamental barriers when the pandemic erupted. Already in March 2020, some HICs were either directly defying the patent monopolies of potential COVID-19 medicines (e.g. Israel[44]) or passing legislation to fast-track compulsory licensing procedures (e.g. Germany,[45] France,[46] Canada[47] or Chile[48]) to avoid supply shortages and/or unaffordable prices. The former US President even invoked a wartime law to force private companies to ramp up manufacturing of medical supplies to stem the pandemic,[49] a move that is also now being considered by President Biden for COVID-19 tests and vaccines.[50]

These political moves by HICs were also backed by influential pro-business media, such as the Financial Times.[51] Previously unthinkable and considered as "hostile", such bold actions suddenly gained support. The former head of intellectual property (IP) of Swiss giant Novartis, Paul Fehlner, stated that *"creating a global platform for governments, funders, companies, and re-*

struggling because of the great strain that overpriced medicines place on their national health budgets,[36] which has led to rationing decisions.[37] Through patent monopolies, Big Pharma can block generic competition and scaling-up of global supplies for at least 20 years.

▶**CONSEQUENCE(S)** In a situation of desperation, where governments are stock piling COVID-19-vaccines, Big Pharma's strategy of keeping their know-how locked up has created supply shortages that have enabled them to set the price they want. It also imposes discriminatory access on LMICs.

"The world has an overwhelming interest in ensuring drugs and vaccines will be universally and cheaply available. Fortunately, trade rules allow compulsory licensing. If necessary, it must be used." Editorial team, The Financial Times, 27.3.20[38]

"For too long, we have bought into the myth that today's IP regime is necessary. The proven success of GISRS [WHO's flu virus sharing system] and other applications of 'open science' shows that it is not. With the COVID-19 death toll rising, we should question the wisdom and morality of a system that silently condemns millions of human beings to suffering and death every year." Joseph Stiglitz, Arjun Jayadev & Achal Prabhala, Project Syndicate, 23.4.2020[39]

searchers to build collective intelligence and equitably share the risks and rewards in innovation is the right thing to do for every stakeholder involved."[52]

The pharmaceutical industry itself has continued to repeat that IP, in particular patents, are not an issue in this pandemic. Albert Bourla, CEO of Pfizer, recently defined IP as *"the blood of the private sector"* and added that *"it is not a barrier right now"*.[53] Thomas Cueni, director of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), claimed that *"a focus on vaccine patents is misplaced since know-how is the larger issue"*,[54] implying that patents do not hinder availability and access. Various examples of past litigations over vaccine patents[55] as well as their chilling effect on the introduction of affordable vaccines in LMICs[56] prove the opposite.

BIG PHARMA REFUSES TO SHARE KNOW-HOW

Many parallels have been drawn between the HIV crisis and the current COVID-19 pandemic in terms of how patents block access. The pandemic *"tragically echoes the early days of the AIDS response when treatment was only available to the rich while poorer countries had to wait years before they could offer their people the same life-saving medicine"*.[57] The HIV/AIDS crisis taught us what happens when the benefits of scientific progress are withheld from the most vulnerable.[58] Fatima Hassan, a South African human rights lawyer, remembered the outrageous episode of 39 pharma corporations suing her government when it used legal alternatives to patented HIV drugs that were out-of-reach.[59] She immediately connected the dots when she saw who was working on COVID-19 vaccines: *"It's the same pharmaceutical companies* [that were working on HIV treatments]. *We have been here before. You could already see what was going to happen in terms of equity and global access"*.[60]

Despite their repeated denials, Big Pharma's secretive and profit-driven model is indeed creating barriers to the development and dissemination of COVID-19 treatments and vaccines. When the COVID-19 Technology Access Pool (or C-TAP) was launched by WHO and Costa Rica at the end of May,[61] Big Pharma immediately dismissed it (see Box 12 p. 23). They preferred to support a global initiative launched one month earlier, sponsored by the Bill and Melinda Gates Foundation, called the Access to COVID-19 Tools Accelerator (or ACT-A),[62] which deliberately ignored the elephant in the room: intellectual property. ACT-A paved the way for a "market-based solution" that did nothing to challenge the sacrosanct monopolies of the pharmaceutical industry. HICs proclaimed it as the best option for LMICs to access COVID-19 health tools – the opinion of LMICs on this matter, however, has never been sought.

Since pharmaceutical companies have refused to voluntarily share their IP and know-how through C-TAP, India and South Africa are now pushing for a temporary TRIPS waiver for COVID-19 medical tools (see Box 16 p. 36). Switzerland and most HICs oppose this initiative. The WTO debates have clearly shown the negative impact of intellectual property on access to COVID-19 health tools,[63] with concrete examples of IP acting as a barrier during this pandemic.[64]

Today's outlook is bleak: monopolies are leading to the artificial rationing of supplies and the unequal distribution of

COVID-19 technologies, COVAX is threatening to fail (see Box 7 p. 14) and politicians in HICs are complaining that the delivery of vaccines is too slow. Both Pfizer[65] and Moderna[66] are embroiled in patent litigations over the technology they rely on for their COVID-19 vaccines. More than 100 patents have been filed for the messenger RNA (mRNA) technology.[67] Many promising COVID-19 treatments are patented and incredibly expensive, and access to diagnostic tests is limited due to monopolies. Intellectual property lawyers think that the biggest disputes over patents have yet to start and will only fully emerge after the COVID-19 crisis.[68] The longer-term impacts of COVID-related patents are thus yet to be felt.

Box 5

OXFORD UNIVERSITY/ASTRAZENECA VACCINE: HOW BIG PHARMA TURNED AN OPEN LICENSING POLICY INTO A MONOPOLY

The University of Oxford's Jenner Institute (UK) is one of the largest academic centres dedicated to non-profit vaccine research, working for decades against a range of diseases. When the current pandemic broke out, they were able to quickly develop a vaccine candidate against COVID-19, and intended to make its recipe available to all (open licensing).[69]

With a limited production capacity, the institute was pushed by their long-time donor, the Bill and Melinda Gates Foundation, to look for a partner for global manufacturing and distribution. In April 2020, the Institute struck a deal with the Anglo-Swedish pharma giant AstraZeneca.[70] However, it came at a price: the IP policy of Oxford University during the pandemic, initially based on open (non-exclusive), royalty-free licensing *"to support free of charge, at-cost or cost + limited margin supply as appropriate",*[71] was turned into an exclusive one.

The deal gave AstraZeneca the sole rights to decide which producer to work with, despite receiving more than US$1 billion in public and philanthropic funding for Oxford's promising vaccine. Following the exclusive deal, AstraZeneca pledged it would sell vaccines at no-profit, but only during the pandemic. However, a contract with Fiocruz, a Brazilian public health institution – one of the rare ones that has been published[72]– showed that AstraZeneca can alone decide when the pandemic is over and has already set this horizon at July 2021.[73]

Oxford University's decision to end its open-license policy after being urged by the Gates Foundation to find a manufacturing and distribution partner[74] is, according to civil society observers, *"the most concrete example of the consequences of the Gates Foundation approach to intellectual property."*[75] Given its financial stake in several companies working on vaccines,[76] the Gates Foundation faces other, similar conflicts of interest. This is just one among many factors reinforcing systemic problems raised by COVID-19.

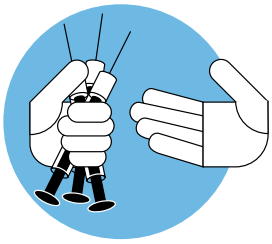
Box 6

INTELLECTUAL PROPERTY RESTRICTS ACCESS TO COVID-19 TREATMENTS AND DIAGNOSTICS

Many treatments, such as Roche's Actemra[77] or Gilead's Remdesivir[78] (see Chapter 2.8), are patented with high price tags, which considerably limits their access. Regeneron's and Eli Lilly's monoclonal antibodies, seen by many professionals as promising COVID-19 treatments, are not only patented and incredibly expensive (see 2.8), but their manufacturing capacity is also very limited.[79] When hydroxychloroquine, an older drug whose primary patents had long expired, was still seen as a potential treatment for COVID-19 patients, Novartis, one of several producers, said in a press release that it *"will also make its hydroxychloroquine intellectual property available to support broad access if medicine is approved for COVID-19".*[80] Legal experts believe the Swiss company has sought patents for second medical use,[81] a controversial practice not universally accepted for a new method of treatment that has detrimental effect on competition – even for a 60 year-old drug.[82]

Intellectual property has also restricted access to diagnostic tests, as seen in March 2020 in the Netherlands. Dutch labs depended heavily on Roche test kits (80 % of the market), but the Swiss pharma giant was only able to supply 30 % of the outstanding orders. One reagent was in particular shortage, preventing the country from carrying out mass testing as recommended by the WHO. Labs could have produced the substance themselves to run more tests if they had had access to its formula, but Roche denied there were shortages and refused to share the recipe.[83] This position prompted a public outcry and a preliminary investigation at both national and EU level by competition authorities for abuse of dominant position. Under mounting pressure, Roche finally released its recipe.[84]

2.3 – DIRECT THE SYSTEM TOWARDS THE NEEDS OF HIGH-INCOME COUNTRIES



▶ **FACT(S)** COVID-19 vaccines and treatments are expensive. As usual, Big Pharma favoured HICs in this pandemic to secure bilateral pre-order deals at excessive prices, as they did during the H1N1 (swine flu) crisis, even though this results in public budgets being squeezed.

▶ **EXPLANATION** Medicines are developed first and foremost to meet prevailing health problems in HICs because prices can be significantly marked up[85] and because the largest pharmaceutical companies are located in a few HICs – USA, Switzerland, EU, Japan – and China.[86] The largest pharmaceutical market is the US with more than US$500 billion in sales in 2019, followed by China, Japan, Germany and France.[87] Simultaneously, medicines for infectious and tropical diseases that predominantly affect people in LMICs are neglected.[88]

▶ **THE RESULT** As at the end of January, only 4 % of the 108 million people vaccinated lived in LMICs, the vast majority in India.[89] Almost 130 countries with a combined population of 2.5 billion were yet to administer any vaccine.[90] HICs, including Switzerland, have bought enough doses to vaccinate their population several times over, while many LMICs may have to wait until 2024 to reach herd immunity. Unfortunately, COVAX, the multilateral scheme aimed at an equal distribution, is likely to fail due to HIC lack of solidarity and Big Pharma monopolies.

"The [COVAX] model of donation and philanthropic expediency cannot solve the disconnect between the monopolistic model it underwrites and the very real desire of developing and least developed countries to produce for themselves. Madam Chair, the problem with philanthropy is that it cannot buy equality." South Africa's intervention at the formal TRIPS Council meeting of 23 February 2021[91]

Despite initial commitments to handle the pandemic in solidarity, as a global health concern, there was an avalanche of bilateral pre-order deals: 44 in 2020 and over a dozen so far in 2021[92] (see details in the table p. 14). In September 2020, Oxfam reported that wealthy nations representing just 13 % of the world's population had already cornered more than half of the promised vaccine doses.[93]

COUNTRIES DO NOT SUFFICIENTLY TRUST COVAX

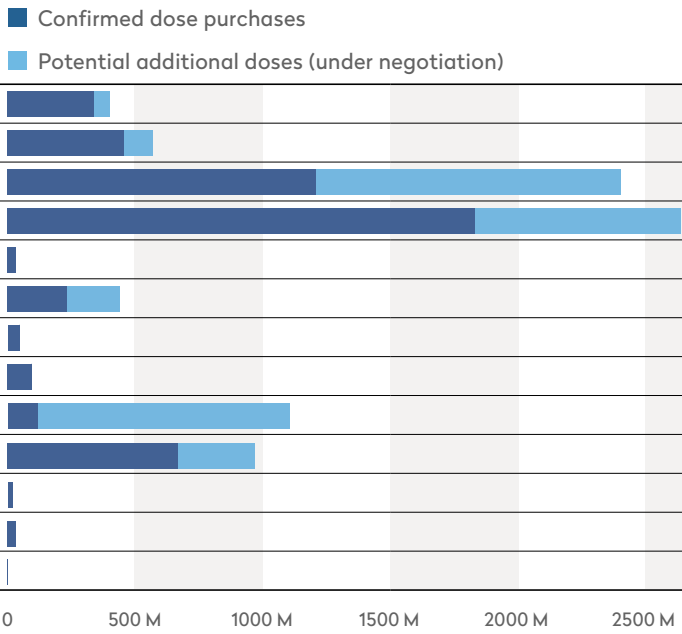
Later analysis shows an even bleaker picture, with HICs (and some MICs) snatching up almost 15 billion doses.[94] This is more than all of the doses that leading vaccine manufacturers said they could produce in 2021, based on their most optimistic manufacturing targets.[95] Several HICs purchased enough to vaccinate their entire populations several times over, with Canada, USA and the UK leading the pack. Some LMICs that were supposed to benefit from COVAX, such as the African Union,[96] Malaysia, Peru, and Bangladesh,[97] also started to secure bilateral vaccine deals as a Plan B, suggesting that no country sufficiently trusts COVAX to deliver the promised doses on time. Those that have the financial means are following the bilateral route blazed by HICs, and LMICs are being left behind.

