



ADVANCED PURCHASE AGREEMENTS FOR COVID-19 VACCINES ANALYSIS AND COMMENTS

Pascale Boulet, Ellen 't Hoen, Katrina Perehudoff, Kaitlin Mara & Ernest Tan

**Advanced Purchase Agreements for Covid-19 vaccines:
Analysis and Comments**

Study for The Left in the European Parliament



B-1047 Brussels, Belgium
+32 (0)2 283 23 01
left-communications@europarl.europa.eu
www.left.eu

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This paper was prepared by Pascale Boulet, Ellen 't Hoen, Katrina Perehudoff, Kaitlin Mara & Ernest Tan



FOREWARD

THE COVID-19 PANDEMIC has changed our societies and daily lives, and the economic crisis caused by the virus has been unprecedented. In our personal lives, many of us and our loved ones have been faced with personal tragedies. Currently, the eyes of the world are on vaccines as they are essential to overcome the pandemic.

In June 2020, the European Commission was given a mandate to negotiate on behalf of the European Union's Member States on advance purchase agreements (APAs) with pharmaceutical companies developing and producing Covid-19 vaccines. Following, the APAs were signed behind closed doors between the companies and the European Commission. Although billions of euros of public funds were allocated to these contracts, they have not received proper public scrutiny. The European citizens and even fellow legislators at the European Parliament have been able to see mere censored versions of the APAs that leave the reader with more questions than answers.

This is not how democracies should work, especially in times like this and in a matter so important. We, The Left at the European Parliament, see that the pandemic is not a reason to undermine our democratic institutions. Quite the contrary, we see that the Covid-19 pandemic and its consequences calls for the expansion of our democracies in Europe and a need for true global solidarity. More than ever, there is a need for a transparent public debate about our institutions and their future development.

This study, commissioned by The Left in the European Parliament and carried out by Medicines Law & Policy, a research group working in the public interest, aims to popularize some of the key content of the APAs and to bring them under the public debate they deserve. It provides tools for the general public to understand the APAs and the choices made while negotiating them. The study shows that the APAs are more than mere technical papers, but documents full of political choices that have an effect on our daily lives and the future development of our societies. They could have been drawn otherwise by emphasizing more the public interests of European citizens and global solidarity, instead of the financial gains of Big Pharma.

This study is a part of a wider campaign led by The Left in the European parliament on #VaccineEquality. It is a call for Covid-19 vaccines and treatments to be treated as global common goods accessible to everyone, everywhere. The campaign is a rallying call for civil society and citizens across Europe placing equality and solidarity at the core of the European response to the Covid-19 pandemic. Another Europe is possible!

**on behalf of The Left MEPs in the European Parliament
Environment, Public Health and Food Safety Committee (ENVI)**

TABLE OF CONTENTS

EXECUTIVE SUMMARY	8
SUMMARY POINTS:	9
1. INTRODUCTION: ADVANCED PURCHASE AGREEMENTS IN THE EUROPEAN UNION	10
1.1. WHAT ARE ADVANCED PURCHASE AGREEMENTS? WHY IS IT IMPORTANT TO UNDERSTAND THEM?	10
1.2. APAS AND PUBLIC GOODS IN THE EUROPEAN UNION	10
1.3. HOW APAS WERE OBTAINED AND ANALYSED FOR THIS RESEARCH PAPER	11
2. COMPANY PROFILES	16
2.1. ASTRAZENECA	16
2.2. CUREVAC	16
2.3. MODERNA	17
3. ANALYSIS OF THE APAS, BY THEME	19
3.1. SUBJECT OF THE AGREEMENT	19
3.2. TRANSPARENCY	20
3.3. PRICING	22
3.4. INDEMNIFICATION FOR LIABILITY	24



3.5. DELIVERY CONDITIONS	28
3.6. PRODUCTION LOCATION REQUIREMENTS	28
3.7. GLOBAL PUBLIC GOOD	31
3.8. INTELLECTUAL PROPERTY	33
3.9. PAYMENT SCHEDULE & CONDITIONS (INCLUDING DOWN PAYMENT)	36
3.10. PAYBACK OBLIGATIONS	37
3.11. TOTAL PAYMENT AMOUNT	38
3.12. ACCESS-RELATED PROVISIONS	39
4. CONCLUSIONS AND RECOMMENDATIONS	41
4.1. SUMMARY POINTS AND POLICY RECOMMENDATIONS:	42
ANNEX A: KEY PROVISIONS IN THE APAS: SUMMARY TABLE	44
ANNEX B: LINKS TO APAS	56
ANNEX C: GLOSSARY	57



ABBREVIATIONS & ACRONYMS

APAs	Advanced Purchase Agreements
AZ	AstraZeneca
BRE	Best Reasonable Efforts
CoGs	Cost of Goods
CMA	Conditional Marketing Authorisation
EU	European Union
FOIA	Freedom of Information Act
IP	Intellectual Property
IPPPR	The Independent Panel on Pandemic Preparedness Response
GMP	Good Manufacturing Practices
OUI	Oxford University Innovation
MA	Marketing Authorisation
R&D	Research and Development
TRIPS	Trade-Related Aspects of Intellectual Property Rights Agreement
USG	United States Government
WHO	World Health Organization
WTO	World Trade Organization
MS	EU Member States

EXECUTIVE SUMMARY

Advanced Purchase Agreements (APAs) were part of a strategy to provide upfront financing for Covid-19 vaccines and to accelerate their development and availability. Since the beginning of the pandemic, governments have spent at least €93 billion on COVID-19 vaccines and therapeutics globally¹. It is the correct public policy response to use public financing to ensure pandemic products are developed rapidly and become available equitably.

APAs can help do this by de-risking company investments in an often-costly research and development process, through upfront payments to speed R&D and through the promise to purchase products when they come to market.

At the beginning of the pandemic, European leaders promised that the Covid-19 vaccines would be global public goods² – that is, they would benefit all. “None of us will be safe until everyone is safe,” said European Commission President Ursula von der Leyen³. The promotion of Covid-19 vaccines as a global public good as a ‘negotiating directive’ was included in the agreement between the Commission and the EU Member States, which is attached to some of the APAs.

This paper examines the texts of several APAs to determine, to the extent possible, if the conditions in the contracts themselves are likely to ensure that this public goods goal is met. Of the 5 contracts the authors were able to obtain for this paper (4 APAs and one research and development funding contract, all of which are linked in Annex B), 3 were heavily redacted, which was a key challenge in the assessment.

In particular the paper looks at the APAs conditions along twelve themes, chosen for their particular significance to achieving widespread, rapid, and equitable access to the vaccines resulting from those contracts. They are:

1. Subject of the Agreement
2. Transparency
3. Pricing
4. Indemnification for liability
5. Delivery conditions
6. Production location requirements
7. Global Public Good
8. Intellectual property
9. Payment schedule & conditions
10. Payback obligations
11. Total payment amount
12. Access-related provisions

For an overview of each of these themes and a brief explanation on why they are relevant, see section 1.3.

¹ <https://healthpolicy-watch.news/81038-2/>

² Marc Botenga, “A Covid-19 vaccine must have a ‘global public good’ guarantee”, EURACTIV, 25 June 2020. Available online: <https://www.euractiv.com/section/health-consumers/opinion/a-covid-19-vaccine-must-have-a-global-public-good-guarantee/>

³ <https://www.who.int/news-room/commentaries/detail/a-global-pandemic-requires-a-world-effort-to-end-it-none-of-us-will-be-safe-until-everyone-is-safe>

SUMMARY POINTS

The APAs analysed focussed on de-risking company investments which offered the companies significant benefits. For example, production capacity that has been created with upfront funding for manufacturing scale-up is a permanent benefit because it will stay with the company after the APA expires. And financing for vaccine development costs, if spent, does not have to be paid back in case a product is not successful (nor is compensation due in case of significant profit from selling the product). In exchange, there is no demand to share the data and knowledge generated. These assets also stay with the company without requiring they be shared, licensed for use, or co-owned in the public interest.

The need for greater transparency was also a key takeaway. For example, none of the agreements disclose the price the EU's health systems will pay for the vaccines. The public is asked to trust that these agreements are for the public's benefit but independent scrutiny of that claim is not possible. The same is true for the companies' stated commitments. For example, AstraZeneca has committed to "no-profit, no loss" for the duration of the pandemic (but retained the right to decide when the pandemic ends). It would be important for the Commission to verify this claim and communicate the result to the public.

While the European Commission and a number of EU Member States have made public commitments to pursue Covid-19 vaccines as global public goods, as far as we have been able to verify, the term global public good does not appear in the APAs, including in the agreements available in full.

As to the question of who owns the IP, all agreements with the EC are clear that the IP – including know-how and data – remains in the hands of the company. Therefore, the Commission either has not attempted to follow the negotiating directive or was rejected in its efforts by the companies. Either way, the result represents a breach of lofty public promises, with consequences not just for Europe but globally.

The growing inequity in vaccine access around the world has been described by the head of the WHO as 'vaccine apartheid'⁴. Nine companies are expected to turnover \$190 billion in Covid vaccine sales in 2021 with products that have been mostly developed with public financing⁵. It would therefore also be important for the private sector to disclose their contribution to the development of the vaccines. As the agreements analysed in this paper demonstrate, the public sector has made significant upfront contributions to the development and availability of Covid-19 vaccines. It would be good to be able to assess if the private sector contributed their fair share.

Concrete policy recommendations are made in Chapter 4: Conclusions and policy recommendations.

