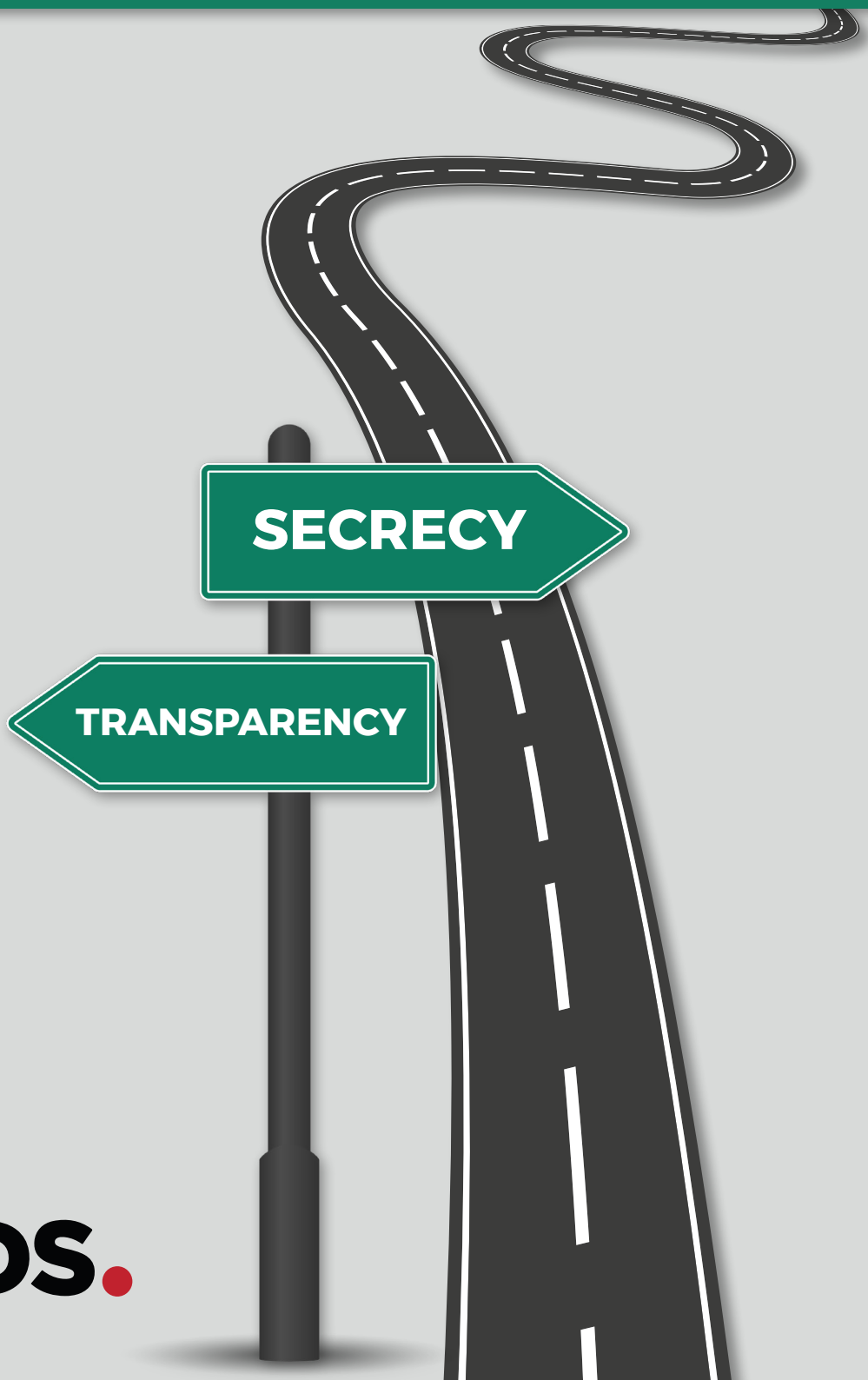
ACCESS DENIED

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

EXECUTIVE SUMMARY



GLOBAL HEALTH ADVOCATES

STOPAIDS.