AN UGLY RACE OF FAVOURITISM

This pandemic has once again highlighted that the whole trade system is directed towards the needs of HICs, where the largest profits can be made. According to a report from UNCTAD, per capita imports of medical goods essential to mitigate the COVID-19 pandemic have been about 100 times larger in HICs than LICs.[98] Although domestic political pressure played a key role in the frenzied bilateral deal-making by HICs, reminiscent of the 2009 stockpiling of vaccines and antivirals during the H1N1 Influenza (swine flu) pandemic, the dynamic has been undoubtedly fuelled by the pharma industry.

In the initial weeks of the pandemic, there was some hope for a new approach, with state leaders calling for vaccines to be considered *"global public goods"*. However, several informed observers predicted that the race for COVID-19 treatments and vaccines would become ugly if monopolies remained in place. Sadly, this has come true; concerns about scarcity emerged as it became clear that demand would outpace supply, at least while Big Pharma retained complete control over supply. Despite the pandemic being global, Big Pharma has fought hard to maintain its HIC-centric strategy by relying on the web of other strategies it has honed over the years, including secretly negotiating treatment supplies and prices, and utilising long-established channels of communication and lobbying with HIC governments.

TABLE 1 – COVID-19 VACCINE ADVANCE MARKET COMMITMENTS AND COVERAGE BY POPULATION



	Total number of doses reserved (confirmed + optional)	Vaccination coverage by population (2 doses/person)
Canada	402,000,000	585 %
UK	569,000,000	465 %
USA	2,410,000,000	413 %
EU	2,825,000,000	360 %
Switzerland	32,800,000	190 %
Brazil	442,000,000	105 %
Argentina	47,750,000	53 %
Egypt	95,000,000	47 %
India	1,200,000,000	41 %
African Union	970,000,000	40 %
Ukraine	18,200,000	21 %
Bangladesh	33,000,000	10 %
South Africa	1,500,000	1 %

Source: Duke University – except for Switzerland (Federal Council and Federal Statistical Office)

Box 7

COVAX IS FAILING BECAUSE OF FALSE PREMISES AND SELFISHNESS

WHO's Director General Dr. Tedros told a high-level U.N. General Assembly meeting on COVID-19 in early December that the cash-strapped global vaccine distribution mechanism COVAX *"is in danger of becoming no more than a noble gesture".*[99] An internal report to the board of GAVI, the public-private partnership in charge of the scheme, confirmed that *"the risk of a failure to establish a successful COVAX Facility is very high",* potentially *"leaving people in poor nations without any access to COVID-19 vaccines until 2024".*[100] WHO also reiterated strong criticisms against vaccine nationalism, calling on countries to *"stop cutting the vaccines queue".*[101]

By multiplying bilateral orders, HICs have side-lined multilateralism and global mechanisms like COVAX. The main goal of Operation Warp Speed was to protect the United States, a government official said, adding it was modelled on the logic of airplane oxygen failure: America will help itself first before helping others.[102] Other HICs were doing the same. Despite co-chairing a group called 'Friends of the [COVAX] Facility' to promote a multilateral approach,[103] Switzerland's officials soon cast doubts over COVAX's chances of success while securing its first deal with Moderna: *"We have to assume that a fair distribution of the vaccines won't be possible".*[104] COVAX has been used by HICs to pretend they care about a multilateral solution for equal distribution, while their priority was to cover their own needs first.

But the 'me-first' mentality of HICs is not the only reason for the likely failure of COVAX. It is designed on the false premise of a *"marriage of markets and philanthropy that will bring vaccines to everyone in the world",*[105] without addressing the entrenched reality of corporate monopolies which limit supply, drive prices up and allow Big Pharma to decide who gets the vaccines first.

COVAX also has a governance issue: its lack of transparency and representation have been repeatedly criticised by civil society.[106] It strived to make itself attractive to richer nations, resulting in a two-tiered system in which HICs will have many more options and privileges than LMICs, which were never involved in decision-making.[107] *"The WHO has outsourced its role in vaccine access and side-lined member states by leaving the running of the COVAX vaccine procurement facility to public-private partnership".*[108]

Box 8

HICs' FAÇADE OF SOLIDARITY

At the initial stages of the COVID-19 crisis, between March and May 2020, the buzz word among WHO member states was 'solidarity' – at least in appearance. In a bid to politically counter the 'America first' approach, the EU block were unanimously calling for a global solution to ensure equitable access to COVID-19 medical tools.

Trump's attempt to buy up the exclusive rights to a COVID-19 vaccine from German biotech firm CureVac in mid-March prompted an angry political reaction from Berlin.[109] Another political firestorm erupted when the CEO of French pharma giant Sanofi announced mid-May that its vaccine, if successful, would go first to Americans since the US government had paid much more for the research.[110] President Macron intervened, with his prime minister saying that *"a vaccine against COVID-19 should be a global public good. Equal access for all to vaccines is not negotiable".*[111]

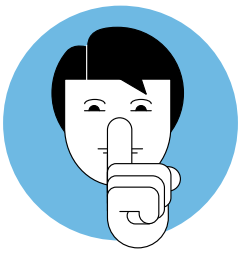
A few weeks earlier, the EU had spearheaded the launch of the Access to COVID-19 Tools Accelerator (ACT-A),[112] with many world leaders pledging to consider vaccines as *"our universal common good"*[113] and to share them equitably around the globe.[114] The USA and China, as well as Switzerland, were absent from the launch event. This orchestrated move was shortly followed by a series of telethon-like global fundraising events organised by the EU which ultimately raised a total of some €16 billion[115] – €10 billion for the development of COVID-19 medical tools alone – a political response to the US Operation Warp Speed.

During the same period, the EU also sponsored a resolution calling on WHO member states to ensure equitable access to COVID-19 treatments and vaccines, which included provisions for the creation of a voluntary pool for sharing patent rights, regulatory test data and know-how. This resolution was adopted by the World Health Assembly on 19 May 2020,[116] although it had been watered down during the marathon negotiations.[117] The USA,[118] and Switzerland,[119] pushed back against references to 'global public good', the so-called TRIPS flexibilities to override patent monopolies, and to WHO taking a lead in the voluntary pool mechanism.[120]

The EU façade of solidarity started crumbling in June, when Germany, France, Italy and the Netherlands decided to create the Inclusive Vaccine Alliance (IVA) to jointly negotiate with several pharmaceutical companies leading the vaccine race to secure future doses.[121] Ironically, they did so on the eve of a major pledging event held by GAVI to secure funding for COVAX.[122] The IVA rallied the Commission-driven joint procurement initiative, established under the new *EU strategy for COVID-19 vaccines,* to secure advance purchase deals with up to 6 potential vaccine makers.[123] Although the strategy insists that the EU will continue to *"play its part in ensuring global access to the vaccine, irrespective of wealth",*[124] the move signalled that the EU was betting more on bilateral deals than on a multilateral scheme to secure its jabs, putting a further nail in COVAX's coffin. Recent media reports showed that, at approximately the same time, Switzerland also started to negotiate directly with pharmaceutical companies.[125]

WHO Director-General Dr Tedros during the closing session of the World Health Assembly in Geneva in May 2020.

2.4 – AVOID PUBLIC ACCOUNTABILITY



▶**FACT(S)** Secrecy is another cornerstone of today's pharmaceutical business model. Reaping financial benefits while avoiding public accountability allows them to systematically squeeze health systems and maximise corporate profits.

▶**EXPLANATION** The lack of regulation around transparency has created a huge power imbalance between payers, such as governments and health insurers, and Big Pharma. The ramifications of this opacity are felt in three ways. Firstly, price setting and the rebates granted by pharmaceutical companies remain secret, which strengthens their bargaining power at the expense of payers, who have no accurate information for comparisons.[126] [127] Secondly, public funding contributions to the innovation of medicines[128] remain unaccounted for, and, according to independent sources, pharmaceutical companies hugely inflate their R&D cost estimates to justify their high prices.[129] Thirdly, conducting an independent analysis of clinical studies is impossible as up to 50 % of those completed are never published.[130]

▶**CONSEQUENCE(S)** Data transparency in clinical research and R&D costs has always been extremely important. But the absence of transparency in a pandemic of this size has unprecedented implications. At a time when the world is focused on tracking progress in finding a treatment and vaccine for COVID-19, it is more essential than ever to lift the veil of secrecy.

"States should ensure that businesses benefiting from State assistance respect human rights and are committed to transparency and accountability." Joint statement of UN Special Rapporteurs and human rights experts, November 2020[131]

"The Assembly urges member States and the European Union to communicate transparently the contents of contracts with vaccine producers and make them publicly available for parliamentary and public scrutiny." Parliamentary Assembly of the Council of Europe, Resolution 2361 (2021), January 21[132]

While opacity in the traditionally highly secretive pharmaceutical sector is unsurprising, governments have bowed even lower to corporate power in the COVID-19 crisis. They have failed to uphold their commitments to transparency and good governance, leaving even their parliaments in the dark. Nor have they leveraged public funding to demand accessibility and affordability clauses or transparency conditions, despite early calls to do so from civil society organisations, including Public Eye.[133] Members of the European Parliament requested that the EU investment be leveraged to demand transparency in the research and development pipeline.[134] Governments could and should have demanded greater transparency and lower prices.[135]

On the contrary, states have agreed to sign confidentiality agreements with Big Pharma over their bilateral procurement contracts. While non-disclosure clauses were common with treatment prices before COVID-19 (e.g. for cancer medicines with secret rebates), the combination of supply scarcities and domestic political pressures appear to have led to even greater secrecy than usual. In this pandemic, the traditional 'pricing power' of pharmaceutical companies has been reinforced by their ever-expanding 'opacity power'.

Bilateral contracts between governments and manufacturers are completely sealed from the public, even though the transaction is paid from the public purse. On the few occasions they have been released, as a result of Freedom of Information (FOI) requests in the USA or because of mounting political pressure in the EU, they had been significantly redacted (see Box 9). But a democratic government needs to be fully accountable to its citizens on what it bets and how it spends tax payers' money. Using public funds without reporting on terms and conditions undermines the human rights principles of transparency and accountability.[136]

Shareholders of six pharma companies leading the COVID-19 race sent them requests for reports detailing *"whether and how [the company's] receipt of public financial support for development and manufacture of preventives and/or therapeutics for COVID-19 is being, or will be, taken into account when making decisions that affect access to such products, such as setting prices"*.[137] Even the US Chamber of Commerce, the leading voice of corporate power in Washington, has called for more transparency on the recent vaccine deals.[138]

The results of treatment and vaccine clinical trials were made public through press releases or via so called pre-print publications before being peer-reviewed, an unusual scientific practice that sets a bad precedent: essentially, companies were *"outsourcing peer review to practicing physicians and journalists"*[139] and *"health professionals and the public are left second-guessing the reported results"*.[140] According to the Financial Times, about half of all available research on COVID-19 published by May had not been pre-approved by other academics. By September, the percentage of pre-print publications was still about five times higher

for COVID-19 (17 %) than for the overall biomedical research published in 2020 (3.6 %).[141] Only after intense public pressure did some companies release trial protocols: Moderna & Pfizer in September,[142] followed by AstraZeneca and Johnson & Johnson. While this was a positive step, academics and health policy experts believe much more can and should be disclosed.[143] In July 2020, the European Ombudsman urged the European Medicines Agency (EMA) to rapidly publish clinical data related to its COVID-19 related activities.[144] Sharing data related to R&D costs is also warranted in view of the massive public subsidies and would assist payers to determine and negotiate a fair price.[145]

Big Pharma's strategy of avoiding public scrutiny has allowed to successfully implement many of the other strategies outlined in this report. Its opacity has repercussions across the whole sector and for global health systems. Without full transparency in all aspects of the pharma industry, governments cannot negotiate lower prices based on true costs, the public cannot know how its taxpayer dollars are used, and there can be no certainty about the clinical trial process. The public has a right to know. And taxpayers have a right to see a public return on the colossal public investments made in COVID-19 R&D.

Box 9

VACCINE CONTRACTS ARE SEALED OFF, EVEN FROM PARLIAMENTARIANS

Although financed with public money, the purchase contracts between states and the pharmaceutical industry for COVID-19 vaccines and treatments are shrouded in secrecy.