⁴ <https://www.reuters.com/business/healthcare-pharmaceuticals/world-has-entered-stage-vaccine-apartheid-who-head-2021-05-17/>

⁵ <https://www.bloomberg.com/news/newsletters/2021-05-29/a-190-billion-covid-vaccine-bonanza>

INTRODUCTION: ADVANCED PURCHASE AGREEMENTS IN THE EUROPEAN UNION

This chapter delves into what Advanced Purchase Agreements are and why they are important to understand both generally and in the specific context of the European Union under the Covid-19 pandemic. It then briefly outlines the research methodology this paper has used to gather and analyse the APAs, including some comments on the limitations caused by redactions in publicly released texts. This paper is a policy analysis based on a reading of the APA texts that was available. The information provided is not meant to be formal legal advice.

1.1. WHAT ARE ADVANCED PURCHASE AGREEMENTS? WHY IS IT IMPORTANT TO UNDERSTAND THEM?

Advance Purchase Agreements (APAs) are so-called ‘pull’ incentives, meant to encourage and de-risk companies’ investments to develop and produce products for which society has a need. APAs are mostly applied in areas where the market does not provide enough ‘pull’ incentives to enlist a company to make the necessary investments. For example, APAs were proposed in the early 2000’s to encourage investment into the development of products needed in global health and for which the ‘market failed’, such as for medicines to treat HIV in children⁶.

APAs de-risk what is normally the function of a commercial company, namely to invest in the development and the production of a product, by committing to spend public money on the innovation before it is developed. Commercial companies invest in the development and production of products they believe will turn a profit once it hits the market. This process can be risky. If the compound fails in clinical trials or it turns out there is no one interested in purchasing the product, the investment will be lost or the return on investment low. APAs take the risk out of this process by giving a clear, financial commitment that the product, once on the market, will indeed be bought. In other words, an APA guarantees a market even when a product is not available yet. In some cases, an APA also offers direct financing for the development of a product. The latter is also the case for

Covid-19 vaccines that are available or being developed for the EU market: companies were offered advanced payments to increase the speed and scale of Covid-19 vaccine late stage development and manufacturing. For some public purchasers, the Covid-19 pandemic was the first time they made an APA for vaccines that were not yet proven effective⁷.

APAs hold benefits for the company but also come with conditions under which the money must be spent and the products delivered. They are important to understand because the specific terms and conditions can have profound impact on how quickly, how widely, and how affordably the medical products they concern are made available. Those conditions are of particular importance to understand in a pandemic context, where speed, equitable distribution, and fair pricing are essential to ending the spread of the disease.

1.2. APAS AND PUBLIC GOODS IN THE EUROPEAN UNION

European Governments and the European Commission have made public statements about basic principles that should rule the development of Covid-19 vaccines; in particular, several European leaders have promised that in return for public investment, future vaccines would benefit the public good.

For example, Commission President Ursula von der Leyen promised that any future vaccine would be “our universal, common good.” Chancellor of

⁶ Michael Kremer, Adrian Towse, and Heidi Williams: Briefing Note on Advance Purchase Commitments. DFID Health Systems Resource Centre, 4 April 2005. Available online: <https://www.heart-resources.org/wp-content/uploads/2012/09/Briefing-note-on-APC.pdf>
⁷ <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2020.02012>

Germany Angela Merkel and France's President Emmanuel Macron both support the idea of a vaccine as a "global public good"⁸.

This commitment to promote Covid-19 vaccines as global public goods is contained in the European Commission's mandate to negotiate APAs on behalf of its Member States. It derives from an agreement between the Commission and EU Member States on procuring Covid-19 vaccines, which was signed on 18 June 2020⁹. From the EU's website, the Commission "entered into Advance Purchase Agreements with individual vaccine producers on behalf of Member States. In return for the right to buy a specified number of vaccine doses in a given timeframe and at a given price, the Commission financed a part of the upfront costs faced by vaccine producers from the €2.7 billion Emergency Support Instrument¹⁰. This funding is considered a down-payment on the vaccines that Member States purchase."¹¹ In an annex titled 'Initial considerations', the agreement details the following directive for the negotiations with pharmaceutical companies:

"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 [meet] 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"¹².

The agreement between the Commission and the EU Member States is annexed to some APAs with vaccine producers. One would therefore expect the terms and conditions of the APAs to reflect the stated negotiation objectives of the Commission to promote Covid-19 vaccines as global public goods and access to the vaccine both equitably throughout Europe as

well as in low- and middle-income countries. It is important to analyse the APAs to assess whether and how these public statements have been translated into terms and conditions of the APA.

1.3. HOW APAS WERE OBTAINED AND ANALYSED FOR THIS RESEARCH PAPER

The texts of several APAs have now been made public, though most of them are partially redacted. This research paper analyses, to the extent possible, 4 APAs and one funding contract: 3 APAs entered into by the EU, one by the UK, and one R&D funding contract between the US and Moderna. The difference between the APAs and the funding contract is that the latter is solely focused on supporting technology development; the former explicitly commit to purchasing the products resulting from the technology development process. The partially redacted EU agreements were released on the European Commission's website¹³. However, the unredacted agreements between the EU and Moderna and the EU and AstraZeneca have been made available in full from other sources, notably thanks to the work of Italian investigative journalists working for the Radiotelevisione Italiana (RAI), the public television.

Redactions include: prices, payment and delivery schedules, local production requirements, aspects of intellectual property, liability and indemnification. There are no references to global public goods, except indirectly in the annexed EC/MS agreement, despite early public commitments to them.

This paper looks at the terms and conditions of these APAs with a view towards analysing, to the extent possible, the degree to which they are likely to ensure equitable access to Covid-19 vaccines. To supplement missing information, the authors have used information about the agreements available from other publicly available sources, when relevant, to help further illuminate the issues.

8 Marc Botenga, "A Covid-19 vaccine must have a 'global public good' guarantee", EURACTIV, 25 June 2020. Available online: <https://www.euractiv.com/section/health-consumers/opinion/a-covid-19-vaccine-must-have-a-global-public-good-guarantee/>

9 European Commission, ANNEX to the Commission Decision on approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures, Brussels, 18.6.2020 C(2020) 4192 final. Available online: https://ec.europa.eu/info/sites/default/files/annex_to_the_commission_decision_on_approving_the_agreement_with_member_states_on_procuring_covid-19_vaccines_on_behalf_of_the_member_states_and_related_procedures.pdf

10 https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/emergency-support-instrument_en

11 https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en#documents

12 European Commission, ANNEX to the Commission Decision on approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures, Brussels, 18.6.2020 C(2020) 4192 final. Available online: https://ec.europa.eu/info/sites/default/files/annex_to_the_commission_decision_on_approving_the_agreement_with_member_states_on_procuring_covid-19_vaccines_on_behalf_of_the_member_states_and_related_procedures.pdf

13 https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en#documents

In particular the paper looks at the APAs conditions along twelve themes, chosen for their particular significance to achieving widespread, rapid, and equitable access to the vaccines resulting from those contracts. They are:

1. *Subject of the Agreement*: What is being agreed between parties; for example, an APA makes product procurement commitments before the product is developed and available. It may also provide upfront funding for either development of the product and/or the scale-up of manufacturing capacity for the product. Agreements that include upfront funding can give leverage to negotiate conditions that aid access, such as sharing of the funded technology.
2. *Transparency*: Transparency can aid public procurement, especially where it concerns the costs of research and development, marketing costs, and sales revenues. Transparency of what is in the contracts themselves facilitates public accountability, which is especially important in cases (as with these APAs) where significant public funds have been spent.
3. *Pricing*: This is the amount agreed to be paid in return for the purchased goods (i.e., the price per dose of vaccine). Price can be an important factor in widespread access. Transparency on how prices are calculated can also add to public accountability, as it allows assessment on how public resources are being spent.
4. *Indemnification for liability*: This refers to releasing manufacturers from claims resulting from unforeseen harms caused by their products. In the case of an urgent need (as in a pandemic), manufacturers are being asked to speed the process of research, development, and provide products before full regulatory approval is obtained. The time normally allotted for testing is shorter, and in many cases vaccines currently in EU markets have been approved with shorter timescales for emergency use. Indemnifying manufacturers makes them more likely to get products to market sooner.
5. *Delivery conditions*: This sets the number of doses and a timeline for their receipt, as well as provisions for what happens in case of delay or failure. The strength of delivery conditions may determine the degree to which companies can be held responsible for failing to deliver promised vaccines under promised timelines.
6. *Production location requirements*: APAs might specify where a vaccine needs to be produced. The need for localised production capacity to meet national and regional needs, especially in emergency situations, is being increasingly recognised, and is one of the reasons that technology, know-how and intellectual property sharing mechanisms have been proposed at the World Health Organization, and an intellectual property waiver has been proposed at the World Trade Organization.
7. *Global Public Good*: The term 'Global Public Good' has been used by multiple world leaders during the Covid-19 pandemic, in recognition of the fact that a pandemic is by definition not over for anyone until it is over for everyone. The commitment to global public goods is meant to ensure the public benefits from public funding. The public policy objective to make Covid-19 vaccines global public goods is specifically mentioned in the agreement between the European Commission and Member States.
8. *Intellectual property*: The vaccines that are the subject of the analysed APAs are subject to a range of intellectual property rights. These govern who has the right to manufacture and sell the vaccines. Who has access to the IP rights of technologies developed under the APAs can have significant consequences for access, for example if the EU were granted rights to use or share any intellectual property and data developed under the APAs as opposed to if they remain fully under the control of the relevant company.