WRITTEN BY STOPAIDS & GLOBAL HEALTH ADVOCATES

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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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3 YEARS ON, the COVID-19 pandemic has officially caused the deaths of over 6 million people, disrupted global livelihoods and continues to have a devastating impact on communities without widespread access to health technologies. The pandemic has re-emphasised the flaws in the existing global system for the research, development and dissemination of health technologies. As of June 2022, only 30% of World Health Organisation (WHO) Member States had reached the WHO's 70% target of vaccine coverage.[1] In low-income countries, just 37% of healthcare workers had received a complete course of primary vaccination.[2]

The pandemic also further exposed the power imbalance between the pharmaceutical industry, governments, and the public. Health technologies are an essential tool for our society's health and survival, yet important decisions around their research, manufacturing, and pricing happen behind closed doors.

The pandemic was a crucial test for EU decision makers to fulfil their public health responsibilities, to steer their national responses to deliver a swift journey out of the pandemic, whilst also working to ensure a concerted global effort to deliver an equitable response. However, when it came to this journey, industry was not just in the vehicle but may have been actually behind the wheel, and the route to ending the pandemic grew longer as pit-stops for commercial interests were made. The extent to which industry was steering EU decision making was hidden from public view.

The EU signed agreements cloaked in secret and resisted efforts to disclose any information. Protecting commercial interests, we argue, came at the expense of transparency around pricing, delivery schedules, dose transfer requirements, and intellectual property commitments that could have helped increase global access to vaccines. Secrecy, in short, hurt public health. With an unaccountable driver, the public have been taken for a ride.

This report series commissioned by ***STOPAIDS*** and ***Global Health Advocates*** (GHA) explores how a lack of transparency in the pharmaceutical industry and the EU has harmed public health outcomes[3]. Through legal and investigative research, the series uncovers the lack of transparency and sets out recommended legal and policy options to ensure those whose responsibility it is to protect the public interest in general and public health more specifically are back in the driver's seat. Through this, the series investigates the clauses and redactions in contracts which we argue undermined public health in the name of private interests; investigates the influence that the pharmaceutical industry exerted on decision making; and outlines the consequences of these decisions.

These two reports highlight how the pharmaceutical industry, not the EU, was often in the driver's seat for the bloc's response to COVID-19. On 17 June 2020, the European Commission (EC) presented the EU Vaccines Strategy to accelerate the development, manufacturing and deployment of vaccines against COVID-19.[4] In order to achieve the Strategy's second objective of "securing timely access to vaccines for Member States and their population while leading the global solidarity effort", the EC signed 11 contracts with eight vaccine manufacturers providing access to up to 4.6 billion vaccine doses at an expected total cost of close to €71 billion.[5] These contracts have never been made fully available to the public, despite them being honoured with public money.

A GLOAL SOLUTION NEEDED

The COVID-19 pandemic was global, and therefore demanded a global solution. The EU originally advocated for global solidarity in its pandemic response, and for vaccines to be considered as public goods.[6] However, it has largely abandoned its global solidarity approach. A lack of transparency meant that it was difficult to assess whether the EU was failing to meet their global objective — until it was too late. Lives were lost, and variants emerged, but contractual secrecy and industry interests were preserved.

Whilst the EC did fulfil its objective of ensuring that the EU had vaccines in sufficient numbers, the process through which the negotiations and establishment of the COVID-19 vaccine contracts between the EC and the pharmaceutical industry was carried out has come under increased scrutiny and criticism.

The process' lack of transparency has been criticised by several stakeholders, including by the European Court of Auditors (ECA). The ECA found that most contracts signed by the EC lacked specific provisions to address supply disruptions, and that procurement processes could have been more scrutinised. Even they, it seems, "did not receive any information on the preliminary negotiations for the EU's biggest contract".[7] The EU's biggest contract, with Pfizer/BioNTech, has raised many questions, from politicians in EU capitals[8] as recently as December 2022, but also by the European Ombudsman[9], and by Civil Society Organisations.

To make matters worse, Pfizer's CEO Albert Bourla has twice refused to appear in front of the European Parliament's (EP) COVI committee to answer questions about how the contract negotiations were carried out[10], an odd decision for a company who claims to be "very transparent".[11]

Finally, the European Public Prosecutor's Office (EPPO) confirmed in October of 2022 that it has opened an investigation into the acquisition of COVID-19 vaccines in the EU, in part motivated by the "extremely high public interest" generated by the affair.[12] Although the EPPO hasn't disclosed exactly who is under investigation and why, the office possesses several legal powers that the Ombudsman and the ECA lack.[13] In addition, the EP's COVI Committee is preparing its report on the lessons learned and recommendations for the future, and the EC is publishing soon its legislative proposal for the revision of the EU general pharmaceuticals legislation.

