ACCESS DENIED

WHAT HAPPENS WHEN BIG PHARMA IS IN THE DRIVER'S SEAT

REPORT 1

EXPLORING EU DECISION-MAKING AROUND THE EU COVID-19 CONTRACT NEGOTIATIONS

GLOBAL HEALTH ADVOCATES

STOP AIDS.

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WITH THANKS TO JOURNALIST PRITI PATNAIK AND A LEGAL RESEARCHER.

About STOPAIDS

STOPAIDS is a UK-based HIV, health and rights network. We draw on our 35-year experience working on the HIV response to support UK and global movements to challenge systemic barriers and inequalities so that we can end AIDS and support people around the world to realise their right to good health and wellbeing.

About Global Health Advocates

Global Health Advocates is a French non-profit NGO whose mission is to carry out political advocacy in France and with the EU institutions to ensure policies and resources are effectively addressing health inequalities. At EU level, GHA advocates for policies to achieve direct and tangible benefits for citizens and society, with a particular focus on research and innovation (R&I) and development policies.

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INTRODUCTION

Pharmaceutical corporations wielded enormous power during the COVID-19 pandemic. Yet, how this power was exercised was often hidden from public view. Governments signed agreements cloaked in secrecy and resisted efforts to disclose more information. Protecting commercial interests often came at the expense of increasing transparency and accountability around pricing, delivery schedules, dose transfer requirements and intellectual property commitments. This is information which could have helped increase global access to COVID-19 vaccines. Secrecy, in short, undermined public health.

This report outlines the circumstances in which the COVID-19 vaccine contract negotiations took place. Key stakeholders who were involved in the negotiations and decision-making shared their insider perspectives for this report.[1] Our analysis explores the level of influence Big Pharma had in steering the EU's decision-making process and how this fuelled global inequalities. We explore how private interests were prioritised; the sidelining of the European Parliament & citizens; and how this impacted the EU's decisions on the COVID-19 contracts and the TRIPS Waiver. This report is followed by a second report, which is a legal review of the contracts themselves.

1. How the EU fuelled global inequalities and put the world at risk

A key consequence of the COVID-19 pandemic has been the exacerbation of global systemic inequalities, most notably those between high and lower income countries.[2] Whilst high income countries largely had widespread access to vaccines and medical countermeasures for their populations, low and middle income countries could not access the same conditions in their fight against COVID-19. This inequity increased preventable infections, deaths and helped to facilitate the emergence of new COVID-19 variants. Indeed, the COVID-19 death toll is four times higher in lower-income countries than high income countries and the pandemic continues to have a devastating impact in communities without wide access to health technologies.[3]

From the beginning of the pandemic, the need to ensure global open access to, and the right to produce and supply COVID-19 countermeasures was widely acknowledged, including by the European Union (EU). The agreement between the European Commission (EC) and Member States on procuring COVID-19-19 vaccines signed on 16th June 2020 states[4]:

> "In the negotiations with the pharmaceutical industry under the present Agreement, **the Commission will promote a Covid-19 vaccine as a global public good.** This promotion will include access for low- and middle-income countries to these vaccines in sufficient quantity and at low prices. The Commission will seek to promote related questions with the pharmaceutical industry regarding intellectual property sharing, especially when such IP has been developed with public support, in order to achieve these objectives. Any vaccines available for purchase under the APAs concluded but not needed and purchased by Participating Member States can be made available to the global solidarity effort."