In the USA, the first Freedom of Information (FOI) requests were rejected, leading the advocacy groups, Public Citizen and Knowledge Ecology International (KEI), to sue the US government.[146] Contracts were eventually released due to public and political pressure. Several companies (Novavax, Pfizer, Sanofi, Johnson & Johnson) have used an alternative mechanism called "Other Transaction Agreement" (OTA), under which a third party company manages and awards the contracts on behalf of the US government.[147] One of the advantages of these flexible contracts is that no legal safeguards are required, thereby by-passing laws that ensure the affordability of taxpayer-funded medicines and vaccines.[148] Government rights to intellectual property contained in normal federal and state contracts allow the government to 'march in' and take over a drug or vaccine if the manufacturer fails to make the subsidised product available or sets an unreasonable price – equalling a compulsory licence.[149] The nearly US$2 billion Pfizer contract has the narrowest protections for taxpayers, preventing government intervention if the company engages in price gouging.[150] All of the contracts have been extensively redacted, with only 14 out of 53 pages of the Moderna contract free of redactions.[151] KEI has created a useful webpage with all the COVID-19 contracts – not limited to the US ones – that have so far been obtained through various means.[152]

Europe has been far more reluctant to publicise contracts. Several FOI requests were simply rejected by the European Commission. The correspondence between the Commission and the advocacy group, Corporate Europe Observatory,[153] showed the refusal was motivated by commercial confidentiality and claimed that there was allegedly *"no overriding public interest in transparency"*(!).[154] The European Ombudsman subsequently opened an inquiry into the Commission's refusal to grant public access to documents concerning the purchase of vaccines against COVID-19.[155]

On several occasions, members of the European parliament (MEP) have also called for greater transparency regarding these bilateral contracts.[156] This pressure led to the European Commission finally allowing selected MEPs to consult a heavily redacted version of the 60-page CureVac contract for 45 minutes in a reading room, under strict conditions, and after having signed a confidentiality agreement.[157] Following mounting pressure from all sides and the authorisation of CureVac – states need to obtain pharma's permission before publishing any contract – the Commission finally posted the same redacted version of the CureVac contract on its website.[158] This was followed by the publications of the AstraZeneca[159] and the Sanofi/GSK[160] contracts. A fully unredacted version of the AstraZeneca contract was recently published by Italy's RAI television, clearly showing that the Commission and EU member had made multiple concessions to the drug maker with no corresponding obligations.[161]

In the UK, in a judicial challenge against the Department of Health brought by a campaign group and 3 parliamentarians over its failure to comply with its transparency obligations, the High Court of London ruled that *"the UK government acted unlawfully in failing to publish timely information about billions of pounds worth of public contracts to tackle the coronavirus crisis".*[162]

Switzerland has turned down all FOI requests from consumer groups and media[163] regarding these contracts. Health minister Alain Berset, however, accidentally confessed that the total amount of the Pfizer contract with Switzerland may still vary as vaccine prices can be readapted at the request of the company and are subject to secret rebates, confirming that governments have their hands tied.[164] The Swiss government was helped in their negotiations by the former chief of Novartis' vaccine division – who was in charge during the H1N1 swine flu vaccine scramble – and by Moderna's manufacturing partner, Lonza.[165] The Swiss Parliament was informed about neither the content of the contracts, nor the negotiated prices.[166]

All of the (partially) disclosed contracts show that tax money has significantly de-risked company investments in R&D, that Big Pharma has fully exploited their bargaining power to set the price they want, and that they retain all intellectual property rights and know-how without any obligation to share them.[167]

2.5 – DESIGN CLINICAL TRIALS FOR SELF-INTEREST

▶**FACT(S)** Pharmaceutical companies exert strong control over the R&D process, in particular the testing of products in clinical trials, and have a strong incentive to shape trials and evidence so as to gain fast marketing approval and reap the longest possible patent monopoly.[168] Although speed is expected in times of emergency, the COVID-19 trials were not designed to provide all the evidence necessary.

▶**EXPLANATION** Clinical trials are designed to allow pharma to get quick approval based on 'low-hanging fruit': modest targets or proxy indicators (e.g. progression free survival in cancer) are set, rather than proof that a drug is effective for hard out-comes such as overall survival.[169] Furthermore, a market approval does not require proof that a drug brings any added therapeutic value – increasingly, the pharmaceutical industry just has to show that its product is not worse than the existing standard treatment, which *"lowers the bar a long way, and makes them easier to do".*[170] Many studies have shown that industry-sponsored trials are more likely to exagge-rate benefits and hide disadvantageous results than those funded by other sponsors.[171]

▶**CONSEQUENCE(S)** The lack of transparency in clinical trial design and results renders impossible an independent scrutiny of the research and testing conducted by the pharmaceutical companies, and may put people at risk. It can also lead to a waste of public resources, as seen during the Tamiflu-scandal when governments bought and stockpiled a drug based on the manipulated and selective publication of positive results.[172] COVID-19 vaccines and treatments may see history repeating itself; renowned experts have stated that, despite the urgency, trials could have been better and more ambitiously designed to answer all the relevant questions.

"It's really problematic to be telling people what the data say but not allowing them to see the data for themselves." Peter Doshi, professor, clinical trials expert, University of Maryland School of Pharmacy[173]

For their self-sponsored clinical trials (CT), the pharmaceutical industry can decide when (market prospects), how (design), with whom (participants), and against what disease a treatment or a vaccine is being tested in humans. Pharma companies have to abide by international regulatory and ethical standards so that the efficacy and safety data resulting from their studies can be duly considered by state medicines agencies like Swissmedic when granting market approval – which is the ultimate aim of industry-sponsored studies – and they have to ensure adequate protection of participants. However, pharma companies have a certain leeway to present their product as quickly as possible and in the best possible light,[174] which is not always compatible with posing the most clinically relevant questions.[175] Firms can decide, within national legal standards, which studies to make public and which to submit to the regulatory authorities. Many biases can be introduced into CT to enhance results, leading to their use more as marketing than scientific tools.[176] All of this combined endows Big Pharma with extraordinary discretionary power.

FAST-TRACKED CLINICAL TRIALS

Big Pharma has utilised this strategy very effectively in the pandemic and been rewarded with advantageous changes to certain CT features. Most, if not all, COVID-19 CT have been fast-tracked, and data have been sent to regulatory authorities on a rolling basis throughout the process, instead of presenting them in one bulk with the request for market approval. Trial phases were mostly run in parallel, *"designed to deliver the quickest possible read-out rather than addressing more relevant questions"*[177] and using *"strategies that are easy to implement but unlikely to yield unbiased effect estimates".*[178] These strategies have resulted in record speed in testing procedures (also for vaccines) during the pandemic. But in bowing to intense pressure for fast results, there is a danger that corners have been cut in terms of ethical and/or regulatory standards.

Robust, publicly funded CT are important, as illustrated by WHO's global SOLIDARITY megatrial launched in March 2020. This was an unprecedented, collaborative effort which compared four potential COVID-19 treatments to collect robust evidence on which works best under what circumstances. It provided solid scientific evidence that neither hydroxychloroquine, lopinavir/ritonavir nor remdesivir were useful for COVID-19 patients, putting an end to debates about those much-touted drugs. Government scientists[179] and academic experts[180] have called in vain for a similar, head-to-head global trial to compare the effectiveness and safety of the favourite vaccines, instead of each one being tested against a placebo. Big Pharma are reluctant to do such a transparent, comparative CT as it could show that their product is worse than one of its competitors, thereby affecting profits.

Woman in South Africa receives shot for a AstraZeneca COVID-19 vaccine trial

While offshoring CT to LMICs is part of the pharma business model in normal times,[181] this was much less the case during the COVID-19 pandemic: at least 90 % of the 2,000 COVID-19 CT registered worldwide by July 2020 were done in wealthy countries,[182] with BRICS countries accounting for much of the rest.[183] The dearth of clinical trials in Africa prompted the creation of a Clinical Research Coalition to conduct CT on the African continent to help find the best regional solutions to the pandemic.[184] The coalition is led by the Geneva-based Drugs for Neglected Diseases initiative (DNDi), used to conduct CT in resource-limited settings, and building on the work of local researchers.[185]

The fight against this global pandemic not only requires transparency in CT data and results, it requires that CT are designed to capture as much relevant information and answer as many questions as possible. Pharma's strategy of designing CT to facilitate approval must be challenged to ensure medicines are developed to meet actual health needs and not just to generate profits.

Box 10

STOCK MARKETS CELEBRATING… HIDDEN DATA

When Germany's BioNTech and US Pfizer, shortly followed by US Moderna, announced the first interim results of their final COVID-19 vaccine trials, global stock markets *"propelled to an all-time high"*, with shares of these companies jumping between 15 % to 25 %.[186] But the news was not accompanied by any detailed data, regulatory review or published study (not even pre-print). It was the latest instance in the pandemic of *"science by press release"*.[187] The global health crisis provides justification to inform as soon as possible, with politics and people desperate for good news. But the few details shared made an informed scientific judgement about these announcements impossible.

The '90 to 95 % efficacy' results that were communicated seemed remarkable at first sight, but required educated guesses as to their exact meaning. As more data became available, it appeared that the trials should have been designed more ambitiously to respond to questions for which we still lack clear answers: will the vaccines be effective in (1) cutting the risk of serious complications from COVID-19 and reducing hospital admissions (2) and interrupting (and to what extent) transmission of the coronavirus? [188] In fact, all the large-scale (phase III) vaccines CT were designed to prove neither.[189]

Not all symptomatic participants were tested to confirm COVID-19,[190] let alone asymptomatic ones. Testing all the participants would have required additional resources, and probably additional time before announcing the results. But the benefit of having clearer answers today on whether the vaccines provide protection from the virus would certainly have outweighed the costs. Tal Zaks, Moderna's chief medical officer, said that their trial *"will not demonstrate prevention of transmission, because in order to do that you have to swab people twice a week for very long periods, and that becomes operationally untenable"*.[191] It is difficult to believe that it was not possible to design more robust trials given the money that has been poured in.

Medicines agencies in the USA, EU and Switzerland have repeated reassurances that no corners were cut for the approval of the first vaccines.[192] However, the raw data from these trials is still missing,[193] despite the massive subsidies. The US government has invested over US$4 billion in Moderna's vaccine,[194] more than enough to justify full data disclosure. Corporations consider the data as their property; in fact, the data should belong to the public. Accordingly, the European Ombudsman has long-since concluded that CT data should not be considered commercially confidential.[195]

2.6 – SOCIALISE RISKS, PRIVATISE PROFITS

▶**FACT(S)** Big Pharma argues that risks and profits go together; high profit margins compensate for the high risks taken in the complex R&D of new drugs. However, Big Pharma is making every legal, political and technical effort to systematically minimise and externalise business risks through publicly funded R&D in order to maximise their profits.

▶**EXPLANATION** Public funding has always been crucial for pharmaceutical innovation. Conservative estimates state that, on average, 30% of the annual global R&D investments that lead to pharmaceutical innovation and profit comes from public funding, a ratio that varies significantly according to the type of medicines (e.g. 65 % for neglected tropical diseases).[196] Every single drug approved by the FDA between 2010 and 2016 involved science funded with tax dollars.[197] Big Pharma also minimises internal R&D risks by focusing on minor innovations that allow them to extend their monopoly position,[198] or by acquiring smaller companies that have taken the greatest, early stage R&D risks.[199] Major innovations emerge from public and biotech companies, not from Big Pharma's labs.[200] Profits, however, flow back to Big Pharma.[201]

▶**CONSEQUENCE(S)** This systemic and very costly imbalance has increased during the current pandemic. The outsourcing of risks and the privatisation of profits is detrimental to the public in multiple ways. The full effects of this damaging dynamic might only be seen in a few years.

"With risks being nationalised and profits privatised, governments gave in to vaccine producers. A key principle of the free-market economy and incentive for people to innovate – the togetherness of risks and profits – has been levered out." Dominik Feusi, Tages Anzeiger, 27.11.20 (free translation)[202]

"The current system, in which private monopolies profit from knowledge that is largely produced by public institutions, is not fit for purpose." Joseph Stiglitz, Project Syndicate, 23.4.20[203]

When American virologist Jonas Salk developed the polio vaccine in 1955, an interviewer asked him who owned the patent. He responded, *"Well, the people, I would say. There is no patent. Could you patent the sun?"*.[204] Unlike Salk's polio vaccine, which has always been freely available, most vaccines that come to market today are patented.

