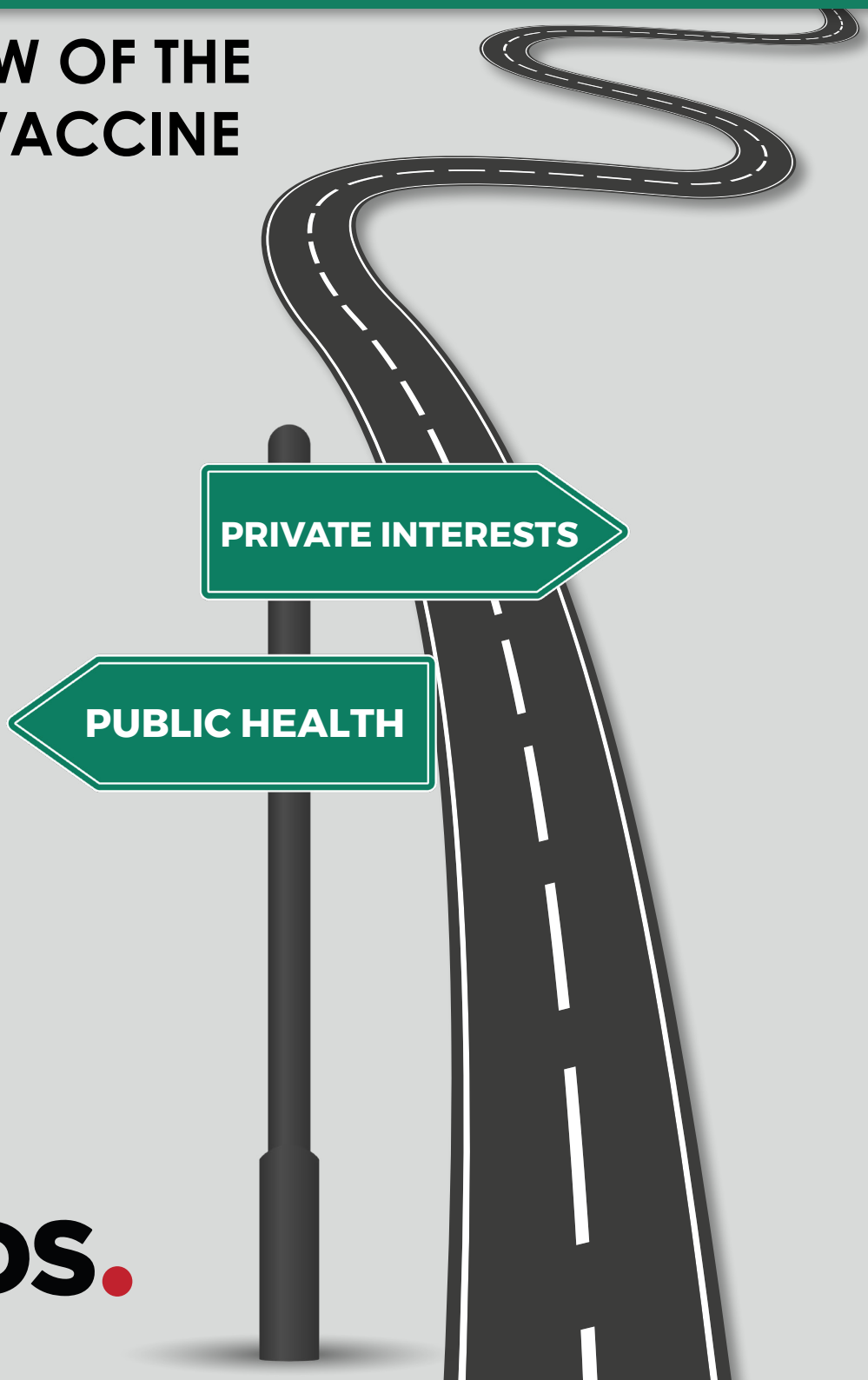
ACCESS DENIED

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

REPORT 2

A LEGAL REVIEW OF THE EU COVID-19 VACCINE CONTRACTS



GLOBAL HEALTH ADVOCATES

STOPAIDS.

WRITTEN BY

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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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THE JOSEPH ROWNTREE CHARITABLE TRUST
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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, information which could have helped increase global access to COVID-19 vaccines. Secrecy, in short, undermined public health.