Even later on in the pandemic, the EC's Communication: 'A united front to beat COVID-19', adopted on 19 January 2021, explicitly states "No one is safe until everyone is safe", which appears in the Communication's section on "Ensuring European Leadership and International Solidarity".[5] Almost three years after the start of the pandemic, there is widespread consensus that the current system has failed to achieve equitable access for all. The Director General of The World Health Organisation (WHO), Dr Tedros Adhanom Ghebreyesus, has labelled the response as a "catastrophic moral failure"[6] and still only 25% of people in low-income countries have received at least one vaccine dose.[7]

We consider that it is clear that it was not global public health considerations that led the global response to the pandemic, but rather commercial, economic and geopolitical considerations. Indeed, global vaccine programmes which aimed to provide access to vaccines to all countries largely failed to fulfil this goal. A key reason for this was the challenges posed by Intellectual Property (IP) rights.[8] Patents prohibit the manufacture, use or sale of an invention without the patent-holder's permission, for a minimum 20-year period.[9]This market exclusivity is meant to incentivise innovation, and in exchange the invention is disclosed and the public is meant to benefit from the innovation. However, in reality patents provide excessive financial rewards to patent holders, mostly large pharmaceutical companies, as the monopoly created by the patent allows high prices to be set. This enabled pharmaceutical companies to block others from producing the same life-saving health technologies.

In this context, it becomes obvious that it could be possible for pharmaceutical companies holding the IP rights to vaccines in a global pandemic to wield enormous power and give significant leverage over Governments and public institutions, like those of the EU.

In the early days of the pandemic, the EU found itself lagging behind the US and the UK when it came to securing vaccine Advanced Purchase Agreements (APAs).[10] However, it quickly caught up, pulling together a negotiating team and investing several billion euros in APAs to secure 4.6 billion vaccine doses. The circumstances under which these agreements were signed, however, have been notably obscure, and shrouded in opacity under the pretext of "commercial interests".[11] The opacity is demonstrated by the significant amount of text that was redacted in the contracts for vaccine procurement that were made publicly available. Global Health Advocates and STOPAIDS carried out a legal review of these contracts, comparing the redacted versions the EC made available with the leaked versions. You can read more about it in our second report, which is a legal review of the COVID-19 vaccine contracts.

The EC's inexperience in procurement for medical technologies and negotiating with pharmaceutical companies is likely to have contributed to the lack of transparency and wider issues with the contracts. Before the COVID-19 pandemic, the EC had no established process or structure to formally negotiate with the pharmaceutical industry, which they traditionally viewed as a partner. A negotiator involved in the procurement of COVID-19 vaccines told us that member states signing up to the idea that the EC will take over procurement was "very unusual".

On a global level, the EU made several statements on the importance of global solidarity during the pandemic, but these statements were not turned into concrete actions. Instead, EU actions translated into an every-country-for-itself attitude, which effectively led to a form of gatekeeping of COVID-19 health technologies.

A striking example of this inconsistency can be seen with the Access to COVID-19 Tools Accelerator (ACT-A). The EU was one of its founders and a global leader in supporting it. ACT-A's COVAX Facility was created to act as the key purchasing agent for the whole world through pooling demand, shaping the market and ensuring equitable distribution of vaccines.[12] However, COVAX largely fell short in delivering its mandate. Instead of using the COVAX self-financing arm for the purchase of vaccines as anticipated, high-income countries pursued bilateral negotiations with vaccine producers. Without there being expanded open licensing for COVID-19 vaccines, this undermined the role of the COVAX initiative and put it at the back of the queue to purchase vaccines. The actions of pharmaceutical companies suggest that they were far more interested in negotiating with desperate high income countries who were ready to accept pharma-imposed terms in order to get access to these vaccines. This had severe consequences for millions of people in low and middle income countries, who are still struggling to gain access to vaccines and other countermeasures. Vaccine inequity also impacted those in higher income countries as new, more transmissible variants emerged. This once again highlights the need for a coordinated response rooted in global solidarity.