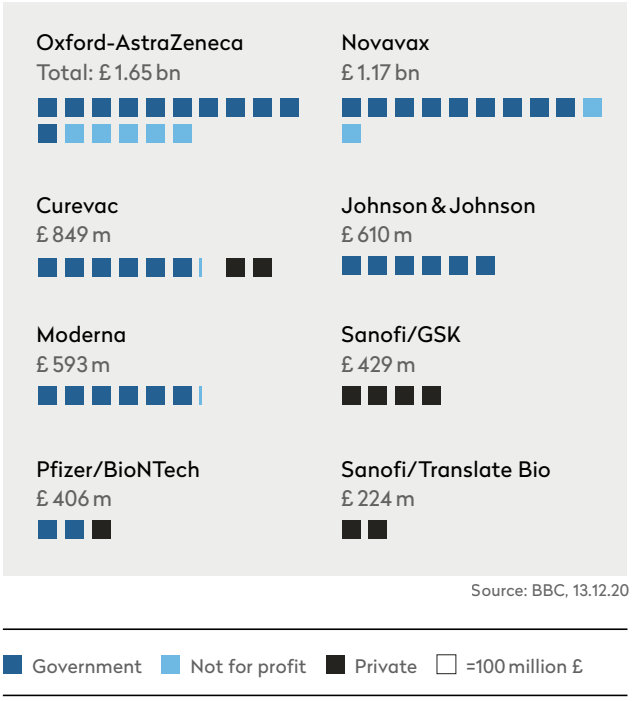
By massively subsidising the discovery, research efforts, testing (clinical trials) and manufacturing capacities, and by securing advance purchase agreements, governments and the philanthropic sector have almost entirely de-risked the R&D and production of COVID-19 health tools. However, these publicly funded endeavours are privatised by the pharmaceutical corporations through intellectual property (IP) protections: patents that last for decades and block other manufacturers, and profits that can be reaped well beyond the pandemic. Further, in the COVID-19 crisis, Big Pharma has even been granted immunity for any possible future harm caused by their vaccines (see Box 11).

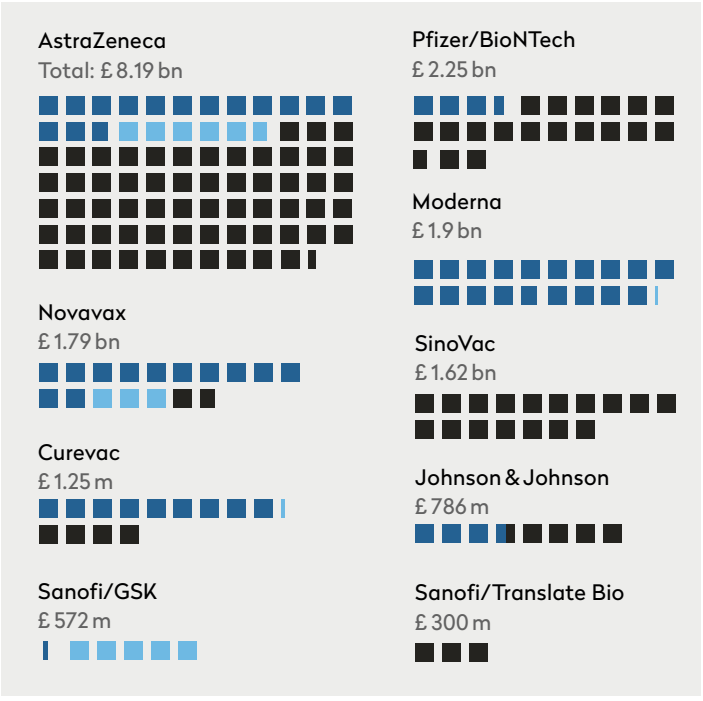
Pharmaceutical companies repeatedly stress that the risks they have taken in the search for a COVID-19 vaccine are worth *"billions of dollars"*.[205] As highlighted in section 2.4, this figure is impossible to verify as they refuse to open their books to reveal their real R&D investments. But their argument is made null and void by the colossal amount of public funds they have benefitted from, which has significantly, if not completely, de-risked their whole endeavour.[206] The KENUP Foundation estimates that, between February and December 2020, governments spent at least €93 billion on COVID-19 vaccines and therapeutics, 95 % of which was in support of vaccines, with the vast majority (93 %) coming through advance market commitments like Operation Warp Speed in the USA or bilateral deals concluded by the EU and other wealthy nations, like Japan and South Korea.[207] Soaring stock market prices are an acknowledgment of this socialised risk and have generated even greater profits for those companies.[208]

BIG PHARMA REINFORCES ITS OWN NARRATIVE

The following graphs illustrate how Big Pharma reinforces its own narrative: the graph on the left shows the extent of public funding for each of the leading vaccines / companies in a BBC article first published on 13 December, 2020.[209] A few days later, the article was updated with the graph on the right, with no additional explanation. What happened in between? It is hard to believe that a media outlet as prestigious as the BBC rushed to publish such a critical piece that was missing so much data, or that Airfinity, the commercial data provider cited as the source, suddenly uncovered new evidence. The striking difference rather hints at an intervention by the pharmaceutical lobby providing unsubstantiated company data in a bid to legitimise the privatisation of profits.

CHART 1 – WHO HAS FUNDED THE COVID-19 VACCINES?





Pharmaceutical companies have a long track-record of profiting from public investment,[210] but probably never at such a scale – or at least never as visibly – as during this coronavirus pandemic. As economist Mariana Mazzucato at University College London argues, *"there is little justice if citizens have to bear many of the financial risks in such an endeavour, but most of the profits go to a small group of companies (and possibly a few universities) once a vaccine is ready to be rolled out".*[211]

Box 11

HICs GRANT PHARMA IMMUNITY IN CASE OF FUTURE HARM CAUSED BY VACCINES

According to a memo circulated by a European industry lobby group to EU member states in August 2020, pharma companies had requested a no-fault compensation scheme and exemption from civil liability for potential side effects after immunisation, on top of the massive public subsidies they had received for the research and manufacturing of COVID-19 vaccines.[212] According to media reports, Big Pharma had exemption clauses included in (confidential) contracts that the European Commission signed with vaccine makers.[213]

Liability exemptions are common in the US, but not in Europe.[214] Although individual European states have signed such agreements in the past, notably during the H1N1 Influenza pandemic, liability exemption has been widely condemned: a 2010 report of the French Senate stated this clause is *"very shocking as it releases producers from any responsibility, except in cases of proven deliberate fault, thereby shifting the burden to national solidarity",* and that it had cost the French government some €15 million.[215]

The vaccination uptake for H1N1 was very low (8 %), but the current, EU-wide exemption clause for COVID-19 may end up costing much more, translating into equivalent higher profits for vaccine producers.

Although impossible to verify from confidential vaccine contracts, it is highly likely that Switzerland has accepted such an exemption. Asked by journalists, the Federal Office of Public Health said that *"a company is liable in Switzerland in case of harms caused by the vaccines, but the State can waive their responsibility in some cases".*[216] According to many observers, COVID-19 vaccines represent such a case.[217] As Switzerland managed to secure a pre-order deal with AstraZeneca through the EU, which granted immunity to the Anglo-Swedish firm[218] (as well as to other vaccine makers), it is reasonable to assume that Switzerland also agreed to such a clause in its contracts.

2.7 – EMBRACE PUBLIC INVESTMENT, REJECT PUBLIC RETURNS

▶**FACT(S)** The absolute necessity of public funding in developing new drugs has never been clearer than in the current pandemic. However, when this reality is ignored in price setting mechanisms, citizens end up paying twice: they heavily subsidise Big Pharma through their taxes, and they are forced to contribute to excessive profits through grossly inflated and underregulated prices.

▶**EXPLANATION** Non-profit initiatives and governments have tried to correct some of the market failures created by the profit-maximising logic of pharmaceutical companies that leads to existential health needs being unmet, such as the development of vaccines, antibiotics and drugs for neglected tropical disease.[219] Since governments have decided to delegate a basic component of the human right to health to the private sector, they must, at the very least, be active regulators. Governments must actively shape the pharmaceutical system and the development of new drugs, for example through attaching access conditionalities to public funding.[220]

▶**CONSEQUENCE(S)** Host governments have both protected Big Pharma and chosen to be at their mercy. They have missed opportunities to regain the upper hand by attaching conditions for access and affordability condition to their public funds.

"The amount of money the government is throwing at companies is unprecedented. Normally when you write bigger checks, you should have more leverage, not less leverage." James Love, Knowledge Ecology International (KEI) in The Washington Post, 1.7.20[221]

According to the latest estimates, governments have so far spent at least €93 billion on COVID-19 vaccines (95%) and treatments (5%), with 32% of public funding coming from the United States, 24% from the EU and its member states, and 13% from Japan and South Korea.[222] States have handed out these billions as COVID-19 'blank cheques' for research, development and manufacturing, enabling new ways of designing vaccines and accelerating their development and delivery.

Incredibly, governments have attached no strings to these billions in order to guarantee public benefit: there were no conditionalities on affordability and access, no requirement to share the know-how and intellectual property of the subsidised technologies, no duty of transparency – nothing. Such government subsidies should at least endow the right to scrutinise the research being funded and its results. However, pharma is keeping its R&D processes and unfavourable results secret. And by monopolising the COVID-19 health tools resulting from these funds, Big Pharma is freeriding on taxpayers' money.

THE ESSENTIAL ROLE OF PUBLIC INVESTMENTS

The very foundation of developing vaccines rests on the scientific research conducted in government institutes and universities.[223] It was government-funded scientists who laid the groundwork for the mRNA technology that underpins the leading COVID-19 vaccines of BioNtech/Pfizer, Moderna and CureVac.[224] The latter got into the business long after the first public mRNA research conducted in the early 1960s: the first was CureVac in 2000, followed by BioNtech in 2008 and Moderna in 2010. Thanks to four decades of public investments, *"the companies could simply take over these scientific breakthroughs that had never been patented"*, said Steve Pascolo of the University of Zurich, one of the co-founders of CureVac.[225] These mRNA vaccines are now all heavily patented, and the companies can expect whopping revenues of US$10–20 billion for 2021 alone as a result of the vaccine prices charged to those very same governments that subsidised their R&D.[226]

Another striking feature is the significant amount of public funding that went into COVID-19 clinical trials. Policy Cures Research, a reference think-tank specialised in global health R&D, has identified over US$9 billion in global funding commitments from January to October, 2020, for COVID-19 diagnostics, treatments and vaccines R&D. This comes predominantly (if not entirely) from public or philanthropic sources and excludes self-investment from private pharmaceutical companies unless reported to the media[227] – which it never is. An investigation by Swiss television RTS in May showed that, from the 421 COVID-19 drug clinical trials listed by WHO since the beginning of the pandemic, only 20% were conducted by Big

Pharma (alone or in collaboration with other actors). The same ratio was about 40 % in 2019.[228]

Pharmaceutical companies also benefit from billions in tax breaks through research tax credits. In France, income derived from the sale or licensing of patent rights is taxed at the reduced rate of 10 %. However, the public receives little in return, judging by the increasing sums paid by health systems for outrageously expensive drugs.[229]

Box 12

C-TAP, OR THE MISSED OPPORTUNITY OF OPEN SCIENCE IN A PANDEMIC

The genetic sequence of the SARS-CoV-2 coronavirus[230] and early research data were immediately shared at the outbreak of the pandemic, accelerating the development of new diagnostic tests and treatments.[231] This prompted Costa Rica, on March 23, 2020, to propose to the WHO to establish a voluntary pool to share all *"existing and future rights in patented inventions and designs, as well as rights in regulatory test data, know-how, cell lines, copyrights and blueprints for manufacturing diagnostic tests, devices, drugs, or vaccines."* [232] The aim was to provide free access or licensing on reasonable and affordable terms for COVID-19 technologies in every member country[233] to accelerate the development of health tools and massively scale-up their production.[234] The initiative was supported by over 70 civil society organisations, including Public Eye,[235] as well as academic experts, former captains of the pharmaceutical industry, international agencies and LMICs.[236] Two months later, the WHO officially launched the *COVID-19 Technology Access Pool* (or C-TAP), as part of its global Solidarity Call to Action.[237] C-TAP was supported and sponsored by 40 member states, including 5 from Europe; apart from Belgium, none were home to the biggest pharmaceutical corporations.[238]

Big Pharma immediately dismissed C-TAP. Pfizer CEO Albert Bourla called the pool *"nonsense"* and *"dangerous"*, while AstraZeneca and GlaxoSmithKline (GSK) refused to participate,[239] and the director of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), Thomas Cueni, commented that he was *"too busy"* to attend the launch of the proposal.[240]

Paul Fehlner, the former IP chief of Novartis, was amazed by their perceptions that C-TAP was undermining their rights: *"As someone who's worked on intellectual property issues at the highest levels of a multinational pharmaceutical company, I urge them all to take another look. C-TAP recognises and respects IP rights around COVID-19 technologies. This is no compulsory licensing scheme or an attack on patents. On the contrary, access to IP, including know-how, will be under license".*[241] However, Big Pharma needed to discredit C-TAP in order to maintain their control over the technologies and continue to cultivate scarcity, thereby allowing them to decide who gets access, when and at what price. To defend their position, industry leaders claimed that *"infrastructure and supply chains are likely to be bigger access obstacles than patents in the current race for a pandemic vaccine",*[242] deliberately silencing the evidence that exclusive rights are, per definition, artificially rationing the production capacity.