9. *Payment schedule & conditions:* Payment schedule determines when and under what conditions money will be distributed; the APAs analysed contained many upfront payments intended to speed development and manufacture of vaccines.
10. *Payback obligations:* These define what funding must be returned against non-delivery or abandonment of the promised product or development project. Depending on the balance struck in specific conditions, these payback obligations can both be an encouragement to deliver on time and in full, or an unintentional gift to companies.
11. *Total payment amount:* This is the maximum payout of an APA, and describes the amount of funding being mobilised under these contracts.
12. *Access-related provisions:* These refer to any provisions that could contribute to global access to vaccines, such as if and how excess doses can be shared with countries outside the agreement, or pricing arrangements that favour access.

These themes were chosen in consultation with The Left. Each of the above provisions are addressed in individual sections in chapter three, with the specific provisions contained in each APA outlined in a summary table at the top and comments on their relevance to access in following narrative text. A full summary table of all relevant provisions in all APAs is contained in Annex A.

• BOX 1: CONTRACTS ANALYSED IN THIS PAPER

- This paper looked at 5 different contracts, including 4 Advanced Purchase Agreements and one R&D Funding contract. The R&D funding contract was specifically to support the development of new technologies; the APAs by contrast also commit to purchasing the products resulting from technology development. The 5 contracts are:
- **EU-AstraZeneca:** This is an Advanced Purchase Agreement for the production, purchase and supply of 300 million doses of a vaccine for distribution within the EU by end June 2021, with an option to order an additional 100 million. The vaccine was granted conditional marketing authorisation in the EU on 29 January 2021¹⁴, as the third such approved vaccine in the EU after Moderna (see below) and BioNTech/Pfizer, which received conditional authorisation on 21 December 2020¹⁵. Supply under this agreement has proven to be a challenge, and on 18 July 2021 the Belgian Court ordered AstraZeneca to “urgently deliver” 50 million doses under a new binding schedule¹⁶. The APA is available both redacted, from the European Commission’s website, and unredacted, from Italian news outlet RAI. The agreement was finalised on 27 August 2020. Links are below.
https://www.rai.it/dl/doc/2021/02/19/1613725900577_AZ_FIRMATO_REPORT.pdf
- **EU-CureVac:** This is an Advanced Purchase Agreement for 225 million vaccine doses, with an option to order an additional 180 million doses after marketing authorisation, for the procurement of a vaccine which is still under development. The purchase will be triggered once the vaccine receives marketing authorisation in Europe. It is only available in redacted form from the EC’s website. The agreement was finalised on 19 November 2020. Link is below.
https://ec.europa.eu/info/sites/default/files/curevac_-_redacted_advance_purchase_agreement_0.pdf
- **EU-Moderna:** This is an Advanced Purchase Agreement for the procurement of 80 million vaccine doses, with an option to order 80 million more (an option that had to be activated by end 2020). On 15 December 2020, the EU decided to indeed purchase the 80 million additional doses¹⁷, and on 17 February 2021 the EC approved a second contract purchasing 150 million doses in 2021, amended on 22 June 2021 to add an additional 150 doses to be delivered in 2022¹⁸. The Moderna vaccine was granted conditional marketing authorisation in the EU on 6 January 2021¹⁹, as the second such approved vaccine in the EU, after BioNTech/Pfizer (see above). The APA is available both redacted, from the European Commission’s website, and unredacted, from Italian news outlet RAI. The agreement was finalised on 25 November 2020. Links are below.
https://www.rai.it/dl/doc/2021/04/17/1618676613043_APA%20Moderna__.pdf
- **UK-AstraZeneca:** This is an Advanced Purchase Agreement for the procurement of 100 million doses of a vaccine granted conditional marketing authorisation in the UK on 30 December 2020. The APA is available only in redacted form at the link below, though the authors of this study originally obtained it thanks to work from investigative journalists at Politico²¹. The agreement was finalised on 28 August 2020. Link is below.
<https://www.contractsfinder.service.gov.uk/Notice/SupplierAttachment/77bb967f-0194-452a-bdae-9999aecc753d>

¹⁴ https://ec.europa.eu/commission/presscorner/detail/en/ip_21_306

¹⁵ https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2466

¹⁶ https://ec.europa.eu/commission/presscorner/detail/en/IP_21_3090

¹⁷ <https://ec.europa.eu/info/sites/default/files/commission-decision-implementing-advance-purchase-agreements-covid-19-vaccines.pdf>

¹⁸

https://ec.europa.eu/commission/presscorner/detail/en/mex_21_3146

¹⁹ https://ec.europa.eu/commission/presscorner/detail/en/ip_21_3

²⁰ <https://www.gov.uk/government/news/oxford-universityastrazeneca-covid-19-vaccine-approved>.

See also here for the conditions around that approval: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/963841/AZ_Conditions_for_Authorisation_final_23.02.21.pdf

²¹ Thanks to journalist Anna Isaac from The Independent (formerly Politico) for sending ML&P a copy of the UK-AstraZeneca APA. Her article with Jillian Deutsch looking at differences between the UK and EU AstraZeneca contracts is here: <https://www.politico.eu/article/the-key-differences-between-the-eu-and-uk-astrazeneca-contracts/>.

- **US-Moderna:** This is an R&D funding contract between the US Health and Human Services department and Moderna, which supported early stage development of the Moderna vaccine without any commitment to purchase any resulting product. Specifically, the agreement provides financial support for pre-clinical, phases 2 and 3 clinical testing, chemistry, manufacturing and control development, and scale-up of manufacturing capacity for 100 million doses by 2021. While not part of the funding contract, the US Government has indeed purchased from Moderna: As of 16 June 2021, the US had ordered 500 million doses from the company²². The vaccine later received emergency use authorisation in the US on 18 December 2020²³. The agreement was finalised on 16 April 2020. Link is below.

<https://www.hhs.gov/sites/default/files/moderna-75a50120c00034.pdf>

²² [https://investors.modernatx.com/news-releases/news-release-details/us-government-purchases-additional-200-million-doses-modernas#:~:text=%2C%20\(Nasdaq%3A%20MRNA\)%20a,vaccine%20candidates%20from%20Moderna's%20pipeline](https://investors.modernatx.com/news-releases/news-release-details/us-government-purchases-additional-200-million-doses-modernas#:~:text=%2C%20(Nasdaq%3A%20MRNA)%20a,vaccine%20candidates%20from%20Moderna's%20pipeline).
²³ <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine>

- **Brazil-AstraZeneca:** This is a Memorandum of Understanding between AstraZeneca and Brazilian research institute the Oswaldo Cruz Foundation (Fiocruz) covering technology transfer and production of the AstraZeneca vaccine in Brazil. While it was not part of the full analysis in this paper, we include a box on it in section 3.12, on access-related provisions, as it has interesting language on local production and regional sales. It was released, unredacted, from FioCruz itself. The agreement was finalised on 31 July 2020. Link is below.

https://medicineslawandpolicy.org/wp-content/uploads/2021/06/MOU_Fiocruz_AZUK_sigilo2.pdf

• BOX 2: VACCINES DISCUSSED IN THIS REPORT

- There are many types of Covid-19 vaccines under development or approved for use, using several different mechanisms of action to train the immune system to respond to SARS-CoV-2. Early vaccine technology often relied on attenuated or inactivated viruses; that is, viruses that had been modified so as to reduce their infectious properties, or killed. These less virulent versions of infectious pathogens allow the immune system to learn to recognise harmful viruses and more easily destroy them if encountered in the future. Vaccines to treat Covid operate off the same principle – that is, training the immune system to recognise and more easily destroy Covid.
- Interestingly, some of the first and most effective vaccines to market for Covid-19 represent new technological innovations in preventing infection. In particular, this paper discusses agreements covering two new types of vac-

cines, which both make use of small pieces of genetic material to prime the immune system to fight off Covid infections by training it to recognise a 'spike protein' that is characteristic of SARS-CoV-2. They include: RNA Vaccines: A ribonucleic acid (RNA) vaccine, or messenger RNA (mRNA) vaccine makes use of a natural ability of the cells: The ability to translate a single-strand of genetic code (the mRNA) into an antigen that can be used in an immune response. The Moderna and CureVac vaccines are mRNA vaccines.

- Viral Vector Vaccines: Viral vector vaccines also use the cell's ability to make antigens, but differ from mRNA vaccines in that they use a harmless virus to deliver the nucleic acid to the cells. The AstraZeneca vaccine is a viral vector vaccine, which is in particular using a weakened 'adenovirus' [which causes the common cold] to deliver antigen-making instructions to the cells²⁴.

²⁴ A helpful video on these and other types of vaccines for the treatment of Covid-19 is available from the GAVI Alliance, here: <https://www.gavi.org/vaccineswork/there-are-four-types-covid-19-vaccines-heres-how-they-work>

COMPANY PROFILES

This paper looks at contracts between various governments (the European Commission (on behalf of EU Member States), the United Kingdom, and the United States) and three different companies: AstraZeneca, CureVac, and Moderna. Profiles of the three companies including their overall product specialisation, revenue increases during 2020 when available, and their Covid-19 relevant product, are included below. This is useful background information to understand the significance of the agreements signed with these companies.

2.1. ASTRAZENECA

Overview: AstraZeneca is an Anglo-Swedish multinational pharmaceutical company²⁵, headquartered in Cambridge, England²⁶. AstraZeneca is traded on the London, Stockholm and Nasdaq exchanges²⁷. AstraZeneca's total revenue increased by 9% to \$26.617 million in 2020²⁸.