This second report follows on from the first report ("Exploring EU decision-making around the EU COVID-19 contract negotiations") which takes stock of EU actions during the pandemic. This report, which is a legal review of the COVID-19 vaccine contracts, analyses the clauses and redactions which we consider undermined public health in the name of profit. This specific report was carried out with the support of a legal consultant and contains evidence gathered through a series of interviews conducted by a journalist. This report first looks into the EU legal framework for information disclosure, focusing on provisions potentially relevant to COVID-19 vaccine contracts. Second, it assesses how officials make decisions about redacting information, including on the basis of protecting commercial interests. Then, it reviews how the European Commission (EC) redacted information during the COVID-19 pandemic, comparing the information contained in three redacted and unredacted contracts. Finally, the report analyses legal and policy tools that can be used to challenge contractual secrecy when it undermines public health.

1.Background

1.1 The Legal Framework

Under the Treaty on the Functioning of the EU, EU institutions are required to conduct their work "as openly as possible" to "promote good governance and ensure the participation of civil society."[1] EU residents and citizens have a "right of access" to documents of the European Parliament (EP), European Council (EUCO) and EC.[2]The scope of this right of access is defined by regulations developed by the EP and Council. The EC is required to "ensure its proceedings are transparent" and develop procedures about access to documents based on these regulations.

Regulation 1049/2001 governs public access to EP, EUCO and EC documents.[3] Its purpose is to define disclosure principles and limits "in such a way as to ensure the widest possible access to documents." **The basic presumption is that all documents held by the institutions are public unless an exception applies.**

Documents are broadly defined as any content, whatever their medium, concerning a matter related to the institutions' sphere of responsibilities.[4] Article 4 of Regulation 1049/2001 protects certain interests and lists a series of exceptions to disclosure. Exceptions potentially relevant to COVID-19 vaccine contract disclosures include[5]:

Exceptions include:

COMMERCIAL INTERESTS:

Disclosure is prohibited if it would "undermine the protection of commercial interests of a natural or legal person, including intellectual property…unless there is an overriding public interest in disclosure."

DECISION-MAKING INTERESTS:

- Disclosure of internal documents, or documents received, that relate to a matter where a decision has not been made if it would "seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure."

- Disclosure of documents "containing opinions for internal use as part of deliberations and preliminary consultations within the institution concerned" is prohibited even after the decision has been made if disclosure would "seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure."

The Court of Justice of the European Union has held "as such exceptions depart from the principle of the widest possible public access to documents, they must be interpreted and applied strictly."[6]

There are three aspects of the disclosure regime worth noting. First, ***the commercial interest and decision-making interest exceptions are discretionary. The institutions are prohibited from disclosing documents protecting commercial and decision-making interests identified above unless there is an overriding public interest in disclosure.*** In theory, the institutions can balance the discretionary interests involved and, in cases where the public interest outweighs competing interests, disclose the documents. Courts, however, have narrowly interpreted the public interest provision, limiting its application and curbing transparency.[7] ***Second, the decisional exception only applies for a period during which protection is justified based on the document content.*** Protection can last a maximum of 30 years. The commercial exception can, if necessary, continue to apply after this period.[8]

Finally, under European rules, ***some documents shall be "automatically provided" on request.*** This includes agendas for EC meetings and ordinary minutes of EC meetings, after approval.[9]

1.2 What Gets Disclosed

How does the EC determine which contracts, meeting minutes and other documents get disclosed or redacted? To request documents, individuals can file what is called "an application for public access"[10] (in other jurisdictions, this is known as a freedom of information request). Once the application has been filed, the EC makes the initial determination on what documents to release, and what exceptions apply.

For documents "which [the institution] holds but which originates from a third party", institutions are required to consult the third-party to assess whether an exception applies, unless it is "clear" that the document should or should not be disclosed.[11] ***But the determination is ultimately the responsibility of the EC. It may be required to consult third parties, but it cannot delegate or defer its responsibility.*** Critically, the requirements also apply to documents which the institution "holds but which originates from a third party", so it is not immediately clear whether the EC is required to consult third parties for documents like contracts, which do not originate from third parties but rather represent the product of a joint negotiation.