Countries, especially HICs that host and provide massive financial contributions to the development of those technologies, are not helpless observers. They had the choice to attach strings to their contributions and to insist that pharmaceutical companies commit joining C-TAP, and share rather than monopolise the products and data resulting from public funding. But they chose not to. The result is that 10 months after the sharing platform C-TAP was established, no single contribution has been received.[243]

Why was the spirit of open science and data sharing seen at the initial outbreak of the pandemic not extended to all stages of R&D, including those steps undertaken by private companies? A framework built around voluntarily shared information would have allowed for scaling-up worldwide availability and lowering costs, thus helping secure universal access. Supply uncertainties, unequal global distribution, and shortages in the delivery of vaccines could have been avoided. It seems that the crisis we have been enduring for the last year has not been enough to change the profit-maximising, business-as-usual approach that lies at the heart of access inequalities. We have squandered an opportunity to do things differently.

2.8 – IMPOSE UNJUSTIFIABLE, UNCHALLENGEABLE PRICES

▶**FACT(S)** Regulatory authorities and payers have little power to negotiate prices that would make essential medicines universally affordable because Big Pharma is free to manipulate a system with few legal requirements for transparency.[244] This is no different for COVID-19 vaccines and treatments.

▶**EXPLANATION** The structural power imbalance allows pharmaceutical companies to play 'divide and rule' with countries and payers; they demand confidentiality clauses and secret rebates in their deals while trying to reassure each country that they are getting the best deal. The lack of transparency on R&D and production costs makes it impossible to determine a 'fair price'.[245] Experts estimate R&D costs at 15 to 40-times less than that claimed by pharmaceutical companies.[246] Big Pharma's argument that high prices are necessary to compensate for risk and investment is hollow in light of the increasing evidence of the importance of public funding[247] and significantly lower, real R&D costs.[248] So companies are now pushing a 'value-based pricing strategy'.[249] But how can we evaluate the price of a human life saved by a vaccine or a medicine? And who decides what constitutes 'value'? And what 'value' should be prioritised over another? Health is unlike all other consumer goods, rendering this argument cynical and baseless.

▶**CONSEQUENCE(S)** Companies and regulatory authorities use the price of existing standards of care as a benchmark to determine the price of new medicines, leading to continuous price increases.[250] The pandemic could have been used to stop this vicious circle and set a new precedent. However, HICs, in particular the host countries of Big Pharma such as Switzerland, blocked this very effectively.

"Some companies initially asked for more than US$100 per dose" of a vaccine, an EU negotiator said in summer 2020.[251]

Patents lead to excessive drug prices by securing monopolies, as frequently evidenced in the past.[252] Despite the increased public scrutiny arising from the pandemic and pledges from some of a 'non-profit' approach, pharma has overpriced many of the COVID-19 diagnostic tests, treatments and vaccines.[253] This practice is highly abusive given the huge amounts of public funding that have been poured into their research and development (R&D).

DIAGNOSTICS

At the end of January, 2020, Roche proudly announced the distribution of its first coronavirus tests free-of-charge, claiming *"there is no time to negotiate about the price given the exponential dissemination of the virus"*.[254] This policy changed rapidly, even as the virus started racing across Europe and the rest of the world. By March 2020, the press noticed that the price of a COVID-19 PCR laboratory test in France was officially €135 while the estimated production cost was €12.[255] PCR lab tests for the detection of the SARS virus – also a coronavirus – were estimated to cost between €6–8 per person for assays developed by the University of Toronto (Canada), but €28 for commercial ones.[256] For rapid COVID-19 tests, the US company Cepheid charged some US$20 per unit in LMICs, including the world's poorest ones, while a similar TB test costs as little as US$3.[257] In April, 2020, many civil society experts condemned this, stating that prices charged by diagnostic companies *"remain unchallenged, thereby leading to supplies that are overpriced and inaccessible for many LMICs"*, and called for more transparency and accountability.[258]

TREATMENTS

Some of the drugs that were initially deemed useful in treating COVID-19 and its consequences (e.g. hydroxychloroquine, dexamethasone) have long existed, and are thus now quite cheap. However, this is not the case for the majority of repurposed treatments investigated for their effectiveness against COVID-19. While most failed to confirm the initial hopes placed in them, those that are still in the race are incredibly, and unjustifiably, expensive. According to a study published in April 2020, repurposed drugs could be manufactured at very low unit prices – between US$1 to US$29 per treatment course.[259] But their list price are significantly higher, as exemplified by Gilead's antiviral remdesivir or Roche's immunosuppressant tocilizumab, two treatments that attracted a lot of hype. It is also true for treatments developed after the outbreak of the pandemic, such as monoclonal antibodies (or mAbs), as shown in the table below.

The stark difference between the manufacturing costs of the mAbs and their selling price yields potentially huge profit margins. Considered possible game changers in treating or prevent-

TABLE 2 – PRODUCTION COSTS AND SELLING PRICES OF POTENTIAL COVID-19 TREATMENTS

Drug*	Highest global selling price per treatment (US$)	Highest selling price per treatment in Switzerland (CHF)	Lowest global selling price per treatment (US$)	Estimated production cost per treatment (US$)[260]	Estimated production cost per day (US$)[261]
Remdesivir ***(Veklury, Gilead)***	2,340[262]	2,283[263]		5.58	0.93
Lopinavir/ritonavir ***(Kaletra, AbbVie)***	503[264]	300[265]	9	4	0.28
Hydroxychloroquine ***(generic)***	19[266]	8[267]	2	1	0.08
Sofosbuvir/daclatasvir ***(Gilead/BMS, generic)***	18,610[268]	N/A	6	5	0.39
Pirfenidone ***(Esbriet, Roche)***	9,606[269]	2,763[270]	100	31	1.09
Tocilizumab ***(Actemra, Roche)***	3,383[271]	1,259[272]	510	56[273]	56[274]
Ruxolitinib ***(Jakavi, Novartis)***	6,917[275]	1,006[276]		6.3[277]	0.45[278]
Canakinumab ***(Ilaris, Novartis)***	17,448[279]	12,084[280]	1,900	15[281]	15[282]
Bamlanivimab ***(Eli Lilly)***	1,250 / vial[283]	N/A	N/A	70[284]	70[285]
REGN-CoV-2 ***(Regeneron)***	2,000 / vial[286]	N/A	N/A	240[287]	240[288]

*** Standard treatment course:**

Remdesivir *100mg IV/day (1 vial) for 5 days, double dose on day 1*
Lopinavir/ritonavir *400/100mg twice daily for 14 days*
Hydroxychloroquine *400mg/day for 14 days*
Sofosbuvir/daclatasvir *400/60mg daily for 14 days*
Pirfenidone *801mg thrice daily for 4 weeks*
Tocilizumab *560mg/day (for 70kg bodyweight)*
Ruxolitinib *5mg twice daily for 14 days*
Canakinumab *150mg/ml, single dose*
Bamlanivimab *one vial containing 0.7g of LY-CoV555*
REGN-CoV-2 *one vial containing 2.4 g of REGN-CoV-2*

Although the cost of manufacture (expressed in US$ per gram of mAb) may vary depending on different factors, several studies have shown that, with the improvements in methods and above a certain capacity of production, it can be estimated at roughly US$100 per gram of mAbs. This average, which does not take into consideration post-manufacture costs like storage and distribution. has been used to calculate the production cost of mAbs. Other costs such as product formulation or packaging, that also contribute to the overall manufacturing costs of mAb therapies are not expected to exceed US$5 per vial.

ing COVID-19, especially after the failure of most repurposed drugs, the two leading mAbs producers (Regeneron and Eli Lilly) have also benefited from considerable public funding. According to filings with the US Securities and Exchange Commission (SEC), taxpayers shouldered most of the R&D costs for REGN-CoV-2 and 80% related to Regeneron's COVID-19 programme.[289] In addition, the company was granted a US$450 million supply contract from the US government in July 2020,[290] followed by another staggering deal of US$2.625 billion following its emergency use authorisation in November last year.[291] While Regeneron has partnered with the Swiss giant Roche to more than triple its manufacturing capacity,[292] it will still be far from able to meet global demand. Eli Lilly has been granted supply deals worth US$1.2 billion by the US government.[293] Bamlanivimab (or LY-CoV555) is the result of the long-standing work of the University of British Columbia and was discovered by a spin-off company (AbCellera Biologicals), both supported by US and Canadian government funds. Eli Lilly entered the picture only in March 2020.[294] Their CEO said they would price bamlanivimab at US$1,250 a vial and expect *"a modest financial return for our investors by the end of 2021"*[295] – although its manufacturing costs can be estimated at just US$70!

VACCINES

Since the beginning of the pandemic, concerns have been expressed about the pricing of coronavirus vaccines. In early March 2020, a group of US lawmakers tried to include price control safeguards in the federal emergency coronavirus funding

package. But these, as well as other intellectual property provisions, were killed off by intensive pharma lobbying.[296] This first episode set the tone for what followed: despite massive state subsidies and ongoing public debate, the pharmaceutical industry has maintained control over the pricing of its vaccines, with Big Pharma host countries advocating politically on their behalf.

TABLE 3 – **PRICES OF THE LEADING 'WESTERN' COVID-19 VACCINES**

	Global price per dose announced by the companies (via press, in US$)	Average price per dose calculated from the US deals (in US$)	Average price per dose resulting from the EU deals (in € and US$)	Price per dose announced for LMIC via press (in US$)
1 – Pfizer/BioNtech *(Comirnaty®, BNT162b2)*	19.5	19.5	€15.5[297]	10 *(South Africa)*[298] 6.75 *(African Union)*[299] 7 *(Tunisia)*[300]
2 – Moderna *(mRNA-1273)*	32–37[301]	25[302]	US$18[303]	30–42 *(South Africa)*[304]
3 – AstraZeneca /Oxford University *(ChAdOx1, AZD1222)*	3–4[305]	4[306]	€2.5[307]	7 *(Uganda)*[308] 5.25 *(Brazil, South Africa)*[309] 4–5 *(Bangladesh)*[310] 5 *(Philippines)*[311] 2.74 *(India)*[312]
4 – Johnson & Johnson *(Ad26.COV2.S)*	10[313]	10[314]	US$8.5[315]	10 *(African Union, South Africa)*[316]
5 – CureVac/Bayer *(CvnCoV)*	15[317]	Unknown (no deal)	€10[318]	Unknown (no deals)
6 – Novavax	No public announcement	16[319]	Unknown (deal under negotiation)[320]	3 *(COVAX & Serum Institute of India)*[321]

Moderna is the most expensive vaccine despite benefiting from considerable public funding (US$4.1 billion from the US government[322] and US$1 million from CEPI[323]), which covered 100 % of its R&D costs,[324] and most of its manufacturing costs resulting from its partnership with the Swiss company, Lonza.[325] The US company also secured sales through advance purchase agreements predominantly with HICs governments,[326] including Switzerland.[327] Financial analysts project its 2021 mRNA-1273 vaccine sales to reach over US$7 billion.[328] Its shares have risen more than 420 % since it went public in 2018, and with a US$7.5bn valuation, it is the biggest biotech public offering ever.[329]

NO-PROFIT PLEDGE IMPOSSIBLE TO VERIFY

Pfizer/BioNtech's BNT162b2 vaccine has also been massively subsidised by taxpayers' money: a US$1.95 billion supply contract with the US government,[330] a non-refundable down payment from the EU of €700 million,[331] a €375 million grant from the German government and a €100 million loan from the European Investment Bank to accelerate its development.[332] At the set price, the EU could pay up to €4.65 billion to secure the supply of 300 million doses.[333] In 2021, Pfizer expects about US$15 billion in revenues from its vaccine, with a staggering profit margin of US$4 billion, which could still increase.[334] Costs and profits are split 50/50 with BioNtech.