Product specialisation: It is stated on AstraZeneca's website that it has a "focus on the discovery, development and commercialisation of prescription medicines in Oncology and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology".

Covid-19 relevant product: The Oxford/AstraZeneca vaccine (codenamed AZD1222) is an adenovirus-vec-tored vaccine²⁹. It was provided a conditional marketing authorisation (CMA) in January 2021 by the European Medicines Agency (EMA)³⁰. AstraZeneca has also committed to supply Europe with up to 400 million doses of its COVID-19 vaccine, though there have been challenges meeting delivery (see section 3.5 below)³¹. In June 2020, AstraZeneca licensed the

Serum Institute of India to produce 1 billion doses of its vaccine for low- and middle-income countries³². AstraZeneca's vaccine can be stored and transported at normal refrigerated temperatures of 2-8°C, making it easier to transport compared to vaccines which require ultra-cold storage³³.

Public investment in the vaccine development: Public funding accounted for 97.1-99.0% of the funding towards the R&D of ChAdOx and the Oxford-AstraZeneca vaccine³⁴.

2.2. CUREVAC

Overview: Founded in 2000³⁵, CureVac is a NASDAQ-listed³⁶ biopharmaceutical company headquartered in Germany³⁷. Its revenue in the same nine-month period increased by 304% from €10.6 million in 2019 to €42.8 million during the first nine months of 2020³⁸.

Product specialisation: Messenger RNA (mRNA) technology (specifically its proprietary technology involving the use of non-chemically modified mRNA for prophylactic vaccines, cancer and antibody

25 European Pharmaceutical Review, "AstraZeneca", <https://www.europeanpharmaceuticalreview.com/organisations/astrazeneca/>

26 AstraZeneca, "Contact Information", <https://www.astrazeneca.com/investor-relations/annual-reports/annual-report-2016/contact-information.html>

27 AstraZeneca, "FAQs", <https://www.astrazeneca.com/investor-relations/faqs.html>

28 AstraZeneca, "What science can do - AstraZeneca Annual Report and Form 20-F Information 2020",

https://www.astrazeneca.com/content/dam/az/Investor_Relations/annual-report-2020/pdf/AstraZeneca_AR_2020.pdf

29 Tonya Villafana, "AstraZeneca COVID-19 Vaccine (AZD1222)", January 27, 2021, <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-01/02-COVID-Villafana.pdf>

30 European Medicines Agency, "Vaxzevria (previously COVID-19 Vaccine AstraZeneca)",

<https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca>

31 Reuters, "AstraZeneca agrees to supply Europe with 400 million doses of COVID-19 vaccine", June 13, 2020,

<https://www.reuters.com/article/us-health-coronavirus-vaccines-idUSKBN23K0HW>

32 Kyle Blankenship, "The Serum Institute of India", December 8, 2020, Fierce Pharma,

<https://www.fiercepharma.com/special-report/top-10-manufacturers-fight-against-covid-19-serum-institute-india>

33 Kyle Blankenship, "AstraZeneca hopes warmer storage needs for COVID-19 vaccine will be an advantage against mRNA competitors", November 23, 2020, Fierce Pharma,

<https://www.fiercepharma.com/manufacturing/astrazeneca-hopes-warmer-storage-needs-for-covid-19-vaccine-will-be-advantage-against>

34 Samuel Cross, et al. Who funded the research behind the Oxford-AstraZeneca COVID-19 vaccine? Approximating the funding to the University of Oxford for the research and development of the ChAdOx vaccine technology. medRxiv, 10 April 2021. Available online: <https://doi.org/10.1101/2021.04.08.21255103>

35 CureVac, "History. How it all began", <https://www.curevac.com/en/about-us/historie-rework/>

36 Ludwig Burger, "CureVac says well on track to request vaccine approval as planned", May 5, 2021, Reuters,

<https://www.reuters.com/business/healthcare-pharmaceuticals/curevac-says-well-track-request-vaccine-approval-planned-2021-05-05/>

37 CureVac, "CVnCoV, CureVac's mRNA-based vaccine candidate against COVID-19", <https://www.curevac.com/en/covid-19/#timeline>

38 BioSpace, "CureVac Announces Financial Results and Business Updates for the Third Quarter and First Nine Months of 2020", November 30, 2020,

<https://www.biospace.com/article/curevac-announces-financial-results-and-business-updates-for-the-third-quarter-and-first-nine-months-of-2020/>

therapies, and rare disease treatment)³⁹. Notably, CureVac claimed to be the first to be granted a patent for the manufacturing process of in vitro transcribed RNA⁴⁰.

Covid-19 relevant product: CureVac's 'CVnCoV' is an mRNA COVID-19 vaccine⁴¹. The European Medicines Agency (EMA) started a rolling review of CVnCoV in February 2021⁴², and CureVac's chief executive said in May 2021 that it is on track to file for European approval⁴³. Novartis, GlaxoSmithKline, Bayer, and several other companies have also joined CureVac's European vaccine manufacturing network to help it produce CVnCoV⁴⁴. CureVac claims that its use of non-modified mRNA in the vaccine closely mimics the natural immune response to COVID-19⁴⁵. Another advantage is that unlike the Pfizer/BioNTech vaccine (also an mRNA vaccine), the CureVac vaccine does not require ultra-cold refrigeration for storage⁴⁶. The European Commission signed a contract to purchase up to 405 million doses of CVnCoV⁴⁷.

Public investment in the vaccine development: CureVac has received the following financial support for the development and production of its Covid-19 vaccine: 300 million Euro from the German Federal government⁴⁸, 75 million Euro loan from the European Investment bank supported by Horizon 2020⁴⁹, the EC's R&D fund, and earlier \$13.5 million from the Coalition for Epidemic Preparedness Innovations, for phase I research⁵⁰. In addition to these financial contributions, according to the APA, the company will benefit from additional undisclosed amounts of money in pre-purchase payments that it is not obliged to refund if the product is not approved by

the EMA and the money has already been spent (see section 3.10).

2.3. MODERNA

Overview: Moderna is a pharmaceutical company that was founded in 2010 and is headquartered in Cambridge, Massachusetts⁵¹. Moderna is listed on NASDAQ⁵². Its total revenue increased from \$60 million in 2019 to \$803 million in 2020⁵³, a 1338.3% increase.

Product specialisation: Discovery and development of mRNA therapeutics and vaccines, such as for infectious, immuno-oncology, and cardiovascular diseases⁵⁴.

Covid-19 relevant product: Moderna's mRNA-1273 vaccine is an mRNA COVID-19 vaccine⁵⁵. The European Commission granted it a conditional marketing authorisation (CMA) in January 2021, making it the second COVID-19 vaccine approved in the European Union⁵⁶. This came after Moderna submitted a marketing authorisation application and the EMA started a rolling review of its data in November 2020⁵⁷. The European Commission approved a second contract with Moderna in February 2021 that provided for a purchase of 300 million doses of the vaccine⁵⁸, adding on to a previous contract in November 2020 that provided for a purchase of 160 million doses⁵⁹.

39 CureVac, "CVnCoV, CureVac's mRNA-based vaccine candidate against COVID-19", <https://www.curevac.com/en/covid-19/#timeline>

40 Joseph Keenan, "CureVac granted patent for its manufacturing process to produce RNA", March 9, 2018, Fierce Pharma, <https://www.fiercepharma.com/manufacturing/curevac-granted-patent-for-its-manufacturing-process-to-produce-rna>

41 European Medicines Agency, "EMA starts rolling review of CureVac's COVID-19 vaccine (CVnCoV)", February 12, 2021, <https://www.ema.europa.eu/en/news/ema-starts-rolling-review-curevacs-covid-19-vaccine-cvncov>

42 Ibid.

43 Ludwig Burger, "CureVac says well on track to request vaccine approval as planned", May 5, 2021, Reuters, <https://www.reuters.com/business/healthcare-pharmaceuticals/curevac-says-well-track-request-vaccine-approval-planned-2021-05-05/>

44 Eric Sagonowsky, "CureVac, Novartis team up in latest pandemic vaccine manufacturing collaboration", March 4, 2021, Fierce Pharma, <https://www.fiercepharma.com/pharma/curevac-novartis-team-up-latest-pandemic-vaccine-manufacturing-collaboration>

45 Allie Nawrat, "Q&A with CureVac: resolving the ultra-cold chain logistics of Covid-19 mRNA vaccines", December 3, 2020, Pharmaceutical Technology, <https://www.pharmaceutical-technology.com/features/mrna-vaccines-covid19-pandemic-curevac/>

46 Ibid.

47 European Commission, "Statement by President von der Leyen on CureVac", November 16, 2020, https://ec.europa.eu/commission/presscorner/detail/en/statement_20_2139

48 CureVac Press Release: German Federal Government invests 300 Million Euros in CureVac, 15 June 2020. Available online: <https://www.curevac.com/en/2020/06/15/bundesregierung-beteiligt-sich-mit-300-millionen-euro-an-curevac/#:~:text=German%20Federal%20Government%20invests%20300%20Million%20Euros%20in%20CureVac%20-%20CureVac>

49 European Commission and European Investment Bank: Commission and EIB provide CureVac with a €75 million financing for vaccine development and expansion of manufacturing, 6 July 2020. Available online: https://ec.europa.eu/commission/presscorner/detail/el/ip_20_1238