In order to get discretionary exceptions, the EC must follow two steps. First, the EC must identify if the disclosure of documents would undermine an interest (e.g., commercial or decision-making interests) covered by those exceptions. If the EC refuses access to a document, or if corporations want certain documents to be withheld, they need to show:

> ***how access to that document could specifically and actually undermine the interest protected by that exception, and the risk of the interest being undermined must be reasonably foreseeable and must not be purely hypothetical.***[12]

In some cases, the EC can base its decision on a general presumption of confidentiality that certain categories of documents would undermine the protected interests, without examining specifically and individually each document.[13] This has typically been the case for judicial and administrative procedures, including prohibiting the disclosure of bids submitted by tenderers in a procurement procedure, but no general presumption has been recognised against procurement contracts per se.[14]

Second, the EC must determine whether there is an overriding public interest justifying the disclosure. This requires determining whether there are "specific circumstances" that establish the interest and illustrate how disclosure could protect it. Commentators have criticised how Courts have interpreted the overriding public interest requirement when institutional redactions are challenged, because the burden of identifying specific circumstances is placed on applicants requesting access—who do not have access to the documents.[15]

Once the EC determines not to disclose documents in full or only redacted versions, individuals can challenge the EC's decision by submitting a complaint to the European Ombudsman or to the Court of Justice of the European Union (CJEU). The Ombudsman is an independent body with the power to inspect all documents held by the EC and determine whether its claims are justified on the basis of commercial sensitivities. "I am very alert to these exceptions - such as commercial sensitivity reasons or the protection of personal data - being over-used. I approach this issue from the point of view of citizens and whether there is overwhelming public interest in documents being released. Sometimes there is not but in many cases I challenge the institutions' use of the exemptions under the EU transparency law for not giving out documents", Emily O'Reilly, the European Ombudsman told us in an interview.

1.3 COVID-19 Landscape

The EC has limited the release of COVID-19 contracts, meeting minutes, other documents and, in general, when some of these documents were made available - after consultation with vaccine manufacturers - they included the redaction of key information. In its response to an application requesting access to these documents, ***the EC provided two justifications to limit disclosure: to protect commercial interests, and to protect the procurement process, including decision-making interests.***[16]

According to the EC, the contracts "contain references to sensitive business information of the companies… such as scientific information on the vaccines, their price, the schedule to deploy the vaccines, their production capacity, their know-how, the involvement of experts or partners, business strategies, and other information carrying a commercial value" that could damage the competitive position of the company if disclosed.[17]

In addition, the EC claimed disclosure would undermine competition and the negotiating and procurement process, because it would reveal preliminary views and policy options under consideration.[18] In support, the EC cites parallel European regulations on protecting competition in public procurement.[19] Although it is not clear whether in some cases the EC has considered the public interest, in other cases, the EC says it has not been able to identify a public interest that could override the other interests.[20]

But how does information about price; delivery schedules; rights in intellectual property; dose transfer; product safety and indemnification; and the structure of the legal framework ***specifically and actually*** undermine commercial interests? Can concrete and ***reasonably foreseeable*** risks be identified by the EC?

In order to challenge the EU's decision not to disclose COVID-19 vaccine contracts, Corporate Europe Observatory (CEO) submitted a complaint to the Ombudsman, who acted strongly on it, opening an inquiry on the EC's refusal to give access to these contracts.[21] Emily O'Reilly shared with us the backbone of her thinking on the matter: "it was clear from the outset of that there was an overriding public interest in knowing the terms of vaccine contracts". She stressed that "public administrations can only be effective if citizens trust that their acting in their best interest. Achieving this requires transparent and accountable decision making, particularly during a major public health crisis such as the COVID-19 pandemic." This complaint put the EC under heavy pressure and resulted in the release of the redacted contracts.

What information has been kept secret in the COVID-19 contracts? Below, we review how the EC's opaque position has limited information disclosure.

2.Investigating COVID-19 Contractual Secrecy

In 2021, the Italian public broadcaster, RAI, published unredacted versions of three COVID-19 vaccine contracts.[22] [23] These included EC advance purchase agreements with AstraZeneca, Pfizer, and Moderna. The contracts provide a unique case-study into the terms agreed to by the EC during the COVID-19 crisis. Comparing the full contracts with the redacted versions[24] also helps shine a light on the decision-making of the EC when it came to applying exceptions, and redacting agreements.