Both AstraZeneca/Oxford and Johnson & Johnson (Janssen) pledged early on to price their vaccine at 'no-profit' during the pandemic. An agreement between AstraZeneca and the Brazilian Institute, Fiocruz, showed that the Anglo-Swedish firm can unilaterally declare the end of the pandemic as soon as July 2021, after which it can sell its vaccine at a much higher price.[335] Their 'no-profit' pledge is also impossible to verify as the real costs of developing and manufacturing the vaccines are not transparently available. AstraZeneca has signed a deal worth more than US$1 billion with the US government,[336] £65.5 million with the UK,[337] US$750 million with the Coalition for Epidemic Preparedness Innovations (CEPI) and the GAVI Vaccine Alliance (COVAX).[338] Some sources estimate the amount of public funding to be as high as US$2.4 billion.[339] This is an astonishing amount of public funding for a vaccine that had already been developed using public funds at a UK University. Through its subsidiary Janssen, Johnson & Johnson has received an initial R&D grant of US$500 million, followed by a supply deal worth over US$1 billion with the US government.[340] It also has a pre-order deal with the EU for potentially 400 million doses, at a price of US$8.5 per dose.[341]

The German company CureVac benefited from a €75 million loan from the European Investment Bank[342] as well as funding of €252 million from the German government[343] for the devel-

opment and large-scale production of their vaccine. It also concluded a €4 billion pre-order deal with the EU,[344] and very recently another one with Switzerland for 5 million doses at an unknown price.[345] In early January this year, the biotech partnered with the German giant Bayer to boost production capacity,[346] and also recently announced a collaboration with the British firm GSK.[347]

PRE-ORDER DEALS AT UNKNOWN PRICES

Novavax, a US company that, like Moderna, has never brought a product to market and faced an 'existential threat'[348] just a few months back, secured a US$1.6 billion deal with the US government for the development and supply of its vaccine.[349] The company has also received US$388 million from CEPI.[350] Like AstraZeneca, Novavax also entered into a manufacturing and licence agreement with the Serum Institute of India for the development and commercialisation of its COVID-19 vaccine candidate.[351] It also concluded a pre-order deal with the EU for up to 200 million doses,[352] and very recently with Switzerland for 6 million doses,[353] both at an unknown price.

The Lancet has recently published a comprehensive article on this topic that includes price points of the Russian (Sputnik V) and various Chinese vaccines, which many LMICs rely on as they cannot ensure sufficient supply from leading 'Western' vaccine makers or from COVAX.[354]

The above shows that taxpayers are paying twice for a treatment or a vaccine. R&D costs cannot be used to justify high prices because public funding has been instrumental in the discovery, development, clinical testing, manufacturing and commercialisation of these COVID-19 vaccines. Marketing costs are non-existent in a pandemic given the global attention and huge demand for products that pass the efficacy and safety exams.[355] If pharma companies have invested the 'billions of dollars' they often claim, then they must open their books for public and political scrutiny. The same applies for 'no-profit' vaccines: it is impossible to verify whether they are really at cost price, and it remains to be seen how long they will be kept at this price level. Vaccines should be public goods, but they are being handled like private, for-profit ones.

An employee works on an assembly line for manufacturing vials of Covishield, AstraZeneca-Oxford's COVID-19 coronavirus vaccine at India's Serum Institute.

Box 13

REMDESIVIR, THE NEW TAMIFLU

Remdesivir, Gilead Sciences' antiviral drug initially developed against the Ebola virus, is a prime example of how Big Pharma is abusing the system during this pandemic. Initially hailed as a promising drug against COVID-19, most of remdesivir's discovery and clinical development was either conducted or funded through the public purse, at a total cost of at least US$70 million.[356] Despite this public funding, Remdesivir is widely patented, including in countries like China and India.[357]

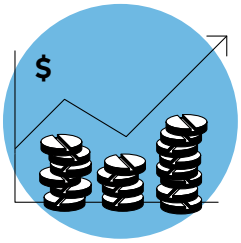
Unlike his predecessor, Greg Alton, who supported a global WHO pool to share know-how and intellectual property,[358] CEO Daniel O'Day (the former head of Roche's pharma division) decided to fully exploit its monopoly power and seek the highest possible profit. In March 2020 (i. e. during the pandemic!), Gilead requested and obtained an orphan drug status for remdesivir to cement its monopoly; only following a massive outcry[359] did the company rescind it.[360] Then, buoyed by Wall Street analysts and potential profits,[361] Gilead set an incredible price tag of US$2,340 for a 5-day course of treatment that can be manufactured at scale, including with a reasonable profit margin, for only US$5.58.[362] At a time when drug's real benefits in terms of survivability were yet to be proven, O'Day stated that remdesivir was priced *"well below its value".*[363]

Confronted with insufficient manufacturing capacity, the company also negotiated opaque licence agreements with 9 generic producers in India, Pakistan and Egypt. But Gilead wanted to continue exercising total monopoly control over manufacture and sale in 73 countries, including 30 LMICs and all HICs, where generic versions are not allowed to be sold. About half of the world's population was thus excluded from the deal.

The US company already had a preferential supply agreement with its home country, when it signed a US$1.2 billion procurement deal with the EU in early October 2020 for 500,000 treatment courses,[364] shortly before the publication of the interim efficacy results. The company knew well that its drug was useless before signing the agreement,[365] as it had previewed the WHO Solidarity trial results showing that remdesivir had little to no effect on mortality and hospitalisation. WHO finally advised against the use of remdesivir for COVID-19 patients in November, 2020. Despite its proven ineffectiveness, Switzerland and many other countries still continue to order the drug at the same high price.[366]

Long before the pandemic, Gilead had a track record for outrageous price tags for their HIV and Hepatitis C medicines. The story of remdesivir is strongly reminiscent of Roche's antiviral Tamiflu: an unjustifiably high price, given the low production costs and massive public funding, compounded by governmental stockpiling of a drug that is ultimately not worth it. Roche earned billions with Tamiflu.[367] And Gilead is now doing the same with remdesivir, raking in sales of US$2.7 billion in 2020.[368]

2.9 – FINANCIALISE INNOVATION



▶**FACT(S)** Over the last 20 years, the pharmaceutical sector has come to resemble the investment industry: it increasingly operates as a private equity fund that invests in financial activities and takeovers rather than the development and manufacturing of drugs.[369] The underlying business model of Big Pharma has shifted from producing and selling products to buying up competitors and biotechnology companies in order to replenish their pipelines while paying out excessive shareholder dividends.

▶**EXPLANATION** The increasing financialization of the economy,[370] which includes non-financial companies such as pharmaceutical corporations, has empowered financial agents and institutional investors. Rather than investing in fixed capital or R&D, there has been increased interest in intangible assets such as intellectual property rights (IPRs). Pharmaceutical companies acquire other firms and their IPRs, paying premiums in expectation of the future income they hope to generate once an IPR-protected drug is approved.[371]

▶**CONSEQUENCE(S)** There is a concentration of a few companies with growing market power that generate income from owning and monopolising intellectual property rather than developing, producing and selling innovative drugs. Not only is it indefensible to create artificial scarcity and profits for the sole purpose of maximising shareholder value, but the current system makes pharmaceutical companies vulnerable to financial cycles and is threatening the stable development and supply of essential medicines for public health.[372]

"Bio-pharma investment is a speculative bet on scientific discoveries and is similar, in this respect to oil, gas and mineral exploration where FDA regulatory approval is like striking oil or finding the seam." Tord Andersson et al., academic experts in finance and accounting research, October 2010[373]

"The current system has been set up to line the pockets of shareholders rather than helping patients around the world." Dutch Centre for Research on Multinational Corporations (SOMO), April 2020[374]

In the current business model, pharmaceutical companies have gradually shifted from developing and manufacturing drugs to operating as private equity funds. Profits are redirected away from investment into R&D on riskier, longer-term research that leads to critically needed therapeutic advances and re-invested in financial markets or hoarded for future financial needs and the acquisition of smaller firms. Exceptionally high compensations are paid to shareholders at the expense of productive investment into R&D and are mostly derived from debt as financial reserves are required to participate in and shape the stock market.[376]

Rather than reinvest accumulated capital into needed R&D, companies focus on boosting short-term share prices. One of the most common tools to do this is share buybacks, in which companies buy back their own shares to boost the value of the remaining ones for shareholders in equity markets. Pfizer, which benefits enormously from government subsidies, has spent US$139 billion on buybacks and dividends in the past decade, compared to US$82 billion on R&D and US$18 billion on capital spending. Novartis also announced to investors in November 2020 a share buyback worth up to US$2.5 billion, immediately gaining 1.4 % in the Swiss stock market.[377] By doing so, companies are effectively passing on their monopoly profits to today's shareholders rather than investing them in future innovation.[378] From 2000 to 2018, the total amount paid out to shareholders by 27 of the largest pharmaceutical companies – including Roche (number 2) and Novartis (number 4) – totalled US$1,540 billion (US$864 billion in dividends and US$676 billion in share buybacks), exceeding R&D expenses (US$1,482 billion). In nominal terms, pay-outs to shareholders have increased by almost 400 %, from US$30 billion in 2000 to US$146 billion in 2018. These pay-outs cannot be explained by an increase in essential investments; however, the price of drugs has increased exponentially.[379]

The pandemic has been no exception: as the world waited anxiously for a treatment or vaccine for COVID-19, even the most modest and unverified positive announcement led to an immediate jump in the stock market.[380] The massive state subsidies that de-risked every R&D effort were also celebrated by the financial markets, as investors smelled big money for a COVID-19 cure.[381] The value of Moderna, a small US company that has never brought a product to market, has more than tripled in value from US$7 billion to US$30 billion since partnering with the US National Institutes of Health in the vaccine race. Shares of Regeneron have climbed nearly 80 % in the same period, after announcing collaboration with the US Department of Health and Human Services to develop a COVID-19 treatment.[382] The stock market value of Novavax, a biotech that had not recorded a profit for more than two decades, soared tenfold to US$10 bil-

"US pharma companies claim that high drug prices fund investments in innovation. Yet the 18 drug companies in the S&P 500 Index in January 2016 and publicly listed from 2006 through 2015 distributed 99% of their profits to shareholders over the decade, 50% as buybacks and 49% as dividends. The total of US$261 billion spent on buybacks alone was equivalent to 56% of their combined R&D expenditures. That US$261 billion could have been returned to households in the form of lower drug prices without infringing on R&D spending, while shareholders would still have received ample dividends." William Lazonick, Professor of Economics. University of Massachusetts, July 2017[375]

lion after the Trump administration agreed to give it US$1.6 billion to make a vaccine.[383] Even the shares of Swiss company Lonza, as Moderna's manufacturing partner, increased by 60% between January and July 2020.[384] And across the pharmaceutical industry, senior executives and board members have been capitalising on that dynamic[385] (see Box 14).

The pandemic has exposed many of the vulnerabilities created by Big Pharma's financialised business model. Despite the crisis, some pharma companies like the French Sanofi have increased dividends to their shareholders.[386] Big Pharma plays jackpot with the market, neglects its core duties and increases society's financial risks. IP monopolies represent a fundamental systemic problem, even more so during a pandemic, as they increase the rent incomes of private corporations and benefit their shareholders, but result in scarcities that are detrimental to public health – and thus to the public benefit.

Box 14

WHEN PHARMA CEOS AND PHILANTHROPISTS GET RICHER THANKS TO COVID-19 AND TAXPAYERS

Senior executives of pharma companies have earned vast profits from selling millions of their shares at particularly crucial moments during the R&D of COVID-19 treatments or vaccines, even though the latter has been massively subsidised by states.