While COVAX faced problems in purchasing vaccines, high income countries started to experience over-supply.[13] The EU purchased 4.6 billion vaccine doses, more than 5 times what was needed to fully vaccinate its entire population.[14] At that point, high income governments started to announce they would donate vaccines to lower income countries. By October 2021, out of 1.8 billion doses which were pledged, only 261 million had been delivered (despite an oversupply of doses in developed countries).[15] COVAX encountered severe issues with delivering these donated doses, including in December 2021, when over 100 million doses donated to the initiative by high income countries were refused by recipient countries because they were too close to their expiry date.[16] In June 2022, analysis from the People's Vaccine Alliance revealed that less than half (49 per cent) of the 2.1 billion COVID-19 vaccine donations promised to lower income countries by G7 countries have been delivered.[17] Analysis from Imperial College London found that 599,300 deaths could have been averted in 2021 had 40 per cent of people in all countries been fully vaccinated.[18] The billion missing doses that G7 countries failed to deliver would have been enough to reach this target.

This brings forth the question of why so few doses were donated through COVAX. The answer is two-fold.

Firstly, the vaccine contracts signed between developed countries and pharmaceutical companies, including those signed by the EC, contained stringent clauses on how said doses could be used and donated.[19] These legal restrictions resulted in significant delays in vaccine rollouts in lower income countries. It also contributed to vaccine hesitancy when vaccines became available too late. In a letter from October 2021, the German government lamented that they would miss their target of 100 million doses due to conditions imposed by vaccine manufacturers. German health minister Thomas Steffen stated there were "ongoing bureaucratic and legal problems"[20] imposed by vaccine makers on EU countries wanting to donate surplus, adding that these factors made "a quick response to international requests for help almost impossible".[21]

Secondly, and intrinsically related to the previous point, is the question of liability. Liability is defined as someone being legally responsible for something,[22]and in the case of the contracts, refers to the vaccine manufacturers being held responsible for unforeseen effects. It must be acknowledged that companies were working to an accelerated time-line in an unprecedented situation to produce vaccine doses. There is an argument that companies needed a reasonable amount of liability protection in this circumstance. Yet, it is not clear why the contracts did not provide transparency on all information on the circumstances by which companies or governments could be held liable for any problems that recipients faced, and what the repercussions would be for affected people.

Indeed, even when dose donations were possible, challenges remained around liability concerns. Dimitri Eynikel, EU Policy Advisor and Representative at Médecins Sans Frontières (MSF) explains:

> "When full market authorisation is granted, companies should hold full liability as is normally the case. That this is not the case [here] and what should be a temporary exception risks now being set as a minimum standard. There is a risk pharmaceutical companies will refuse to sell much-needed products unless governments take on the liability. Also, donations did not take off for most of 2021 to a certain extent because of liability. Countries accepting doses did not want to take on or could not afford liability while donating countries did not want to keep liability for donated doses."

In other words, pharmaceutical companies transferred their liabilities to their customers, such as the EU, and these liabilities were also transferred to any lower income countries the EU donated doses to. Members of the European Parliament (MEP) Marc Botenga (The Left, Belgium) described this as "disastrous for vaccine sharing", because most developing countries were not willing to take on this liability.

In a nutshell, EU policy choices to protect the current system fuelled global health inequalities between the Global North and the Global South, putting hundreds of millions of lives at risk.

2.Big Pharma's way or the highway

The problems and consequences outlined in the previous section can be explained through three features that illustrate the relationship between the EU and the pharma industry: an imbalance of power, which leads to secrecy and what some have termed as "threats".[23]

The power held by the pharmaceutical industry is something that has long been acknowledged. This once again came to the forefront of public debates during the COVID-19 pandemic as questions arose on the influence private interests exercise on public decisions.

2.1 Private interests in the fast lane

A historically uneven playing-field

Even before the COVID-19 pandemic, Civil Society Organisations (CSOs) have been raising concerns about the role and power that the pharmaceutical industry has in shaping EU decision-making. After the European Council issued a political recognition[24] of the problems with the current model of 'profits-over-people' in 2016 and asked the European Commission to review its system of incentives, the pharmaceutical industry has substantially increased its lobby machine in Brussels.[25] A proposal for the revision of the basic pharmaceutical legislation is foreseen for early 2023.