We identified seven major[25] categories of redactions, including information associated with:

1.DELIVERIES

2.PRICES

3.RIGHTS IN INTELLECTUAL PROPERTY (IP)

4.PRODUCT DESCRIPTION, FACILITIES, AND KNOW-HOW

5.DOSE TRANSFER

6.PRODUCT SAFETY AND INDEMNIFICATION

7.THE LEGAL FRAMEWORK

We describe each in turn below, and then synthesise key findings.

2.1 Vaccine Contract Case-Studies: AstraZeneca, Moderna and Pfizer

DELIVERIES

Delivery schedules represented some of the most crucial public health information in the pandemic: when would doses start to arrive, and in what quantity? Unfortunately, at the beginning of the pandemic we did not have answers to these questions because vaccine delivery information was redacted by the EC across all three contracts. In the case of AstraZeneca, delayed dose deliveries led to litigation with the EU, which was eventually settled out of court.[26]

On this issue, the Swedish negotiator in the team, Richard Bergström, told us: "we should have been much more suspicious about manufacturing capabilities, which unlike for clinical trials is much more secretive. Manufacturing was internal. We did not know anything. We were caught by surprise by this AstraZeneca debacle."

Redaction Excerpt

MODERNA, I.4.7, DELIVERY:

For Initial Doses

- 10 million doses for Participating Member States in Q1 2021
- 35 million doses for Participating Member States in Q2 2021
- 35 million doses for Participating Member States in Q3 2021

There were two striking features about the redactions on deliveries. First, the redactions were maintained even for historical data, including deliveries that had already occurred, which would otherwise seem to lack any commercial significance. Second, some information about the choices made by the EC itself was redacted. For example, in the Pfizer and AstraZeneca contract, the fact that the doses provided to the EC would be split pro-rata was redacted. The same information was not redacted in the Moderna contract. It was not clear on what basis the EC redacted this decision.

PRICE

Information about pricing was also redacted by the EC across all three contracts. This includes information about the total price, payment schedules, and the intended purpose of the payments. For the Oxford-AstraZeneca vaccine, this included information about calculating the Cost of Goods for the not-for-profit pricing pledge, and determining the end of the pledge period.

Redaction Excerpt

ASTRAZENECA, 9.3, ADDITIONAL DOSES:

AstraZeneca shall provide any agreed Additional Doses at Cost of Goods ***until 1 July 2021, unless AstraZeneca determines in good faith that the COVID-19 pandemic has not ceased as of 1 July 2021, in which case AstraZeneca shall provide any agreed Additional Doses at Cost of Goods until such later date as AstraZeneca determines in good faith that the COVID-19 pandemic has ceased…***

Notably, in contrast to the EC, the United States disclosed COVID-19 vaccine prices in its contracts.[27] In a hearing of the EP Special Committee on COVID-19 (COVI) in October, Janine Small, Pfizer's President of International Developed Markets shared with the EP that "it is important for us all to acknowledge and understand that the redacted information does actually constitute commercially confidential information".[28] A EC spokesperson told us that "it takes two to tango" and that "there are confidentiality clauses and we respect them. That being said, the Commission has always been in favour of transparency. But we need the agreement of the companies." It is surprising that prices are commercially confidential information in the EU, but not in the United States.

RIGHTS IN INTELLECTUAL PROPERTY

Information about IP rights was inconsistently redacted by the EC. In the Pfizer contract, the EC redacted that Pfizer held rights to the IP. The Moderna and the AstraZeneca contract, in contrast, disclosed that the companies retained the rights.

Redaction Excerpt

PFIZER, EXPLOITATION OF RESULTS OF APA, 1.11:

The Commission acknowledges and agrees ***that the Contractor shall be the sole owner of all intellectual property rights generated during the development, manufacture, and supply of the Vaccine or otherwise related to the Vaccine, including all know-how*** (collectively, the "Vaccine IP Rights.") ***The Contractor shall be entitled to exclusively exploit any such Vaccine IP Rights. Except as expressly set forth in this APA, the Contractor does not grant to the Commission by implication, estoppel, or otherwise, any right, title, license or interest in the Vaccine IP Rights.*** All rights not expressly granted by the Contractor hereunder are reserved by the Contractor.

In addition, in the AstraZeneca contract, the EC redacted that AstraZeneca had pre-existing obligations to its upstream licensor (e.g., Vaccitech and University of Oxford).

Mr. Bergström told us that "in the steering board we never talked about intellectual property. It was never discussed." This is surprising because the EC had a clear mandate from Member States to work towards ensuring COVID-19 vaccines as a global public good.