Pfizer CEO Albert Bourla sold 62% of his stock on the same day the company announced that its experimental COVID-19 vaccine had succeeded in clinical trials. The announcement sent Pfizer's shares soaring almost 15% on the same day. Bourla sold 132,508 shares at an average price of US$41.94 per share, or US$5.6 million, almost its highest value in the past year.[387] Following the sale, Pfizer said that Mr Bourla owns shares in the group worth about nine times his salary.[388]

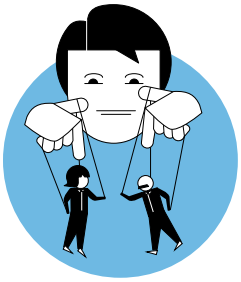
From January to August 2020, CEO Stéphane Bancel sold roughly US$40 million worth of Moderna stock held by himself or associated investment funds. According to the Guardian, this had risen to nearly US$50 million by mid-November 2020.[389] Chief Medical Officer Tal Zaks has sold around US$60 million and President Stephen Hoge has sold more than US$10 million. Advocates have questioned whether it is appropriate for executives to privately profit before bringing the vaccine to market, especially when American taxpayers have committed roughly US$2.5 billion to the company's vaccine development and manufacture.[390] By STAT's estimate, Tal Zaks was on track to sell roughly US$90 million worth of stock by the end of 2020, regardless of whether the vaccine he was helping to develop actually works.[391] Moderna's company executives had already made tens of millions of dollars by cashing in stock after the release of its positive — but highly limited — data in September.[392]

While Moderna claimed that the share sales were part of a pre-arranged plan established in 2018, those of CEO Bourla were rescheduled in August 2020 when the company was already engaged in the final testing of its vaccine, according to Mediapart.[393]

Novavax's Chief Executive Stanley Erck and three of his top lieutenants have sold roughly US$46 million of company stock since the start of 2020, capitalizing on a near 3,000% rally in Novavax shares fueled by investors betting on the success of the vaccine under development.[394]

Bill Gates is potentially also reaping considerable financial gains from the pandemic, since his foundation has stakes worth US$250 million in dozens of companies working on COVID-19 vaccines, therapeutics, diagnostics or manufacturing.[395]

2.10 – LOBBY PERVASIVELY



▶**FACT(S)** The pharmaceutical industry has the highest rate of investment in lobbying activities in the US, which is by far the most lucrative drug market.[396] Of the 40 senators and representatives who received the most contributions from pharmaceutical companies, 39 belonged to committees with jurisdiction over health-related legislative matters. Swiss pharma Roche and Novartis also spend significant amounts on lobbying activities in the US.[397] In Switzerland, where lobbying activities are omnipresent and weakly regulated,[398] the powerful pharmaceutical industry is fighting hard against any attempt to lower drug prices, which are among the highest in the world.[399]

▶**EXPLANATION** Big Pharma has successfully entwined itself in pharmaceutical-related policy areas by framing the debate, providing "expertise", shaping trade deals and funnelling public cash and privileges to maximize its profits.[400] Lobbying and political campaign financing are among those strategies deployed to systematically influence political processes and decisions, which in many countries are opaque and weakly regulated. This creates serious conflicts of interest and leads to corporate capture, meaning the long-term influence on political processes, structures, and decisions by individuals, groups and organisations to their advantage and to the detriment of the public interest. Corporate capture includes legal and illegal activities as well as direct in indirect means and describes a systemic and lasting influence.[401]

▶**CONSEQUENCE(S)** The financial reliance on industry as a customer, or multiple roles such as a parliamentarian sitting on a pharmaceutical advisory board do not necessarily translate into harmful or illegal practices. However, they create serious conflicts of interest which should be made transparent, discussed publicly and avoided through appropriate and binding regulation.

In 2019, the pharmaceutical industry spent US$295 million on lobbying, far more than any other sector in the U.S,[404] giving them exceptional power to frame the political debate and influence the legislative system. The pandemic has been no exception; lobbyists for more than a dozen companies developing COVID-19 vaccines, therapies and diagnostics, including several of the largest drug makers, are connected to the President of the United States[405] and federal lobbying expenditure in the first quarter of 2020 roughly equalled the all-time record for a single quarter.[406] Pfizer spent more than US$6 million lobbying the US Federal government between January and October 2020.[407] Pharma has directly influenced the US emergency coronavirus bill and had language regarding intellectual property and price controls removed, while retaining massive public funding.[408] Concrete outcomes of successful lobbying regarding vaccine contracts can be seen in the Box 9 at page 17.

Pharma lobbying is also intense in Brussels, where the industry employs around 175 lobbyists working on EU decision-making (58 of whom have permanent access passes to the European Parliament). The primary aim is, of course, to protect and expand their traditional monopoly, pricing and opacity privileges. But they also fight against legislation like the planned EU joint procurement mechanism, a tool designed to facilitate equitable access and pricing for pandemic treatments in Europe.[409] And of course, governments have signed confidentiality clauses with pharma forbidding them to disclose contractual terms – as they did pre-pandemic to keep drug rebates secret.

SHORTER TIMELINES FOR MARKET APPROVALS

The COVID-19 crisis has also delivered something lobbyists have long been pursuing: the fast-tracking of R&D processes and market approvals. Obtaining shorter timelines for approvals has been one of Big Pharma's main regulatory battles in order to commercialise their drugs more quickly, thereby benefitting from longer monopoly protection once on the market. Such fast-track attempts were made, for example, in the framework of the European Medicines Agency's controversial "adapted pathway" project,[410] potentially allowing for earlier market approval on the basis of the preliminary data of a phase II clinical trial. This would have, in effect, transformed society into a giant (Phase III) confirmatory clinical trial. Although the project never moved beyond the pilot phase, the pharma industry is still pursuing this agenda, as illustrated by Novartis CEO Vas Narasimhan's remarks: *"That is unheard of speed in our industry – a process that would normally take six to nine months, happened in less than 30 days. I would be surprised if we can maintain that pace, but even some reductions [in timelines], some learnings ... to speed up some of the basics in the process would be very welcome. I think there's an opportunity here to fundamentally change some elements of drug development".*[411]

"The [pharma] industry's fear-and-scarcity based arguments – fuelling vaccine nationalism, pushing stricter intellectual property controls – depend on accepting the flawed monopoly-profit model that it is lobbying to protect, and which actually threatens to prolong the pandemic by leaving many countries unable to afford treatments or vaccines." Corporate Europe Observatory, September 2020[402]

"Layer on constant lobbying pressure and the reputational boost drugmakers have received from the development of COVID-19 vaccines and treatments, and it's hard to envision lawmakers mustering the will to crack down on the bad behavior of pharmaceutical companies. Yet this is exactly the kind of deep structural change that is needed if we want to address a prescription drug crisis that is careening out of control." Tahir Amin, cofounder and co-executive director of I-MAK, in Jacobin, 18.12.20[403]

Big Pharma has also managed to install one of its own as the US vaccine czar: Moncef Slaoui, former GlaxoSmithKline executive (he formerly ran GSK's vaccines programme) and Board member of Moderna and Lonza,[412] was designated head of Operation Warp Speed, in charge of selecting and allocating billions of public subsidies to vaccine makers. Following his nomination, Slaoui was required to resign from a number of biotech boards funded by Operation Warp Speed, but was allowed to keep his stock in GSK (reported to be about US$10m) as well as, apparently, his 156,000 Moderna stock options, worth over US$10 million.[413] Other long-time Pfizer executives were also hired by Operation Warp Speed. *"Slaoui is the sitting, walking, conflict of interest in Operation Warp Speed."*, said Public Citizen.[414]

Big Pharma's defence of intellectual property, even in times of a pandemic, have created the impression that IP rules and pharmaceutical monopolies reflect the natural order of things, and are common sense with obvious benefits to society. In reality, these international norms that were shaped by Big Pharma are relatively recent. Big Pharma is holding governments hostage, and governments are showing little resistance. Through their accommodation of pharma opacity, governments are, in fact, complicit.

3

Switzerland is ‘Pharmaland’

Switzerland has been neither particularly vocal nor present on the international stage, but from the early stages of the pandemic it has been quietly acting behind the scenes to protect its powerful pharmaceutical industry – at the cost of sacrificing equitable access to COVID-19 medical tools.

BILATERAL DEALS INSTEAD OF MULTILATERAL APPROACHES

The Swiss government never replied to Public Eye's open letter of 3 April 2020 requesting Switzerland to support C-TAP, WHO's IP and know-how sharing pool, and to facilitate the issuance of compulsory licensing in case of supply shortages or excessive pricing, as neighbours like France and Germany did.[415] It took the Federal Council more than 4 months to announce its official position on C-TAP, in response to a parliamentary request.[416] Not surprisingly, Switzerland was absent and showed no support when C-TAP was launched on 29 May 2020.[417] Switzerland, host of WHO in Geneva, was also absent from the launch of the ACT-Accelerator initiative on 24 April 2020,[418] despite claiming that it supported the initiative. The Swiss government committed just CHF 20 million to COVAX[419] (the Vaccine pillar of ACT-A) and some CHF 30 million for the other two Therapeutic and Diagnostics pillars.[420] That it clearly favours the bilateral, 'Switzerland-first' approach over the multilateral route is evidenced by its decision to earmark CHF 400 million[421] for pre-orders of COVID-19 vaccines and treatments directly negotiated with manufacturers.

PROTECTION OF INTELLECTUAL PROPERTY RIGHTS AT ALL COSTS

During negotiations of the World Health Assembly COVID-19 resolution in May, 2020, Switzerland opposed the inclusion of "global public good" in relation to COVID-19 vaccines.[422] Switzerland also wanted to remove from the resolution an explicit reference to WTO's Doha Declaration on IP and Public Health (which gives member states legal flexibilities to navigate IP, in particular during health crises).[423] Switzerland is also among the fiercest opponents of a COVID-19 TRIPS Waiver proposed by India and South Africa, which is currently being discussed at the WTO (see Box 15).

INVESTMENT OF PUBLIC MONEY IN BIG PHARMA

Switzerland was among the prime investors in Moderna (National Bank, Pictet), owning 10 % of its capital, and is hosting its operations outside the US. It is not known if the government offered tax advantages for the opening of Moderna's new Basel office, but appears quite likely. Switzerland was one of the first countries to secure a bilateral deal with Moderna, facilitated by Swiss company Lonza, Moderna's manufacturing partner.[424]

ADAPTING LAWS TO ENTRENCH OPACITY AND OPEN THE GATES TO SECRET DEALS WITH BIG PHARMA

Switzerland has a long track record of protecting its powerful pharmaceutical industry. This was seen again in summer, 2020, with the proposed Federal Council amendment to the health insurance law legalising secret rebates for new costly treatments (in particular for cancer). If accepted, information about drug discounts that is generally available today would remain secret and be exempt from Freedom of Information requests.[425] Just one year before, in May 2019, Switzerland had been a vocal supporter of the World Health Assembly resolution WHA72.8 calling on all WHO member states to share real prices (after discounts) with each other.[426] This new move blatantly contradicts Switzerland's international commitments and demonstrates how the Swiss government places pharma's interests above public health.

Box 15

SWISS-BASED BIG PHARMA ROCHE AND NOVARTIS

Apart from Roche, one of the world's leaders in diagnostics (CHF 13.8 billion sales in 2020, +14 %),[427] Swiss pharma giants have not yet been on the frontline during this pandemic, mostly signing manufacturing deals with companies involved in the COVID-19 race. Novartis sold its vaccine division in 2014 to GSK[428] but re-entered the business through its subsidiary AveXis in a collaboration with the Massachusetts Eye & Ear Hospital in a manufacturing deal for a coronavirus vaccine in May 2020.[429] Novartis also sold its remaining Marburg (Germany) vaccine plant to the German BioNtech[430] in October 2020 and finalised an initial agreement to fill and finish the company's mRNA vaccine in Switzerland in January 2021.[431]

In terms of treatments, both companies attempted to repurpose older drugs from their pipelines, albeit with many setbacks. Novartis placed initial bets on hydroxychloroquine but it failed to pass confirmatory trials and WHO strongly recommended against its use.[432] Novartis has also tested two of its anti-inflammatory drugs, Jakavi (ruxolitinib)[433] and Ilaris (canakinumab),[434] for complications in COVID-19 patients, but neither has showed any benefit so far. Roche tested similar drugs in its existing portfolio, Esbriet (pirfenidone) and Actemra (tocilizumab). While the former did not receive much attention, Roche continued testing Actemra in various trial designs and combinations. After mixed results, preliminary data (not yet peer-reviewed) in January 2021 suggested Actemra could help save lives of 1 in 12 intensive care patients with severe COVID-19.[435] In February 2021, a larger trial found Actemra to significantly improve the survival of patients hospitalised with severe COVID-19, shortening hospital stays and reducing the need for mechanical ventilation when used in combination with steroids such as dexamethasone, a cheap generic drug.[436] Roche's persistence has paid off: Actemra sales jumped +32 % in 2020,[437] becoming Roche's fifth-best-selling drug at more than US$3 billion, with nearly US$600 million of that from COVID-19 treatments.[438] The fact that Roche concluded a deal in July with the EU, well before Actemra's efficacy was proven, certainly contributed to this result.[439] The recent findings and authorisation suggest a further boost in sales in 2021. Roche benefited from important public funding for nearly all of the research and testing of Actemra.[440]

Both companies have also teamed up with other companies: Roche with US Regeneron for the production and distribution of its antibody cocktail REGN-COV2 outside of the USA,[441] and with Atea Pharmaceuticals, signing a similar deal worth US$350 million for an oral antiviral drug (AT-527).[442] Novartis has signed a licence agreement with Swiss biotech Molecular Partners for the development and manufacture of two antiviral drug candidates,[443] and a similar deal with Australian-based Mesoblast Ltd. to secure the rights of a stem cell therapy (remestemcel-L) for treating acute respiratory distress syndrome (ARDS) in COVID-19 patients.[444]

Although not front runners in the COVID-19 race, both Roche sales (CHF58.3 billion, +1 % at constant exchange rate[445]) and Novartis sales (US$48.7 billion, +3 %[446]) did more than well in 2020 despite the pandemic's impact on other parts of their operations. Compared to 2019, Novartis increased its core net income after taxes (US$ 13.1 billion, +6 %) while Roche's reached a whopping CHF 17.4 billion (+5 % at constant exchange rate). Both are proposing an increase of 1–2 % in the dividends paid to shareholders.[447] This again highlights that Big Pharma is one of the winners of the COVID-19 race, and has successfully managed to convert into profit some of the public money dedicated to the crisis response. This is set to continue as both Swiss firms have managed to harness their huge manufacturing capacities, thereby securing deals that are potentially profitable in the long term. All of this without risking or investing much of their own capital.