50 CEPI, Our Portfolio: https://cepi.net/research_dev/our-portfolio/

51 Moderna, "Moderna's Company History", <https://www.modernatx.com/about-us/moderna-facts>

52 Nasdaq, "Moderna, Inc. Common Stock (MRNA)", <https://www.nasdaq.com/market-activity/stocks/mrna>

53 Moderna, "Moderna Reports Fourth Quarter and Fiscal Year 2020 Financial Results and Provides Business Updates", February 25, 2021, <https://investors.modernatx.com/news-releases/news-release-details/moderna-reports-fourth-quarter-and-fiscal-year-2020-financial#:~:text=Total%20revenue%20was%20%24803%20million,grant%20revenue%20and%20product%20sales>

54 Bloomberg, "Moderna Inc", <https://www.bloomberg.com/profile/company/MRNA:US>

55 European Commission, "European Commission authorises second safe and effective vaccine against COVID-19", January 6, 2021, https://ec.europa.eu/commission/presscorner/detail/en/ip_21_3

56 Ibid.

57 Ibid.

58 European Commission, "Coronavirus: Commission approves second contract with Moderna to ensure up to additional 300 million doses", February 17, 2021, https://ec.europa.eu/commission/presscorner/detail/en/ip_21_655

59 European Commission, "Coronavirus: Commission approves contract with Moderna to ensure access to a potential vaccine", November 25, 2020, https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2200

Moderna's second vaccine, the mRNA-1283 vaccine, is currently in Phase 1 clinical trials⁶⁰. Moderna describes it as a "next-generation COVID-19 vaccine candidate", saying that it could be a "potential refrigerator-stable vaccine that could facilitate easier distribution and administration in a wider range of settings, including potentially for developing countries"⁶¹. Currently, mRNA-1273 can be stored at -20°C for up to 6 months and at normal refrigerator conditions for up to 30 days⁶².

Public investment in the vaccine development: Moderna benefited from US government funding of \$ 2.5 billion⁶³. The development of the vaccine further benefited from private donations (such as from the Dolly Parton COVID-19 Research Fund). Funding for the manufacture of mRNA-1273 phase 1 material was provided by the Coalition for Epidemic Preparedness Innovation (CEPI)⁶⁴.

60 ModernaTX, Inc., "A Study to Evaluate Safety, Reactogenicity, and Immunogenicity of mRNA-1283 and mRNA-1273 Vaccines in Healthy Adults Between 18 Years and 55 Years of Age to Prevent COVID-19", ClinicalTrials.gov, March 24, 2021, <https://clinicaltrials.gov/ct2/show/NCT04813796>

61 Businesswire, "First Participants Dosed in Phase 1 Study Evaluating mRNA-1283, Moderna's Next Generation COVID-19 Vaccine", March 15, 2021, <https://www.businesswire.com/news/home/20210315005475/en/First-Participants-Dosed-in-Phase-1-Study-Evaluating-mRNA-1283-Moderna%E2%80%99s-Next-Generation-COVID-19-Vaccine>

62 Moderna, "Moderna Announces Longer Shelf Life for its COVID-19 Vaccine Candidate at Refrigerated Temperatures", November 16, 2020, <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-longer-shelf-life-its-covid-19-vaccine>

63 <https://eu.usatoday.com/story/news/factcheck/2020/11/24/fact-check-donations-research-grants-helped-fund-moderna-vaccine/6398486002/>

64 <https://www.nejm.org/doi/full/10.1056/NEJMoa2022483>

ANALYSIS OF THE APAS, BY THEME

This chapter delves into the conditions found in the APAs along twelve themes chosen for their particular significance to achieving rapid, widespread and equitable access to Covid-19 vaccines as global public goods. For an overview of these themes and a brief explanation on why they were chosen, see section 1.3. Each section below is organised as follows: First, a summary table notes the specifics of the conditions in each agreement, or notes where that information was unavailable due to redactions. A complete summary table with information from all themes is available in Annex A. Then, a narrative text explains why that theme is significant and provides comments on the differing conditions in the contracts studied might mean for vaccine access. Where relevant and available, additional information from sources outside the APAs is brought in to shed further light on the theme.

3.1. SUBJECT OF THE AGREEMENT

Summary table: Subject of the agreement

EU- AstraZeneca	EU- CureVac	EU- Moderna	UK- AstraZeneca	US- Moderna
Production, purchase and supply of 300 million doses at no profit/no loss for distribution within EU by end June 2021 ⁶⁵ , with an option to order an additional 100 million doses.	Advance purchase of 225 million doses and an option to order up to a total of 180 million additional doses, the latter once MA is granted. CureVac BRE (i) to obtain EU marketing authorisation and (ii) to establish sufficient manufacturing capacities.	80 million doses + option to order an additional 80 million (an option to be exercised before the end of 2020).	100 million doses manufacture and supply agreement (contemplated in exclusive licence of Oxford University Innovation (OUI) to AZ) – without exclusive purchase obligation.	Financial support for pre-clinical, phase 2 & 3 clinical, chemistry, manufacturing and control (CMC) development, scale up and validation of manuf. Capability for 100 million doses by 2021.

The subject of the advance purchase agreements details what is being agreed to, and may differ per contract. The APA may concern, for example, the procurement of a product to be delivered as soon as it is available. It may also concern the funding of some development activities of a product, e.g. the APA with CureVac, or scaling up production, e.g. the EC APA with Moderna, and thus offer upfront financing for such activities, in addition to purchasing commitments. The US/Moderna contract covers costs associated with the development of the vaccine up

to registration, with an option for domestic manufacturing scale-out. In most cases, public money spent on development or production costs will not be refunded in case the company was unsuccessful in bringing a product to market (see section 3.10 on payback obligations). A funding contract for R&D earlier in the development process can provide leverage to obtain conditions with regards to sharing of intellectual property and other enabling conditions for equitable global access to the vaccine.

⁶⁵ See Jillian Deutsch, "Commission's vaccine contract with AstraZeneca ties EU's hands on lawsuits," Politico, 19 February 2021. Available online: <https://www.politico.eu/article/coronavirus-vaccine-europe-commission-contract-astrazeneca-ties-hands-lawsuits/>

3.2. TRANSPARENCY

Summary table: Transparency

EU- AstraZeneca	EU- CureVac	EU- Moderna	UK- AstraZeneca	US- Moderna
<p>Confidential Information broadly defined as any information disclosed by one party to the other party and which is not public knowledge.</p> <p>No obligation for AZ to disclose Vaccine development results that AZ is not legally or contractually permitted to share and may be required to first disclose to Oxford University.</p>	<p>Strict confidentiality of any information or document disclosed or given between the Parties or on their behalf in the context of the negotiation and conclusion of the APA (including the terms of the APA and the Vaccine Order Forms) and/ or the performance of the APA.</p>	<p>Confidentiality of any info or doc related to the implementation of the APA.</p>	<p>AZ to provide transparency to UK Gov on calculation of CoGs on an "Open Book Basis" (though details of CoGs redacted). AZ consents to UK publication of Supply Agreement in its entirety (but with any information which is exempt from disclosure in accordance with the provisions of the FOIA ... redacted) to the general public. UK Gov. sole discretion to redact prior to publication for reasons of national security, personal data, IP, confidentiality, etc.</p>	<p>Confidential information to be identified by the Parties.</p> <p>Moderna's obligation to acknowledge USG funding in any publications and publicity, including the percentage and dollar amount of the total costs of the programme financed by USG.</p>

Transparency is a critical issue for a number of reasons. Transparent purchase contracts support efficient and accountable public procurement. Transparency of what is contained within the contracts themselves allows for them to be exchanged and compared with other purchasers. In the medium term, transparent contract terms can also be monitored and evaluated by stakeholders, from legislators to policy experts to investigative journalists. Transparency is key to good governance of medicines and part of a human rights-based approach to essential medicines⁶⁶.

Over the long term, publicly disclosed contracts related to health tools R&D and procurement support

the move towards 'radical' transparency on vaccine supply that is endorsed by David Malpas, president of the World Bank⁶⁷. Transparent APAs can help track how public funds are used to support research and development of new medicines, and their production and supply. With this knowledge public funders negotiate conditionalities so that those products be made available and affordable to the public. (See section 3.12 on access-related provisions).

Confidential R&D and purchase agreements for medicines and vaccines are commonplace among public purchasers. As a result, in 2019 the 72nd World Health Assembly passed resolution WHA72.8 to

66 Kohler JC, Wright T. The Urgent Need for Transparent and Accountable Procurement of Medicine and Medical Supplies in Times of COVID-19 Pandemic. *Journal of Pharmaceutical Policy and Practice*. 2020 Dec;13(1):1-4. Pehudoff SK, Alexandrov NV, Hogerzeil HV. Access to essential medicines in 195 countries: A human rights approach to sustainable development. *Global public health*. 2019 Mar 4;14(3):431-44. 67 <https://www.ft.com/content/c2ba2620-1785-434f-a574-7d54036f8182>

improve the transparency of markets for health products⁶⁸. A key component of this resolution is a call to Member States to publicly share information on the net prices of health products such as vaccines, as well as the sales revenue, prices, marketing costs, subsidies and incentives. Resolution WHA72.8 also calls on Member States to facilitate better reporting of the patent status of health products. Several EU Member States have adopted legislation or regulation supporting the disclosure of the R&D costs and public investments in new medicines⁶⁹.

The US-Moderna contract requires the company to acknowledge the US government funding (as percent and dollar value) it receives and the total cost of the programme financed by the US government in publications and publicity.

A key challenge in the present study was the substantial redaction of the APAs, rendering large parts of the text unreadable. Redacting a narrow scope of genuine commercially confidential information in purchase contracts is an acceptable practice. However, the present report concludes that far more than commercially sensitive confidential information is being hidden from these contracts, as suggested by the sheer volume of redactions. This conclusion is supported by a comparison showing that UK vaccine procurement contracts from 2019 had 4 to 8 pages of redactions, while the UK-AstraZeneca contract had 22⁷⁰.