Some people believe that the EC should have discussed liability in the context of intellectual property rights, including MEP Marc Botenga (The Left, Belgium). "If you take the industrial risk, you should also own the Intellectual Property Rights or at least put in the conditions that avoid exclusive licences, whatever legal shape or form, you choose", he said during an interview.

PRODUCT DESCRIPTION, FACILITIES, AND KNOW-HOW

Product characteristics, suppliers, and know-how were redacted in the Pfizer and Moderna contracts. There were three notable redactions. First, the EC kept secret vaccine "specifications", which contain important information about manufacturing requirements that could be helpful to other vaccine producers. Second, the EC redacted information about Moderna's obligation to produce initial doses in European sites. Third, the dose used in the mRNA vaccines was kept secret, even as this was public knowledge.

Redaction Excerpt

MODERNA, DEVELOPMENT TIMELINE; SPECIAL COMMITMENTS, I.45

To produce the Initial Doses, the contractor may not manufacture or have manufactured the Product at manufacturing sites located outside the territory of the European Union, the EEA, or Switzerland without the prior consent of the Commission, which consent may not be unreasonably withheld, conditioned, or delayed if the manufacturing at such sites is required to accelerate the production of the Initial Doses…

The AstraZeneca contained less information about characteristics, suppliers, and know-how, and hence contained fewer redactions.

DOSE TRANSFER

The EC also redacted information about how vaccine doses could be transferred, donated, and/or resold in all three contracts.

Redaction Excerpt

PFIZER, PRODUCT SUPPLY, I.6.2

Each Participating Member State will have the right to resell or donate them to [sic] in need third countries or public institutions, contributing to a global and fair access to the Vaccine across the world. The right to resell or donate excess doses under the preceding sentence shall be subject to the Contractor's consent…

The redactions were striking, in part, because they concealed the EC's own rights to the doses it purchased. Industry was concerned about liability issues: if the doses purchased by the EU were donated to a third country, and an individual in the third-country experienced adverse effects, who would be liable?[29] However, it is not clear why this needed to be secret, particularly since the contractual clauses would later pose significant barriers to the ability of the EC to donate doses and help vaccinate developing countries.[30] (Industry's substantive concerns also could have been addressed without giving it the discretion to unilaterally control donations.)

PRODUCT SAFETY

The EC redacted the most information about product safety and indemnification in the Pfizer and Moderna contract. Information about indemnification was much less redacted in the AstraZeneca contract.

Redaction Excerpt

MODERNA, INDEMNIFICATION, II.5

The Commission, on behalf the [sic] Participating Member States, declares that the use of Products produced under this APA will happen

A Pfizer spokesperson shared with us that "indemnification clauses are often included in contracts with governments for the supply of vaccines during public health emergencies", that "Pfizer seeks indemnity and liability protections in such contracts consistent with the local applicable laws" and that their main focus is "to help countries find solutions which give both sides the comfort that an appropriate balance of risks between the parties has been attained". However, looking at the unredacted COVID-19 contracts that were leaked, it does not seem like there is a balance of risks. Instead, it looks like most of the risk was borne by the EU in a desperate attempt to get access to these vaccines as soon as possible in order to reduce the devastating impact of the pandemic.

STRUCTURE OF LEGAL FRAMEWORK

Finally, the structure of the legal framework was also largely redacted by the EC across all three contracts. The EC redacted information about how certain key terms would be interpreted (definitions); how disputes would be resolved; and the legal liability of the EC and the contractor. Across the contracts, key dates were also redacted, which made it difficult to interpret specific contractual obligations and demand accountability.

In the Pfizer contract, some parts of the confidentiality obligation itself were redacted, underscoring the extent of the secrecy. In addition, the EC was prohibited from disclosing confidential information without the prior written consent of Pfizer. Finally, the contract categorically prohibited member states from disclosing "any of the financial or indemnification provisions contained in this APA." While it is not immediately clear whether the EC was also prohibited from disclosing this information, if this were the case, the bright-line exclusion would be inconsistent with the EC's obligations to balance disclosure of information with the public interest.

Redaction Excerpt

PFIZER, CONFIDENTIALITY, II.9

II.9.1

Neither the Commission, a Participating Member State nor the Contractor shall, at any time, without the disclosing party's written consent, disclose to any third party any of the other party's Confidential Information.