An example of the pharmaceutical industry's power over the EU can be seen in the 2019 investigation of Global Health Advocates and Corporate Europe Observatory ""In the Name of Innovation" in health research".[26] This highlights how the pharmaceutical trade association and lobby group EFPIA (European Federation of Pharmaceutical Industries and Associations) steered the agenda and priority-setting of the €2.5 billion in EU public research funds of the Innovative Medicines Initiative (IMI). The investigation finds that instead of using these funds to meaningfully invest in unmet medical needs, the IMI focused on areas that were more commercially profitable for the industry. The prevalence of industry's influence in IMI's governance, finance and accountability structures allowed EFPIA to have enormous power in deciding how these public funds were spent.

RESOURCED TO THE MAX – BIG PHARMA LOBBYING CAPABILITIES

The level of influence of pharmaceutical companies only grew during the COVID-19 pandemic. Lobbying data shows that pharmaceutical lobby groups and companies had extensive access to EU decision-makers. In fact, between January 2020 and September 2022, they held close to 100 meetings with the most senior EC officials.[27] This figure does not account for informal communications such as impromptu phone calls, which do not need to be recorded on the transparency registers. In 2020 and 2021 alone, Big Pharma dedicated over €30 million to EU lobby spending.[28]

As soon as COVID-19 vaccines were developed, there was a frenzy for countries to get access to them. These included EU Member States, who were very keen to try and stem the rise in infections and hospitalisations. A handful of pharmaceutical companies therefore had an upper hand in negotiations, in what was then an emergency context. In order to be more efficient and faster, EU Member States agreed on a joint approach where the EC would negotiate and enter into agreements with pharma companies on their behalf.

Firstly, it is important to note that the EC had no established process or structure to formally negotiate with industry, which it considered "partners" as highlighted by Dimitri Eynikel (MSF). Yet, this term does not accurately reflect the power dynamics which characterised the negotiating process. Eynikel goes on to say:

> "We should not underestimate the leverage the industry has had at the time when Europe needed access to these doses. With overflowing hospitals and a high mortality, all countries wanted doses to get this pandemic under control as soon as possible. Yet, at some point, global access to these tools also turned into competition, not just to save lives but about who's going to be the first to reopen their industry, their markets, their bars, their hairdressers. Vaccines saved lives but could also provide a competitive economic advantage on the global market. I think the industry knew this very well and how to play out this global competition over vaccine supplies to their advantage."

NEGOTIATING – BUT ON BEHALF OF WHO?

Questions have also arisen around the people composing the negotiating team and possible conflict of interest. Indeed, certain lead negotiators from Member States have been found to have close ties to the pharmaceutical industry. The lead of the Swedish negotiating team for example, Richard Bergström[29], was previously Director General of EFPIA until 2016, and has his own consultancy – Bergström Consulting GmbH – whose clients include the Swiss and American pharmaceutical lobbies VIPS and PhRMA. PhRMA members include Pfizer, Sanofi, and Johnson and Johnson[30], which all have COVID-19 vaccine contracts with the EU. This does leave open the possibility of a conflict of interest.

Nowhere is this imbalance of power more evident than in the controversy surrounding the publication of the COVID-19 vaccine contracts. Indeed, the full contracts have not been made available to the public, with the EC instead publishing heavily redacted contracts. It is worth noting that the most heavily redacted contract, that was signed between the EC and Pfizer BioNTech, also belongs to the EU's biggest supplier (2.4 billion doses).[31] Hence, it seems plausible that Pfizer had some control over the redactions.

This was a situation where a corporate entity was able to dictate what a public institution like the EC could and could not disclose to the citizens whose interests it was meant to represent (as our legal analysis of the contracts demonstrates in a detailed manner in Report 2). This was of great concern to several stakeholders, including to the EP.