The public interest is undoubtedly impaired as a result of the significant redactions of the APAs studied in this report. Policy makers and the public are prevented from knowing how sizable public funds are spent⁷¹. Intransparency also keeps important information in the public interest about vaccine patents and licence terms (if any) out of public knowledge (See section 3.8 on intellectual property).

One contract is particularly noteworthy for its step towards greater transparency and public sector scrutiny of public funding and price components. Under the UK-AstraZeneca APA, AstraZeneca committed to disclose to the UK government its calculation of the cost of goods on an 'open book basis'. This clause, which allows the UK government to request insight into the basis of the vaccine price, was only identified in the UK-AstraZeneca APA (See section 3.3 on pricing).

68 WHA 72.8 Resolution on Improving the transparency of markets for medicines, vaccines, and other health products. 28 May 2019.

https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf

69 Medicines Law & Policy has a forthcoming report on the importance of transparency in medical markets for the World Health Organization's Health Evidence Network (HEN), which will be made available here: <https://www.euro.who.int/en/data-and-evidence/evidence-informed-policy-making/health-evidence-network-hen>

70 <http://ti-health.org/wp-content/uploads/2021/05/For-Whose-Benefit-Transparency-International.pdf>

71 <http://ti-health.org/wp-content/uploads/2021/05/For-Whose-Benefit-Transparency-International.pdf>

3.3. PRICING

Summary table: Pricing

EU- AstraZeneca	EU- CureVac	EU- Moderna	UK- AstraZeneca	US- Moderna
<p>Price equal to Cost of Goods (CoGs) (€2.90 / dose) which shall not be at a loss for AZ.</p> <p>AZ has right to increase Price per Dose if increase of CoGs by less than 20%. If CoGs increase by 20% or more, AZ and EC to agree on increase of price or reduction of doses number.</p> <p>Fair and equitable way to return excess payments of EC/MS to AZ if CoGs less than estimated price.</p> <p>EC right to audit up to 5 years after agreement expires to protect EU financial interests.</p>	<p>Redacted.</p> <p>EC can audit performance of APA for 5 years.</p>	<p>\$22.5/dose</p> <p>EC can audit performance of APA for 5 years.</p>	<p>Redacted.</p> <p>Price equal to Cost of Goods (excluding VAT), e.g. fully burdened aggregate reasonable direct and indirect costs and expenses incurred by AZ (on no profit no loss basis) to manufacture the Product (full def. redacted). AZ to automatically pass on any increase or decrease in CoGs as compared to the Target Costs of Goods (redacted). If audit determines price exceeds actual CoGs, AZ to refund overpayment with interests.</p>	<p>Redacted.</p> <p>Excess of cost/price ceiling agreed upon is at the Company's own risk</p> <p>Cost-Plus-Fixed-Fee⁷².</p> <p>Subject to audit by the EC.</p>

Vaccine pricing is the cost agreed to be paid in return for goods purchased. Greater understanding about the price components for vaccines can help public procurers to negotiate lower prices from all vaccine manufacturers. Price transparency also helps to inform the public on whether the authorities have been successful in the negotiations and to assess whether the spending of public resources is being done prudently. It is also important information to assess claims by companies that they practice not for profit pricing.

This pricing information should be understood against the manufacturers' commitments to a pricing policy in the public interest. During the pandemic, AstraZeneca-Oxford committed to a non-profit pricing strategy⁷³ while Moderna underscored its intention to profit from vaccine sales, saying it would not sell at cost⁷⁴. AstraZeneca, by contrast, committed to passing on any increase or decrease in cost of goods to the purchaser, at least in its agreement with the UK.

⁷² According to acquisitions.gov, "A cost-plus-fixed-fee contract is a cost-reimbursement contract that provides for payment to the contractor of a negotiated fee that is fixed at the inception of the contract. The fixed fee does not vary with actual cost, but may be adjusted as a result of changes in the work to be performed under the contract. This contract type permits contracting for efforts that might otherwise present too great a risk to contractors, but it provides the contractor only a minimum incentive to control costs." See here for more information: <https://www.acquisition.gov/far/16.306>

⁷³ <https://www.farmatervanverantwoording.nl/en/covid-19-practices/gccp-scorecard/>
 Vaccitech and Oxford University announce landmark partnership with AstraZeneca for the development and large-scale distribution of the COVID-19 vaccine candidate' (Vaccitech, 30 April 2020) accessed 29 November 2020
 Donato Paolo Mancini, 'AstraZeneca Vaccine Document Shows Limit of Non-Profit Pledge' (Financial Times, 7 October 2020) [https://www.ft.com/content/c474f9e1-8807-4e57-9c79-6f4af145b686?accessed=17 November 2020](https://www.ft.com/content/c474f9e1-8807-4e57-9c79-6f4af145b686?accessed=17%20November%202020); Memorandum of Understanding between AstraZeneca and Fiocruz, dd. 31 July 2020 (on file); Donato Paolo Mancini, Clive Cookson & Hannah Kuchler, 'Moderna Pitches Virus Vaccine at \$50-\$60 per Course' (Financial Times, 28 July 2020)

⁷⁴ <https://www.nytimes.com/2020/07/21/health/covid-19-vaccine-coronavirus-moderna-pfizer.html>

Table 1: Know vaccine prices per dose⁷⁵

EU-AstraZeneca	€2.9/dose
EU-CureVac	€10/dose
EU-Moderna	\$22.5/dose

The price information in this report is from unredacted versions of the APAs. Price information was redacted in the APAs formally published by government authorities. Both the EU-AstraZeneca and UK-AstraZeneca vaccine price is equal to the cost of goods, which is defined in great detail in the agreement to cover all expenses incurred by AstraZeneca. The EU-AstraZeneca price is set at €2.90/dose and the EU-Moderna price is set at \$22.90/dose. As noted in the previous section on transparency, AstraZeneca committed to disclose to the UK government its calculation of the cost of goods on an 'open book basis'. This clause, which allows the UK government to request insight into the basis of the vaccine price, was only identified in the UK-AstraZeneca APA.

The cost to the company of supplying the vaccines may change throughout the duration of the contract (i.e. if the price of the raw materials increases). How this change should impact on the prices paid by public purchasers was only identified in AstraZeneca's contracts which grant the company the right to increase the price or reduce the number of doses to be supplied if the cost of goods increases (to the extent that AstraZeneca would not supply at a loss). The EU-AstraZeneca contract also allows the company to unilaterally increase the price per dose if the cost of goods increases by less than 20% as compared to the estimated CoGs upon the signature of the contract. If the cost of goods increases by 20% or more, the EU and AstraZeneca shall agree to a further payment or another mechanism, which may include a reduction in the number of doses to be supplied⁷⁵.

The price section of the EU-CureVac APA is redacted, but a price per dose was briefly made public on Twitter and set at €10/dose⁷⁶.

All three EU APAs grant the European Commission the right to audit the companies within five years in order to protect the EU's financial interests. The UK-AstraZeneca contract also permits the government to audit the company. If an audit finds that the price exceeds the actual cost of goods, then the APA requires AstraZeneca to refund the government the overpayment with interest. Similarly, the EU-AstraZeneca contract contemplates a fair and equitable way to return excess payments of EC/MS to AZ if applicable.,

⁷⁵ For the AstraZeneca and Moderna prices, see unredacted versions of those APAs respectively here: https://www.rai.it/dl/doc/2021/02/19/1613725900577_AZ_FIRMATO_REPORT.pdf and here: https://www.rai.it/dl/doc/2021/04/17/1618676613043_APA%20Moderna_.pdf. For the CureVac pricing, see this article: <https://www.theguardian.com/world/2020/dec/18/belgian-minister-accidentally-tweets-eus-covid-vaccine-price-list>.

We were not able to verify the CureVac price in the contract because the pricing information was redacted.

⁷⁶ <https://www.theguardian.com/world/2020/dec/18/belgian-minister-accidentally-tweets-eus-covid-vaccine-price-list>

3.4. INDEMNIFICATION FOR LIABILITY

Summary table: Indemnification for liability

EU- AstraZeneca	EU- CureVac	EU- Moderna	UK- AstraZeneca	US- Moderna
MS to indemnify AZ for any loss relating to or arising from the use or administration of the Vaccine regardless of where the Vaccine is administered, where the claim is brought, and whether the claim of a Defect originates from the distribution, administration and use, clinical testing or investigation, manufacture (except if not GMP), labelling, formulation, packaging, donation, dispensing, prescribing or licensing of the Vaccine in its jurisdiction.	Administration of the Products conducted under the sole responsibility of MS. No warranty from CureVac about the efficacy to prevent COVID 19 or lack of unacceptable side-effects of the vaccine. Obligation of MS to indemnify CureVac and its subcontractors in case of liability incurred, settlements paid and certain costs relating to third party claims. (several provisions redacted).	Products used under sole responsibility of MS. MS obligation to indemnify Moderna and its contractors. Indemnification "to be interpreted broadly" for any claim of loss, including Product testing and development - except in cases of willful misconduct, gross negligence, non-compliance with marketing authorisation (MA) specifications or GMP product deficiency.	All provisions related to Indemnities are redacted. AZ solely responsible for manufacturing Products in accordance with applicable laws, GMP and marketing authorisation.	Product use in the US protected from liability under a declaration issued under PREP Act 42 U.S.C. 247d-6d ⁷⁷ .