II.9.5

Notwithstanding the foregoing, in all cases, (a) the Participating Member States may not disclose any of the financial or indemnification provisions contained in this APA, including the price per dose of Vaccine or refundability of the Advance Payment or any information that could reasonably ascertain the price per dose of Vaccine, without the prior written consent of the Contractor...

2.2 Secrecy Analysis

When making COVID-19 vaccine contracts available, the EC redacted a huge volume of information related to public health. This information varied in its commercial significance, ranging from information already in the public domain, such as the dosage of the vaccines, to information with more commercial potential, such as manufacturing specifications. In some cases, the EC kept more information secret than other jurisdictions.

While the EC maintains that pricing is commercially sensitive, civil society, as well as members of the EP, have questioned why this is the case given that it has significant implications for countries' procurement budgets. Indeed in 2021 it was reported that South Africa was paying more than double the EU's price for the Oxford-AstraZeneca vaccine.[31] Greater price transparency would allow lower income countries to secure fairer prices. Corporations may argue that the disclosure of the EU price would undermine commercial interests across other markets, because other purchasers may want EU pricing if it is favourable. But that risk appears hypothetical—not reasonably foreseeable nor demonstrable in practice. It also stands in stark contrast to the U.S. example, where the government made the price public for COVID-19 vaccines.

The EC also withheld information that was not related to the reasons it used to justify secrecy. For example, ascertaining contractor obligations was difficult in the redacted contracts because details around dates and time periods were redacted, yet it is unclear how this protected commercial interests or the procurement process. It was also not clear on what basis information was kept secret about purely EU decisions, such as the decision to distribute doses on a pro-rata basis.

One of the most striking features of the redactions was their arbitrariness: information that was redacted in one contract was not redacted in another, suggesting that the EC was not neccessarily making independent, consistent judgments as to whether certain categories of information met Article 4 exceptions and, instead, may have deferred to the preferences of pharmaceutical corporations. This arbitrariness raises questions about the EC's procedural independence, which may violate Regulation 1049/2001. According to the General Court, the EC itself is expected to make the determinations about Regulation 1049/2001: "Ultimate responsibility for the proper application of that regulation lies with the EU institution and it is also for the latter to defend the validity of a decision refusing access to documents emanating from a third party before the Courts of the European Union or the Ombudsman."[32]

The broad use of non-disclosure agreements and confidentiality clauses may also undermine Regulation 1049/2001. While some of these clauses are common in business deals, the EC is a public entity. If the EC contractually agrees to disclose confidential information only with the consent of the contractor, it is de facto entering into commitments for corporations to effectively veto Regulation 1049/2001, where corporations could allow certain information to be kept out of the public domain, even if there was an overriding public interest.

Across the three contracts analysed, the Pfizer contract was the most significantly redacted. This is consistent with prior analysis finding that Pfizer exercised its power to extract significant concessions from governments[33], including the EC. It is also consistent with the findings of the first report "Exploring EU decision-making around the EU COVID-19 contract negotiations" published together with this legal analysis. The first report highlights the imbalance of power in the relationship between the EU and the industry and its implications during the COVID-19 pandemic.

The EC also claims that disclosure would undermine the "decision-making process of the Commission, as it would reveal preliminary views and policy options, which are currently under consideration."[34] However, the decisional exception only applies for a period during which protection is justified based on the document content. When the contract is signed, by definition, the decision-making has already taken place, and secrecy cannot be justified with respect to the particular contract. The risks to the decision-making for future contracts appear purely hypothetical.

Although there has been considerable pressure on the EC to publish COVID-19 vaccine contracts in their entirety, these contracts have only been published with heavy redactions. Advocates have already articulated a number of specific and compelling public interest reasons for contract disclosures[35] and several Members of EP have filed a complaint to the European Court of Justice challenging contractual secrecy.[36] "We took the EC to court because we say it is about public interest and you own it to us, you are obliged to be transparent or at least we have to define very precisely how are commercial interests really at risk", said MEP Rivasi during a COVI Committee meeting in October 2022.[37]

CONCLUSION

This report has reviewed a selection of COVID-19 vaccine contracts made between the EC and pharmaceutical companies. It has outlined the EU legal frameworks for information disclosure, redaction of information and protection of commercial interests and analysed how the EC redacted information during the pandemic.