2.2 No room in the backseat for the public and the European Parliament

> "Transparency in a democratic system enables people to participate more easily in the decision-making process. The institutions can only enjoy greater legitimacy and effectiveness as long as they remain fully accountable to citizens".

Anyone can read these powerful words on the website of the European Parliament (EP). However when we look at the EU's COVID-19 vaccine contracts, this is not exactly how things unravelled. In fact, public knowledge of the specific terms of the contracts was purposely highly limited.

A VEHICLE WITH TINTED WINDOWS

Following the opacity of the COVID-19 vaccine contract negotiating process, the EP began raising questions on the process and how public money was spent in the name of accountability, but also on the content of the contracts themselves.

In 2021, the New-York Times[32] reported that preliminary negotiations between the EC's President, Ursula von der Leyen, and Pfizer CEO Albert Bourla, had been carried out by text message, bypassing all official channels of communication and effectively removing the EC President's actions from public scrutiny.

In January 2022, the European Ombudsman – Emily O'Reilly – criticised how the EC handled a request for public access to text messages between its President and Pfizer, and concluded there was "maladministration" on the EC's part.[33] The EC responded to this request by saying that no record had been kept of such messages[34], but the Ombudsman's enquiry found that the EC had not explicitly asked the President's personal office (cabinet) to look for the text messages.

Ombudsman O'Reilly told us: "Not all text messages need to be recorded, **but text messages clearly fall under the EU transparency law** which states, broadly, that it is the content not the medium that counts when it comes to recording EU documents. My view is that work-related text messages need to be treated as EU documents - registered so that the public can request access to them."

In September 2020, several NGOs[35] as well as MEPs[36] started to submit freedom of information requests to access documents from the EC, in line with their rights under EU Regulation 1049/2001.[37] They sought the names of the negotiators, meeting minutes, access to correspondence between industry and the negotiators or the EC, the reports and minutes of the meetings, and above all: access to the contracts which had been concluded.

Corporate Europe Observatory (CEO) submitted two different freedom of information requests, one for the contracts and one for related documents. Olivier Hoedeman, Research and Campaign Coordinator at CEO shared with us the following regarding their requests:

> "The one for the contracts, we got a rejection very early on and the other one we didn't get a response at all. Maybe the EC felt they had more grounds, legally speaking, for the rejection of the transparency around contracts, while rejecting any access to documents related to the negotiations was a little bit more difficult to justify. So, they just did not respond."

To challenge the EC's behaviour, CEO submitted a complaint to the European Ombudsman.

The Ombudsman then opened an investigation on the refusal by the EC to give public access to the requested documents and the EC's failure to deal with the request in a timely manner. This in turn led to the publication of heavily redacted contracts and a promise to consider making 365 documents related to the negotiations publicly available. Satisfied with the EC response, the Ombudsman closed the inquiry.[38]

Five Green MEPs, on the other hand, were dissatisfied with receiving the heavily blackened documents and went so far as to file a complaint against the EC to the Court of Justice of the EU (CJEU).[39] Tilly Metz, one of the Green MEPs involved with the CJEU complaint told us in an interview[40]:

> "As Members of the European Parliament, it is our role to oversee the use of public money and ensure the interest of citizens is well represented. That is the balance of powers. But as our right was denied, we decided with my colleagues that we would go through all the necessary legal steps to obtain the COVID-19 vaccines contracts"

MEP Michèle Rivasi (Greens, France), who is also part of the team that filed the court case against the EC is of the view that the EC is not in favour of making these contracts public because these have been badly negotiated and have worked against the interests of EU citizens. Green MEPs were not alone in their unhappiness with the EC's handling of the matter. In fact, in October 2021, the EP Plenary adopted a resolution on EU transparency in the development, purchase and distribution of COVID-19 vaccines.[41] This resolution expressed regret for the lack of transparency and called on the EC to take several actions to improve transparency as well as strengthen dialogue with citizens. After unfulfilled promises from the EC to release most of the documents related to the COVID-19 vaccine negotiations, the Ombudsman reopened the investigation in January 2022. This resulted in the publication of additional batches of redacted contracts up until June, after which the second inquiry was closed. However, the Ombudsman requested that the EC share how they had fulfilled their promise to review the redactions of the documents by 18 January 2023. As of January 9th 2023, CEO had received no update on the matter.