Box 16

BY OPPOSING A TRIPS WAIVER, SWITZERLAND PRIORITISES CORPORATE INTERESTS ABOVE THE RIGHT TO HEALTH

In early October, 2020, afraid of being left behind in the scramble for vaccines, India and South Africa jointly submitted a proposal to waive some provisions of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to enable *"timely access to affordable medical products including vaccines and medicines or to scaling-up of research, development, manufacturing and supply of medical products essential to combat COVID-19".*[448]

If accepted, this so-called 'TRIPS waiver' would facilitate deep technology transfer of effective COVID-19-related vaccines, therapeutics and diagnostic tests by covering patents, copyright, industrial designs, and undisclosed information including know-how and trade secrets.[449] As a temporary waiver, it would apply specifically to the coronavirus situation (only for COVID-19 products and until global herd immunity is achieved), and WTO members could choose whether they want to use it. It has the support of the vast majority of LMICs as well as WHO, UN Human Rights Experts, UNITAID, UNAIDS, members of the European Parliament[450] and hundreds of civil society groups worldwide.[451]

Switzerland and other HICs have opposed the move, arguing that intellectual property (IP) is not an obstacle in this crisis. As detailed in section 2.2 of this report, this argument ignores evidence that the pharmaceutical industry is pursuing its 'business as usual' approach in this pandemic to entrench monopolistic intellectual property (IP) controls over COVID-19 health technologies that restrict scale-up of manufacturing, lock out diversified suppliers, and undermine competition that results in lower prices.

Several rounds of discussions have taken place, but HICs continue to obstruct progress[452] despite clear evidence of IP acting as a barrier during this pandemic.[453] Opponents of the proposal have been promoting myths regarding the impact of IP on COVID-19 technologies[454] and some negotiators claim that HICs are adopting "diversionary" stalling tactics to block it, despite increasing international support (some 100 member states are in support).[455] Consensus had still not been reached by the end of February 2021.[456] Opposition by a handful of HICs is undermining global efforts to control COVID-19 and endangering the lives of billions of people.

While the TRIPS Agreement contains flexibilities that can promote access – an argument that is often put forward by opponents of the waiver like Switzerland – many WTO Members may face challenges in using them promptly and effectively. For instance, compulsory license offers a "product by product", and "country by country" approach with variations in national laws, whereas the pandemic requires collective global action to tackle IP barriers and facilitate technology transfer.

In a recent open letter, Public Eye, Amnesty Switzerland and many other civil society organisations have called on the Swiss government to stop blocking the TRIPS waiver.[457] Several reports in the Swiss media have addressed the issue, but the government is still blocking.[458] By opposing the TRIPS Waiver, Switzerland is putting corporate monopolies before people's life.

"It makes little sense that high-income countries are blocking a proposal at the World Trade Organization that would allow them, and the rest of the world, to get more of the vaccines and treatments we all need."[459] This is especially pertinent now at a time when European countries, including Switzerland, are facing vaccine supply shortages – a direct consequence of Big Pharma's monopolies.

4

Conclusion: what COVID-19 shows us

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The current pandemic is a global health crisis of unprecedented scale with devastating economic and social impacts on people. These are felt everywhere, but nowhere harder than in LMICs. A pandemic, by definition, cannot be controlled nationally; it requires a sustained, consistent and coordinated international effort. What we are witnessing instead is an increasingly inequitable and unequal access to COVID-19 technologies (diagnostics, vaccines, treatments), which is likely to boomerang back on HICs, including Switzerland, in the form of multiple, more contagious coronavirus variants.

Access to life-saving and essential medicines has always been a problem for LMICs. Increasingly, it is also a problem for HICs, whose social security systems cannot afford the monopoly-based prices of pharmaceutical companies that lead to ballooning health expenditures and rationing decisions.[460] These problems are the direct consequence of Big Pharma's greed for profit.

The alarm bells have been ringing for decades, and yet, even as they have become deafening during this COVID-19 pandemic, which has served to magnify an unsustainable and unjust business model, it is business-as-usual for Big Pharma. This report shows that the HIC governments hosting pharmaceutical companies have caved in to the toxic combination of corporate power, public pressure and pharma-instigated fears of scarcity. They have failed to tackle a perverted system and support collaborative and potentially game-changing international efforts like C-TAP. By resorting to vaccine nationalism, they are now struggling with a scarcity that is the logical by-product of the very same patent-based monopoly system they politically enable and protect.

HYPOCRITICAL PLEDGES ALL OVER

This report unmasks as hypocritical the pledges of governments and pharmaceutical companies to collaborate, be transparent, and foster accessibility: in short, their pledge to behave differently this time. It demonstrates how Big Pharma has once again implemented its 10 key strategies, long since exposed by Public Eye and other civil society organisations, to cash in during the COVID-19 pandemic.

Without doubt, the pharmaceutical industry deserves praise for developing several COVID-19 vaccines in record time, although this has often been the result of harnessing the know-how and patents of smaller companies or public institutes. These vaccines should be public goods because they have received colossal public subsidies. Instead, they are being handled like private luxury goods – with the blessing of HICs. It was not intellectual property that enabled the unprecedented international research drive, but rather massive public funding. Today's proprietary system promotes secretive competition over open science, prioritises power games over global public-health impact, and erects barriers to efficient distribution and equal access. The result is that billions of people in LMICs will have a long wait for their vaccine, thus drastically increasing health, economic and social risks, also for HICs. Ironically, and perversely, the pharmaceutical industry has been able to use the current crisis to redeem its bad reputation while cashing in on misery and fear.

Big Pharma should not be in the driver's seat, deciding unilaterally who gets access to lifesaving medical tools and on what conditions. The COVID-19 pandemic has shown with absolute clarity how pharmaceutical companies are gaming an outbalanced system, to devastating effect, and how HIC governments are complicit through their protection of pharmaceutical companies. By allowing pharmaceutical companies to use a government-protected patent system to hoard knowledge and prevent production scale-ups to meet global demand, pharma-hosting HICs have shown their unwillingness to learn from past mistakes.

Health is a human right and medicines save lives. States have a duty to protect human rights, including the right to health. In order to meet this responsibility, they must guarantee access, availability and affordability to life-saving treatments and vaccines. Governments have to actively regulate the pharmaceutical industry because the industry uses massive amounts of public funding to produce and profit from the sale of its medicines. Governments must implement measures and mechanisms that restore their control and enable them to fulfil their duty to protect the right to health.

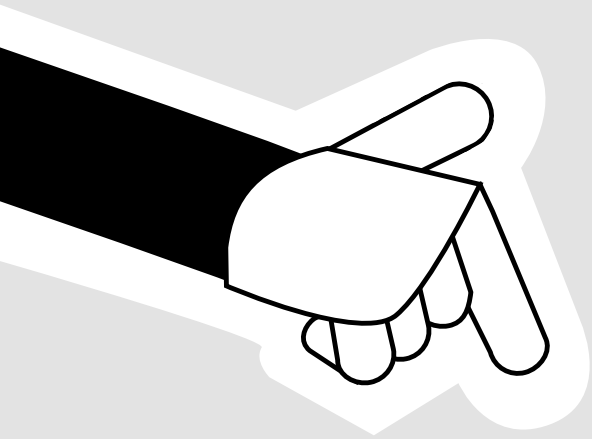
Health is a human right and medicines save lives. States have a duty to protect human rights, including the right to health. In order to meet this responsibility, they must guarantee access, availability and affordability to life-saving treatments and vaccines.

Visions and proposals for change have been discussed by experts and civil society for years: fixing the broken patent system, ensuring that pharmaceutical companies cannot exploit the incentives they are granted, attaching conditions to patent-protected monopolies and public-money investments. The long-overdue decision on and democratic implementation of these and other measures are simply a question of political will.

The developments chronicled in this report represent – so far – an historic opportunity that has been badly squandered. The situation is urgent because the pandemic and its effect on people's health, livelihoods and social lives is far from over. And as long as it lasts, companies can continue to exploit and perpetuate the crisis for profit. COVID-19 seems to be *"simply a new chapter of the same access crisis, caused by the same structural factors that we have been seeing over and over again."*[461] Without reshaping the industry politically through attaching conditions to the privileges granted, HIC governments like Switzerland are perpetuating a devastating global system of privilege and corporate power, failing their own citizens and aggravating global inequality and the right to health of everyone.

5

Time to act: our demands



WE CALL ON THE SWISS GOVERNMENT TO

IMMEDIATELY

- support C-TAP as the global solution for equitable access to COVID-19 medical tools;
- support the TRIPS waiver proposed by India and South Africa allowing countries to temporarily suspend IP rights during the COVID-19 pandemic;
- refrain from further hoarding and unambiguously support the current multilateral mechanism COVAX to tackle equitable distribution of COVID-19 vaccines;
- publish its contracts with pharmaceutical companies for COVID-19 vaccines;

AS A PRINCIPLE

- promote open science initiatives for equitable access to disease prevention, diagnosis, and treatment;
- fully implement the World Health Assembly's transparency resolution on drug pricing (WHA72.8, May 2019), in particular ensuring no secret deals over drug pricing in Switzerland and no exclusions from the Freedom of Information law regarding drug pricing;
- include reasonable pricing and access conditionalities in return for public funding of research and development;
- use the existing TRIPS flexibilities such as compulsory licensing to deal with abusive monopolies.

WE CALL ON PHARMACEUTICAL COMPANIES TO

IMMEDIATELY

- stop taking advantage of the COVID-19 pandemic;
- commit to not enforcing intellectual property (IP) rights during the COVID-19 pandemic, and share all IP and know-how with C-TAP for a rapid scale-up of global production;
- ensure deep technology transfer to other qualified producers with potential manufacturing capacity, including through collaboration with C-TAP;
- make all clinical trial information available, including all protocols, entire clinical study reports and all the raw data;
- abide by the guidance and decision of official health authorities (WHO) regarding the declaration of the end of the pandemic and refrain from all commercially motivated actions to take advantage of the pandemic;
- refrain from exerting pressure to include confidentiality clauses and agree to the publication of vaccine contracts with governments;
- disclose publicly and separately the corporate investment and public funding for the development of COVID-19 technologies to enable a detailed calculation of fair end prices.

Public Eye

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The COVID-19 pandemic is a global crisis with devastating effects on people's lives. Disadvantaged people everywhere, but especially in low- and middle-income countries, have been particularly hard-hit. Wealthier states have snatched up nearly all of the global supply of COVID-19 vaccines, treatments and diagnostics. This inequitable access to life-saving medical tools is due to the artificial scarcity created by the patent-based monopoly system, which high-income countries like Switzerland protect. This is likely to boomerang back on our public health and economic systems, because controlling a pandemic requires coordinated international efforts. No one is safe until everybody is safe.

Unequal access to live-saving medicines has always been a problem in poorer countries. Increasingly, it is also an issue for high-income countries, whose social security systems can no longer afford the excessive drug prices resulting from Big Pharma's unsustainable business model and the complicity of host countries like Switzerland.

This Public Eye report unmasks the hypocrisy of wealthy states and Big Pharma in pledging solidarity during this crisis. It demonstrates how Big Pharma has once again rolled out its 10 key strategies to cash in, relying on massive amounts of public funding while redeeming its bad reputation. States are responsible for protecting the human right to health and must actively shape the pharmaceutical system in order to guarantee sustainable access to lifesaving medical tools. This is a question of political will – visions and concrete solutions exist.

Public Eye (formerly the Berne Declaration) is a non-profit, independent Swiss organisation with around 27,000 members. Public Eye has been campaigning for more equitable relations between Switzerland and underprivileged countries for more than fifty years. Among its most important concerns are the global safeguarding of human rights, the socially and ecologically responsible conduct of business enterprises and the promotion of fair economic relations.

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