WITH INDUSTRY INFLUENCE SEEMING TO LEAD TO SOME CAR CRASH DECISIONS,

GHA and STOPAIDS have conducted two analyses to understand what happened, how it happened, and why it happened. This document is structured in two parts:

IN THE FIRST REPORT,

we set the scene, by speaking to key actors and stakeholders who were involved in or following the contract negotiations.

IN THE SECOND REPORT,

we ran a legal review of the contracts and analysed the pattern of redactions.

We find that whilst industry influence existed even before the pandemic, this influence was magnified at a time when the continent was desperate to vaccinate its population in the face of a new virus.[14] This resulted in accommodating 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 conclude with a Call to Action, outlining some proposed recommendations on Access, Transparency, and Accountability, to reclaim control of EU public decision making when it comes to public money, and ultimately - our health.

RECOMMENDATIONS:
ON THE ROAD TO RECOVERY

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. World Health Organisation (2022) Vaccine equity. Available at: https://www.who.int/campaigns/vaccine-equity

2. Ibid

3. See Report 1 :Exploring EU decision-making around the EU COVID-19 contract negotiations, and Report 2: A legal Review of the EU COVID-19 vaccine contracts. Available at: https://www.ghadvocates.eu/access-denied-what-happens-when-big-pharma-is-in-the-drivers-seat/

4. Euroepan Commission (2020) Vaccines Strategy. Available at: https://commission.europa.eu/strategy-and-policy/coronavirus-response/public-health/eu-vaccines-strategy_en

5. European Court of Auditors (2022) EU COVID-19 vaccine procurement Sufficient doses secured after initial challenges, but performance of the process not sufficiently assessed. Available at:https://www.politico.eu/wp-content/uploads/2022/09/12/SR-19-2022-COVID-19-vaccine-procurement.pdf

6. European Commission (2022) Von der Leyen on Coronavirus Global Response: World stands united against coronavirus and will win. Available at: https://ec.europa.eu/commission/presscorner/detail/en/ac_20_811

7. European Court of Auditors (2022) EU COVID-19 vaccine procurement Sufficient doses secured after initial challenges, but performance of the process not sufficiently assessed, page 29. Available at:https://www.politico.eu/wp-content/uploads/2022/09/12/SR-19-2022-COVID-19-vaccine-procurement.pdf

8. Martuscelli, Bencharif (2022) 'Von der Leyen's COVID vaccine deal comes under fire from EU capitals' 9th December. Available at: https://www.politico.eu/article/ursula-von-der-leyen-covid-vaccine-deal-under-fire-eu-capitals/

9.Holmgaard Mersh (2022) 'EU watchdog: Commission's lack of will to find texts with Pfizer boss is a wake-up call' 14th July. Available at: https://www.euractiv.com/section/coronavirus/news/eu-watchdog-commissions-lack-of-will-to-find-texts-with-pfizer-boss-is-a-wake-up-call/

10. Bencharif (2022) 'Pfizer boss refuses to testify to EU Parliament COVID panel — again' 5th December. Available at: https://www.politico.eu/article/pfizer-coronavirus-albert-bourla-europea-union-refuses-testify/

11. Special Committee on COVID-19 pandemic. (2022) Meeting on 10/10/2022. Available at: https://multimedia.europarl.europa.eu/en/webstreaming/special-committee-on-covid-19-pandemic_20221010-1430-COMMITTEE-COVI

12. European Public Proscecutor's Office (2022) Ongoing EPPO investigation into the acquisition of COVID-19 vaccines in the EU. Available at: https://www.eppo.europa.eu/en/news/ongoing-eppo-investigation-acquisition-covid-19-vaccines-eu

13. https://www.politico.eu/article/ursula-von-der-leyen-pfizer-eu-prosecutors-office-opens-investigation-into-covid-vaccine-purchases/

14. See Report 1 :Exploring EU decision-making around the EU COVID-19 contract negotiations, and Report 2: A legal Review of the EU COVID-19 vaccine contracts. Available at: https://www.ghadvocates.eu/access-denied-what-happens-when-big-pharma-is-in-the-drivers-seat/