ROADBLOCKS AHEAD: "YOU'VE GOT TO BE FRUSTRATED"

In order to examine the European response to the COVID-19 pandemic, the EP established a special committee in March 2022, which they called "COVID-19 pandemic: lessons learned and recommendations for the future"[42] (COVI for short). "The lessons learned can contribute to future action in a variety of EU policy areas," according to the EP. The committee's work[43]focuses on four pandemic-related areas: health; a coordinated response respecting democracy and fundamental rights; the societal and economic impact; and the EU and the world.

Over the past months the COVI Committee has been inviting Commissioners, Member States representatives, experts, and industry to exchange on these four areas. Among the people invited to a hearing was Pfizer CEO, Albert Bourla. MEPs were particularly interested in this exchange, in order to shed light on how the COVID-19 vaccines contracts were struck. Unfortunately, Mr. Bourla pulled out of the appearance a few days before the hearing, following the publication of a report[44] by the European Court of Auditors (ECA) which raised new questions about the way the 3rd contract between the EU and Pfizer was negotiated. "Regrettably, we didn't receive any information on the preliminary negotiations for the EU's biggest contract, which were conducted directly by the president of the European Commission", Joëlle Elvinger, a member of ECA, told the COVI Committee in October.

COVI members were outraged with Mr. Bourla's refusal to appear in front of the Committee. Although Pfizer did send a representative to the hearing, Janine Small, President of international development markets, this did not satisfy COVI members. Pfizer's justification for this last-minute replacement was that she was "best placed to support the committee in meeting their objectives."[45] However, during the meeting in question[46], Ms. Small was grilled on several crucial aspects of the negotiation, including contract and price transparency, IP rights, and access and equity – to name a few.

Her responses were short in providing answers, using statements such as "we have from the beginning engaged in an unprecedented level of transparency throughout the process", to later on say that "I understand your frustration, but we cannot discuss pricing, pricing is confidential." In order to try to get the answers they needed to ensure public scrutiny and accountability, the COVI committee invited Mr. Bourla for a second time to hold an exchange with them. "Since the October hearing, we have no further information to share with the Committee, so we respectfully decline the invitation to again revisit these issues," Bourla wrote in a letter dated December 2022 sent to MEPs, and seen by EURACTIV.[47]

MEP Marc Botenga (The Left, Belgium), a COVI Committee member, gave the following analysis:

> "There was no real transparency in the [contract] negotiations. On the contracts, there have been minor steps forward – under pressure. So, from the first contracts basically the Commission outsourced transparency, meaning we will give you what the company tells us we can give you. You are in a situation where the company decides."

This was not denied by the EC, with DG SANTE's Director General Sandra Gallina acknowledging that the EC favoured transparency, but that it was not possible without the companies' agreement[48] – effectively admitting that the pharmaceutical corporations had the final say in what was shared with the public.[49]

After much back and forth, some MEPs were, however, granted access to the unredacted contracts – but under stringent circumstances. MEP Tilly Metz (Greens, Luxembourg) described the process "I have been able to have a look at the contracts, but you are not allowed to take

your phone with you. You are not allowed to take an adviser with you. You can take some notes, but even at the beginning, that was not clear. Even if I can take some notes, I was observed while looking at this contract. I want transparency for the public, for the journalists, so that we can discuss and analyse." MEPs were given a maximum of 30 minutes in the room where the contracts were kept. It was only in November 2022, after growing pressure, that DG SANTE gave permission to Members of the Committee on Budgetary Control (CONT) to view the EU's vaccine procurement agreements, following similar conditions described above (in a secure reading room, with no cell phones).[50] This is the first time in years that the EC will finally provide the CONT Committee – whose role is to supervise and control use of the EU budget – with the information it needs to fulfil its mandate.