Our analysis found that the EC accommodated industry requests on several matters, from pricing, liability, transparency, to intellectual property. It is noteworthy that the EC was more secretive regarding these types of information than other state actors. Withheld information was often arbitrary, inconsistent, and not related to the exceptions invoked under existing law to justify secrecy. The EC also agreed to extensive confidentiality requirements with pharmaceutical corporations that may not be fully consistent with EU legislation. We provided Pfizer, AstraZeneca and Moderna the opportunity to react to the claims across the reports but we did receive a response.

Overall, given the lack of publicly available information, it is difficult to assess whether the EC redacted more information in pandemic contracts compared to other kinds of contracts. However, it is clear that the public health emergency allowed pharmaceutical corporations to wield significant power. Desperate for timely doses, governments may have agreed to have terms that otherwise would have been rejected, or at least been the subject of longer negotiations, including demands for more secrecy. As one official told the Telegraph, "It's still a seller's market. As a result, a lot of manufacturers have been able to dictate their conditions to a large extent."[38]

When the EC was given the mandate to negotiate COVID-19 vaccine contracts by member states in June 2020, one objective was to promote global access:

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 [sic] these objectives.[39]

A lack of transparency meant that it was difficult to assess that the EC was failing to meet this objective — until it was too late. Lives were lost, and variants emerged[40], but contractual secrecy was preserved and pharmaceutical companies steered the direction of the EU's COVID-19 response. The same mistake cannot be repeated for the next health crisis.

The conclusions of this report, together with learnings from the first report in this series, have informed a series of recommendations 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.

ENDNOTES:

1. Article 15. TFEU ("In order to promote good governance and ensure the participation of civil society, the Union's institutions, bodies, offices and institutions shall conduct their work as openly as possible."). Available at: https://www.legislation.gov.uk/eut/teec/article/15

2. Non-residents and non-citizens of Member States can also request documents, but they cannot file a complaint with the European Ombudsmen. However, they may pursue judicial action. Article 1, Detailed rules for the application of Regulation (EC) No 1049/2001 of the European Parliament and of the Council regarding public access to European Parliament, Council and Commission documents.

3. Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32001R1049.

4. Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32001R1049. However, the European Ombudsmen has criticised the Commission for restrictively interpreting this provision in the inquiry into the text messages between the head of Pfizer and the President of the Commission. See Ombudsman inquiry on Commission President's text messages is a wake-up call for EU (July 13, 2022). Available at: https://www.ombudsman.europa.eu/en/press-release/en/158303 ("The Ombudsman inquiry revealed that the Commission did not explicitly ask the President's cabinet to look for text messages. Instead, it asked her cabinet to look for documents that fulfil the Commission's internal criteria for recording – text messages are not considered to meet these criteria. The Ombudsman found that this amounted to maladministration and asked it to do a more extensive research for the text messages.")

5. There are also other non-discretionary exceptions, like public security, but those appear less relevant to COVID-19 vaccine contracts. Article 4. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32001R1049

6. Judgement of the Court (Grand Chamber) of 4 September 2018, ClientEarth v European Commission, EU:C:2018:660, paragraph 78. Available at: https://curia.europa.eu/juris/document/document.jsf?text=aarhus&docid=205322&pageIndex=0&doclang=en

7. Daniel Wyatt. (2020) The Anaemic Existence of the Overriding Public Interest in Disclosure in the EU's Access to Documents Regime, 21 German Law Journal 686–701. Available at: https://www.cambridge.org/core/journals/german-law-journal/article/anaemic-existence-of-the-overriding-public-interest-in-disclosure-in-the-eus-access-to-documents-regime/8F3FDC72C71789AA4C1555B659A5F039

8. Article 4.7. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32001R1049

9 . Article 9 Detailed rules for application of Regulation (EC) No 1049/2001 of the European Parliament and of the Council regarding public access to European Parliament, Council and Commission documents. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001D0937&from=FR

10. Document Request, European Commission Register of Documents. Available at: https://ec.europa.eu/transparency/regdoc/index.cfm?fuseaction=fmb&language=en. Non-residents and non-citizens of Member States can also request documents, but they cannot file a complaint with the European Ombudsmen. However, they may pursue judicial action. Detailed rules for application of Regulation (EC) No 1049/2001 of the European Parliament and of the Council regarding public access to European Parliament, Council and Commission documents. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001D0937&from=FR

11. Article 4.4. Available at: Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32001R1049

12. Judgement of the Court (Fourth Chamber) of 22 January 2020. PTC Therapeutics International Ltd v European Medicines Agency, Case C-175/18 P, EU:C:2020:23, paragraph 57.