Indemnification refers to absolving manufacturers of liability for claims resulting from unforeseen harms caused by their product, in this case pandemic vaccines. All EU APAs contain such indemnification clauses, which protect companies from the financial risks of liability claims.

The EU APAs all indemnify the manufacturer for possible liability claims. However, the clauses in question are heavily redacted which makes it difficult to offer a comparison and detailed commentary.

The US-Moderna contract references a US law that regulates issues related to liability⁷⁸. All provisions related to indemnity were redacted in the UK-AstraZeneca APA.

The indemnification clauses in the EU APA's find their roots in the mandate on vaccine procurement between the Commission and Member States, which reads in Article 6: "Participating Member States acquiring a vaccine shall be responsible for the deployment and

⁷⁷ <https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>

⁷⁸ <https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>

use of the vaccines under their national vaccination strategies, and shall bear any liability associated with such use and deployment. This shall extend to and include any indemnification of vaccine manufacturers under the terms and conditions of the relevant APA for liability related to the use and deployment of vaccines normally borne by such manufacturer⁷⁹. Normally manufacturers can take out liability insurance coverage to protect against product liability claims involving unexpected serious adverse effects. In a pandemic situation where products are rushed through development such insurance may not be available⁸⁰.

Normally manufacturers can be held liable for faults in their products⁸¹. This is the principle echoed in various consumer protection laws. For example, the Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products⁸² established that where a defective product causes damage to a consumer, the producer may be liable even without negligence or fault on their part. Indeed, the Commission has acknowledged that product liability is usually borne by the manufacturer. In the current pandemic situation where regulators issue emergency and conditional use authorisation to promising vaccines that are still under clinical investigation, this principle has been abandoned. As a result of the abbreviated testing timeline, serious adverse events or significantly reduced immune responses that occur in small subsets of the population may only be detected after the vaccine is marketed (rather than in a controlled phase III trial). However, the urgency to develop, manufacture and distribute vaccines in the midst of a deadly pandemic must be balanced against concerns over the short testing timeline; it is governments' responsibility to determine what that balance is. An additional consideration is that vaccines in general are used by healthy people and serve a greater good beyond the health needs of the individual.

Indemnifying manufacturers for possible liability claims may help to accelerate the availability of pandemic vaccines. Vaccine development and regulatory approval is normally a lengthy process, starting with pre-clinical testing (i.e. on animals) and then progressing to clinical trials in humans, which is usually done in three phases. In general, phase one looks at safety and dosage using a small population, phase two looks at efficacy and side effects on a larger population, and phase three continues to measure efficiency and potential adverse reactions on a larger population⁸³. This can take more than 10 years under normal circumstances⁸⁴, which is not ideal in the midst of a pandemic. In response, researchers have been innovating ways to safely speed up the process⁸⁵. In such a public health emergency, it is critical to strike the right balance between ensuring due diligence to protect public health is undertaken while also avoiding as much as possible delays in bringing to market urgently needed life-saving vaccines. Yet the lack of transparency of the indemnification clauses makes it difficult to determine whether the right balance was found.

79 https://ec.europa.eu/info/sites/default/files/annex_to_the_commission_decision_on_approving_the_agreement_with_member_states_on_procuring_covid-19_vaccines_on_behalf_of_the_member_states_and_related_procedures.pdf

80 <https://www.who.int/docs/default-source/coronaviruse/act-accelerator/briefing-note-indemnification-and-compensation-covax-amc-countries.pdf>

81 Halabi S, Heinrich A, Omer SB. No-fault compensation for vaccine injury-The other side of equitable access to Covid-19 vaccines. *New England Journal of Medicine*. 2020 Dec 3;383(23):e125, page 2.

82 <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31985L0374>

83 <https://www.fda.gov/patients/drug-development-process/step-3-clinical-research>

84 <https://www.euro.who.int/en/health-topics/disease-prevention/vaccines-and-immunization/vaccines-and-immunization/development-of-new-vaccines>

85 <https://www.gavi.org/vaccineswork/how-covid-19-leading-innovation-clinical-trials>

3.5. DELIVERY CONDITIONS

Summary table: Delivery conditions

EU- AstraZeneca	EU- CureVac	EU- Moderna	UK- AstraZeneca	US- Moderna
<p>Estimated delivery schedule: 120 million doses by Q1 2021, reminder by Q2 2021.</p> <p>MS payment obligation suspended in case of non-delivery or late delivery past the firm delivery date. Capacity limitation foreseen and subject to AZ BRE. Delays due to performance of competing agreements is not deemed a contract breach.</p>	<p>225 million doses in 2021/Q1 2022. Additional 180 doses as of Q2 2022.</p> <p>Risk of delay in EU marketing authorisation and production scale-up acknowledged. CureVac to submit a revised delivery schedule.</p>	<p>Delivery dates acknowledged to be “best estimates and subject to change”, based on the expected approval date. 10 mil Q1 2021, 35 mil Q2 2021, 35 mil, Q3 2021. In case of delays, Moderna submits an updated delivery schedule after prior consultation with the EC. If more than 90 days later than originally scheduled, MS may cancel their order and will be fully reimbursed.</p>	<p>Details redacted.</p> <p>AZ Best Reasonable Efforts (BRE) to keep as close to original Proposed Delivery Schedule. No adjustment (without written prior consent) to firm and final Delivery Schedule. If AZ experiences capacity limitations or shortages, Parties discuss in good faith how to resolve the issues. UK right to cancel or refuse Delivery not conformed to Schedule, with no obligation to pay, unless... redacted text.</p>	<p>Redacted</p>

Delivery conditions set the number of doses and timeline for their receipt as well as provisions for what happens in case of delay or other failure. In general, public money spent through APAs on development or production costs will not be refunded in case the company was unsuccessful in bringing a product to market.

The data contained in the table above was all redacted in the originally published APA sources; the information available was obtained from leaked texts or other sources, which are referenced in the footnotes. These sources show commitments to a variety of doses and time scales, with some consequences for failure or delayed delivery, such as being free of an obligation to pay. The suspension of payment obligation is an encouragement to avoid delays and to deliver in full.

Both AstraZeneca agreements commit the company to undertaking “Best Reasonable Efforts” to deliver according to estimated schedules, and the CureVac contract commits the company to “reasonable best effort”. Interestingly, the Moderna contract specifies that for delays of longer than 90 days from the original estimate, Member States can cancel orders and be fully reimbursed. The UK-AstraZeneca agreement seems to have a similar provision, though it is partially redacted.

Best Reasonable Efforts in the AstraZeneca contracts is defined as *“the activities and degree of effort that a company of similar size with a similarly-sized infrastructure and similar resources as AstraZeneca would undertake or use at the relevant stage of development or commercialisation, having regard to the urgent need for a vaccine to end a global pandemic which is resulting in serious public health issues, restrictions on personal freedoms and economic impact, across the world but taking into account efficacy and safety.”*

An interesting comparison can be made between the UK’s deal with AstraZeneca and the EU’s deal with the same company. In practice, the UK has not experienced delays that the EU has in receiving its promised vaccine from the company, which some have argued is as a result of stronger language within the UK agreement⁸⁶. In particular, the UK contract has more precise language on how delivery dates will be monitored, contains redacted consequences in case of failed delivery, and releases the UK from obligation to accept or pay for late doses. A Deloitte analysis of the EU-AstraZeneca agreement, by contrast, warned on 17 August 2020 that the APA’s language “does not provide for sanctions when the delivery dates and quantities are not respected⁸⁷”. Further, the language in the EU agreement stating that “delays due to performance of competing agreements is not deemed a contract breach” appears to effectively waive the EU’s right to legal recourse should AstraZeneca prioritise another contract over the EU’s (as they have done)⁸⁸.

While the UK and EU agreements were signed a day apart (28 and 27 August, respectively), the UK also had an earlier agreement with AstraZeneca from May of 2020 to develop a supply chain for their vaccine in the UK, ensuring that the manufacturing capacity to deliver doses was already locked down before the supply agreement was made⁸⁹.

The EU sued AstraZeneca for breach of contract, as the company had only delivered 30 of a promised 90 million doses by the end of the first quarter of 2021 and is now estimating it can only provide 70 of a promised 180 million doses by end June⁹⁰. AstraZeneca had countered that it has “fully complied” with its obligations to the EU. A decision on 18 June from a Brussels court did not impose fines on AstraZeneca sought by the EU unless the company could deliver the originally promised doses, but did say that AstraZeneca had not been fully consistent with making the required ‘best reasonable efforts’⁹¹. The court ordered AstraZeneca “to urgently deliver 50 million doses of vaccine by 27 September 2021 - according to a binding schedule: 15 million doses by 26 July, at 9 a.m., 20 million doses by 23 August, and 15 million doses at 27 September” lest the company be subject to a fine of €10 per undelivered dose⁹².