2.3 Very Bad TRIPS

The feeling of unease felt by MEPs as they gained brief access to the unredacted COVID-19 vaccine contracts under strict observation was not the only instance of public representatives feeling uncomfortable. Indeed, it has come to light that the pharmaceutical industry was able to manipulate certain processes to its advantage.

In October 2020, South Africa and India rocked the World Trade Organisation (WTO) in Geneva by seeking a temporary suspension of certain intellectual property rules[51] in a bid to boost manufacturing capacities of COVID-19 health technologies. This came to be known as the TRIPS Waiver proposal. Discussions on the TRIPs Waiver went on for 20 months until a resolution over a narrow legal mechanism was forged at the WTO ministerial conference in June 2022, limited only to COVID-19 vaccines.

Although the EU was providing public statements strongly supporting global solidarity and equal access to COVID-19 tools, behind closed doors, the EU was blocking the TRIPs Waiver proposal at the WTO.[52]The EU eventually offered limited support, perhaps because it was worried about the consequences of opposing the Waiver for its image and the possible public health impact. These concerns became stronger once the newly elected US President, Biden, announced his support to the Waiver. In the end, the EU offered limited support, proposing an alternative text that merely resulted in minor clarifications of existing rules.[53]

However, in the meantime, the EP had passed two concrete resolutions: first asking the EC to negotiate at the WTO, and second lending support to the Waiver proposal put forward by South Africa and India.[54] [55] These positions by the EP revealed two things. Firstly, that the EP was seriously engaging on the matter of temporarily suspending intellectual property rules at the time of a pandemic. Second, it also showed the extent to which the EC did not take into account the EP's position on the matter. MEP van Brempt (S&D, Belgium) told us: "the Commission was very political regarding the Waiver." One of the reasons why Ms. van Brempt believes that happened is because "Amidst the fight for getting vaccines in Europe, they promised to protect intellectual

property rights." For Ms. van Brempt, the EC could have acted on this "by looking at the Parliament as the institution that is the directly elected body and then convince the Council. They did not operate that way in this case."

If this contention proved true (it will be hard to prove it with so much secrecy surrounding these processes) this would have serious implications. It could suggest that industry held the EU to ransom over vaccine procurement in order to have its way on the TRIPS waiver. A second MEP, who asked to remain anonymous, commented on this process:

> "When I say there is a certain crossroad between these two files [Covid-19 vaccine contracts & the TRIPS waiver], I think it lays there. May be also that politicians, national health ministries, promised the vaccine producers and Pfizer, the most important one, that they would defend intellectual property, but they needed to step up their production in Europe. That is how it all happened and Europe didn't close its borders on the vaccines. It did export half of the production in Europe, but I think there is a connection to be made."

Since our interviews were carried out in the summer of 2022, POLITICO reported in its November investigation[56]that several Member States, such as Belgium, had received threatening calls from major pharmaceutical companies, including a call made by a Janssen spokesperson to an adviser of the Belgian Prime Minister warning them that if Belgium decided to support the TRIPS waiver proposal at the WTO, Janssen would likely reconsider its billion dollar research and development investments in Belgium, including in academia.[57] Janssen is a subsidiary of Johnson & Johnson, which provided 200 million of its single dose COVID-19 vaccine to the EU.[58] Furthermore, the same investigation reveals that "EU member countries who benefit economically from a large pharmaceutical industry — such as Germany, Belgium, Italy, France and Denmark — were "very keen" to understand the potential impact of the waiver", as explained by Koen Berden, executive director for international affairs at EFPIA.