13. Id at 59. ("The objective of such presumptions is thus the possibility, for the EU institution, body, office or agency concerned, to consider that the disclosure of certain categories of documents undermines, in principle, the interest protected by the exception which it is invoking, by relying on such general considerations, without being required to examine specifically and individually each of the documents requested.")

14. European Commission, How to Access Commission Documents. Available at: https://ec.europa.eu/info/about-european-commission/service-standards-and-principles/transparency/freedom-information/access-documents/how-access-commission-documents_en, ("According to the Courts, a general presumption of non-disclosure applies for documents relating to ongoing EU pilot procedures; ongoing infringement and audit cases; state aid cases; competition cases; documents sent by national competition authorities; merger cases; fraud (OLAF) investigations; court cases; bids submitted by other tenderers in a procurement procedure; grant proposals submitted by other candidates; written questions asked in staff selection procedures.) See also, Judgment of the General Court (Sixth Chamber) of 21 September 2016. Secolux, Association pour le contrôle de la sécurité de la construction v European Commission., Case T-363/14, EU:T:2016:521 ("The case-law has established the existence of a general presumption according to which that access to the bids submitted by tenderers would, in principle, undermine the interest protected.")

15. Daniel Wyatt, The Anaemic Existence of the Overriding Public Interest in Disclosure in the EU's Access to Documents Regime, 21 German Law Journal 686–701 (2020). Available at: Available at: https://www.cambridge.org/core/journals/german-law-journal/article/anaemic-existence-of-the-overriding-public-interest-in-disclosure-in-the-eus-access-to-documents-regime/8F3FDC72C71789AA4C1555B659A5F039. See e.g., Secolux, Association pour le contrôle de la sécurité de la construction v European Commission., Case T-363/14, EU:T:2016:521 ("It is, however, for the party requesting access to refer to specific circumstances to establish an overriding public interest which justifies the disclosure of the documents concerned.")

16. Response to Request for APA. Available at: https://www.asktheeu.org/de/request/request_for_access_to_advance_pu ("It is also in the interest of the Union and in line with applicable EU legislation, to protect the tendering process, not only for reasons linked to contractors' commercial interests, but also because disclosing sensitive business information would weaken the position of the Commission in the negotiations that are currently being held with other companies, thus nullifying the beneficial effects of fair competition.")

17. Response to Request for APA, Ref. Ares(2021)3684121 - 04/06/2021. Available at: https://www.asktheeu.org/de/request/8791/response/31931/attach/html/2/Partial%20negative%20reply%20GESTDEM%202020%207063.pdf.html

18. Response to Request, Ref. Ares(2022)117753 - 07/01/2022. Available at: https://www.asktheeu.org/de/request/8562/response/34967/attach/html/2/Fair%20solution%20proposal%20GESTDEM%202020%205436%20and%20GESTDEM%202021%200559.pdf.html

19. Response to Request, Ref. Ares(2021)3684121 - 04/06/2021. Available at: https://www.asktheeu.org/de/request/8791/response/31931/attach/html/2/Partial%20negative%20reply%20GESTDEM%202020%207063.pdf.html

20. Subject: Your application for access to documents – GESTDEM 2020/5436 and GESTDEM 2021/0559. Available at: https://www.asktheeu.org/de/request/8562/response/30558/attach/html/3/Reply%20Gestdem%202020%205436%20and%20GestDem%202021%200559%201%204%204.pdf.html ("In all cases where documents are only partially released or published because full disclosure would undermine the protection of one of the interests referred to in Art 4 of Regulation 1049/2001, should the interest in question cease to warrant the protection afforded by that provision, the Commission will review and adjust the corresponding redactions as needed."). See also, Response to Request for APA, Ref. Ares(2021)3684121 - 04/06/2021. Available at: https://www.asktheeu.org/de/request/8791/response/31931/attach/html/2/Partial%20negative%20reply%20GESTDEM%202020%207063.pdf.html

21. Decision in joint cases 85/2021/MIG and 86/2021/MIG on the European Commission's refusal to give public access to documents concerning the purchase of vaccines against COVID-19. (2021) Available at: https://www.ombudsman.europa.eu/en/decision/en/141706

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