CONCLUSION

This report has examined key moments for the EC during the COVID-19 pandemic, including the vaccine procurement and the TRIPS waiver processes. We conclude that the EU was in a position of weakness vis-à-vis the pharmaceutical industry. In an emergency pandemic situation like that of COVID-19, obtaining the lifesaving vaccines was the EU's number one priority, and the industry saw a clear opportunity here. Protecting commercial interests came at the expense of supporting policy interventions that could have increased global vaccine access, and which harmed transparency. With an unaccountable driver, the public were taken for a ride.

In the next report, we conducted a legal review of the vaccine contracts themselves and explored the impact of confidentiality clauses on European and global health. It is essential that lessons are learned from the COVID-19 pandemic to protect global health now, and in future pandemics. Ensuring access, transparency, and accountability are fundamental to bettering the EC's pandemic response. Together, the learnings from these reports have informed a series of recommendations below that decision-makers can implement to increase transparency and protect both public health and democratic spaces.

OUR RECOMMENDATIONS:

1. ACCESS: A CLEAR PATH TO MEDICAL COUNTERMEASURES FOR ALL

1.1 The upcoming revision of the General Pharmaceutical legislation should create a more competitive environment, remove unnecessary barriers to competition and address abuses of the system and unfair practices. In particular, the EU should shorten regulatory protection periods.

1.2 When EU public funding is used to develop biomedical countermeasures, it must be accompanied by access conditions to guarantee the availability, affordability, and accessibility of medical products to all those in need, including to low and middle income countries.

1.3 In the framework of the renewal of the EU Global Health Strategy, the EU and its Member States must take concrete steps to ensure that medical countermeasures are available and accessible and affordable to all.

2. TRANSPARENCY TO AVOID CORPORATE CAPTURE OF EU PROCESSES

2.1 Any future preliminary negotiations held between the EC and pharmaceutical companies before contracts are signed should be conducted in a fully open and transparent manner and using established processes rather than informal channels[R1] [R2] .

2.2 In the future, any official document bearing redactions should list the specific exception under Art. 4 Reg. 1049/2001 (commercial or decision-making) under which it was sought for each individual redaction, rather than for the document as a whole.

2.3 The upcoming revision of the General Pharmaceutical legislation should include specific measures to guarantee transparency of R&D costs in its revised incentives framework in alignment with the WHO Transparency Resolution.

2.4 The EU should champion strong transparency norms in the framework of the proposed WHO Pandemic Accord.

3. ACCOUNTABILITY TO ENSURE PUBLIC INTEREST REMAINS THE PRIORITY IN ALL AGREEMENTS

3.1 DG HERA should abide by high standards of transparency and accountability and disclose in a timely matter all documents related to its work, including past and future contracts, minutes of meetings and R&D agendas. DG HERA should ensure meaningful consultation with all relevant stakeholders. Whilst it should take into consideration a wide variety of interests, it must ensure public interest remains the ultimate priority

3.2 The burden of proof demanded under Reg. 1049/2001, Art. 4, should be reversed, with companies being required to prove that withheld information would damage their commercial interests.

3.3 In the case of a conflict arising between an exception provided for under Reg. 1049/2001 Art. 4 (commercial or decision-making) with the overriding public interest, the latter should prevail.

ANNEX 1: LIST OF INTERVIEWEES

1. Richard Bergström, Swedish Negotiator
2. Marc Botenga, MEP
3. Dimitri Eynikel, MSF Europe
4. Olivier Hoedeman, Corporate Europe Observatory
5. Elizabeth Kuiper, The European Policy Centre (EPC) [Formerly at The European Federation of Pharmaceutical Industries and Associations (EFPIA)]
6. Tilly Metz, MEP
7. Michèle Rivasi, MEP
8. Kathleen Van Brempt, MEP
9. European Commission [spokespersons]
10. EU Ombudsman [Written format]
11. Moderna [Written format]
12. Pfizer [Written format]

ENDNOTES:

1. See Annex 1 for the list of interviewees

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