86 <https://www.politico.eu/article/the-key-differences-between-the-eu-and-uk-astrazeneca-contracts/>

87 <https://www.politico.eu/article/belgium-was-warned-eus-astrazeneca-contract-lacked-teeth-documents/>

88 <https://www.politico.eu/article/the-key-differences-between-the-eu-and-uk-astrazeneca-contracts/>

89 *Ibid.*

90 <https://www.bbc.com/news/56483766>

91 https://www.ft.com/content/6c535f67-c154-4044-91d0-8ed375cab361?accessToken=zwAAAXpBrV8Ykc9sU19nwVRARNOR0I7TdcqzYQ_MEQCIEPDjLrNBpYxiOGsJIWSOCJbXqTXOts4lav-we8RhpqQAiA5FivIE2wfOyED869O5fG3Zmnoe-aGKZPx5Vmla622vw&sharetype=gif?token=f57e67b4-a6d0-4a06-a5b4-06806df071e1

92 https://ec.europa.eu/commission/presscorner/detail/en/IP_21_3090

3.6. PRODUCTION LOCATION REQUIREMENTS

Summary table: Production location requirements

EU- AstraZeneca	EU- CureVac	EU- Moderna	UK- AstraZeneca	US- Moderna
AZ BRE to manufacture in the EU (which includes the UK). 30-40 mil by end 2020, 80-100 by Q1 2021, remainder end Q2 2021. Manufacture outside of the EU subject to prior written notice and explanation to the EC. AZ BRE to contracts with EU contract manufacturing organisations, proposed by EC, if AZ does manufacture in the EU. EC/MS BRE to assist AZ in supply of materials.	Manufacture outside of the territory of the European Union, the UK, the EEA or Switzerland is subject to prior consent of the EC.	API manufacture in Lonza, Switzerland. Fill and finish in Rovi Pharma, Spain. Manufacture of initial doses outside of the EU only upon EC approval.	AZ commitment to use supply chain manufacturers listed in Schedule 2 (redacted) for API and product.	Requirement for domestic production and assurance of material sourcing.

An APA may prescribe where the vaccines need to be produced. The EU-AstraZeneca agreement contains the requirement that production, including contract manufacturing, should preferably take place in the EU (which for this purpose includes the UK). The reasons for this requirement may be because the APA pursues an industrial development objective – e.g. to support the European pharma industry; to ensure priority access; or to protect against the risks of dependency on import from other regions or countries.

All of the agreements assessed in this study contain local production requirements, which makes it all the more understandable that countries around the world also seek to strengthen their production capacity. Local production of health products and the need to increase manufacturing capacity globally were key

considerations for the proposal for the pandemic “TRIPS-waiver⁹³” currently under discussion at the World Trade Organization. This waiver, once adopted, would allow WTO Members to postpone meeting their obligations under the TRIPS Agreement for the duration of the pandemic with regards to intellectual property related to Covid-19 products. The WHO initiated the Covid-19 Technology Access Pool (C-TAP)⁹⁴, a voluntary licensing and technology transfer mechanism to meet the same objectives. While the European Commission seems to support voluntary and compulsory licensing to expand manufacturing capacity⁹⁵, the Commission so far has not supported the two initiatives that would help in increasing production capacity globally and support pharmaceutical industrial development in low- and middle-income countries (see Boxes 3 and 4).

⁹³ <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>

⁹⁴ <https://www.who.int/initiatives/covid-19-technology-access-pool>

⁹⁵ <https://twitter.com/vonderleyen/status/1402612800887865350>

In the EU as well as globally the need to localise production of products to respond to the pandemic is increasingly recognised. Today the world is seeing the consequences of India's restrictions on export of Covid-19 vaccines (India's Serum Institute was set to supply about half the vaccine doses required by the Covax facility, an international scheme for equitable vaccine procurement and distribution), for example, as well as the hoarding of vaccines and therapeutics by wealthy nations to the detriment of poor countries.

The Independent Panel on Pandemic Preparedness Response (IPPPR) had found that "Concentration of manufacturing capacity, and of trials and knowledge generation, for vaccines, therapeutics, diagnostics and other essential supplies in a small number of countries has been a major contributor to inequity." The IPPPR recommends establishing regional capacities for manufacturing of tools for equitable and effective access to vaccines, therapeutics, diagnostics and essential supplies⁹⁶.

• BOX 3: WAIVING INTELLECTUAL PROPERTY RIGHTS AT THE WORLD TRADE ORGANIZATION

- In response to concerns about 'vaccine nationalism'⁹⁷ and the failure of voluntary IP sharing mechanisms such as C-TAP⁹⁸, South Africa and India on 2 October 2020 requested that the World Trade Organization (WTO) institute a waiver of most of the obligations under the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) in relationship to products needed for Covid-19 diagnosis, prevention, containment and treatment until the pandemic is under control⁹⁹. The proposal received support from over 100 other WTO Members.
- Citing "extraordinary circumstances" US Ambassador Katherine Tai announced the country's support for the waiver on 5 May 2021, albeit limited to only vaccines¹⁰⁰.
- The European Union has continued to oppose a waiver, and in a communication of 4 June 2021

to the WTO¹⁰¹ have instead proposed using the existing flexibilities contained within the TRIPS agreement in cases where it interferes with access and to make it easier to export products produced under a compulsory licence. Critics of this approach note that these existing flexibilities are unlikely to meet the scale of a pandemic demand, as they must be enacted country-by-country and product-by-product, inefficient at a time when many products are needed in many countries and with extreme urgency¹⁰². The European Parliament has, however, come out in support of the waiver in a resolution passed on 10 June 2021¹⁰³.

- Whether a waiver is agreed or not, it is not likely to be enough to ensure vaccine manufacturing scale-up. For this, technology and know-how transfer are also critical (see Box 4).

97 <https://www.sciencemag.org/news/2020/07/vaccine-nationalism-threatens-global-plan-distribute-covid-19-shots-fairly>

98 <https://www.barrons.com/articles/the-arguments-against-sharing-covid-19-intellectual-property-dont-add-up-51620056595>

99 <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>

100 <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>

101 https://trade.ec.europa.eu/doclib/docs/2021/june/tradoc_159606.pdf

102 https://mkus3lurbh3lbtg254fzode-wpengine.netdna-ssl.com/wp-content/uploads/TRIPS-waiver_Existing-TRIPS-Flexibilities-Unworkable-for-Scale-Up-of-Covid-19-Medicines-Production-.pdf

103 <https://www.europarl.europa.eu/news/en/press-room/20210604IPR05514/parliament-calls-for-temporary-covid-19-vaccine-patent-waiver>

96 https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf

• BOX 4: THE COVID-19 TECHNOLOGY ACCESS POOL (C-TAP)

- The creation of a technology pool was proposed to the WHO by Costa Rica on 23 March 2020¹⁰⁴ as a way to share intellectual property, including know-how, data, technology, and materials needed to expand and speed product development and manufacturing. The Covid-19 Technology Access Pool (C-TAP) was endorsed on 27 March in an open letter to the WHO signed by nearly 100 public health organisations and experts and on 3 April 2020 the Board of the Medicines Patent Pool and UNITAID decided to expand MPP's mandate to include health technology to support a Covid-19 response globally¹⁰⁵. On 6 April WHO Director-General Dr Tedros Adhanom Ghebreyesus said he supported the proposal to create a pool and would work with Costa Rica to finalise details. C-TAP was launched two months later, on 29 May 2020¹⁰⁶.
- In the year since, the WHO has not managed to fully operationalise C-TAP. In an attempt to regain momentum, the WHO held a relaunch event for C-TAP on 28 May 2021, at the World Health Assembly, at which the Spanish Minister of Foreign Affairs Arancha González Laya announced Spain had joined C-TAP, and a representative of El Consejo Superior de Investigaciones Científicas (CSIC), headquartered in Spain, declared the intention to make a Covid-19 diagnostic technology available to the body¹⁰⁷. Pharmaceutical companies however have so far refused to collaborate with C-TAP.

104 <https://www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf>

105 <https://medicinespatentpool.org/mpp-media-post/the-medicines-patent-pool-and-unitaid-respond-to-access-efforts-for-covid-19-treatments-and-technologies/>

106 https://www.youtube.com/watch?v=RLJRMiU1YY8&feature=emb_title

107 https://www.swissinfo.ch/spa/coronavirus-investigaci%C3%B3n_el-csic-ofrece-tecnolog%C3%ADa-para-la-fabricaci%C3%B3n-de-test-serol%C3%B3gicos-en-%C3%A1frica/46660104

3.7. GLOBAL PUBLIC GOOD

Summary table: Global Public Good

EU- AstraZeneca	EU- CureVac	EU- Moderna	UK- AstraZeneca	US- Moderna
EC/MS Agreement on COVID-19 procurement is not annexed to the EC/AZ APA.	Mentioned as a negotiation objective in the Annex of the EC/MS Agreement on COVID-19 vaccine procurement on behalf of MS, the latter being included as an annex to the APA, (“in negotiations... EC shall...promote COVID 19 vaccine as global public good, including access for LMICs... sharing of IP especially developed with public support”).	Mentioned as a negotiation objective in the Annex of the EC/MS Agreement on COVID-19 vaccine procurement on behalf of MS, the latter being included as an annex to the APA, (“in negotiations... EC shall...promote COVID 19 vaccine as global public good, including access for LMICs... sharing of IP especially developed with public support”).	n/a	n/a

The term ‘Global Public Good’ is often used in the context of Covid-19 vaccines. UN Secretary-General António Guterres at the launch of the “Only Together” campaign, which calls for Covid vaccines to be available to everyone, said that Covid-19 vaccines must be Global Public Goods¹⁰⁸. In June of last year promises were made by EU leaders: European Commission President Ursula von der Leyen promised that any future vaccine would be “our universal, common good”. Germany’s Angela Merkel and France’s Emmanuel Macron support the idea of a vaccine as a “global public good”¹⁰⁹. No-one would own the vaccine.

The UN General Assembly resolution on “International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19” adopted on 20 April 2020 refers to global public goods as follows: “the role of extensive immunisation against COVID-19 as a global public good for health

in preventing, containing and stopping transmission in order to bring the pandemic to an end, once safe, quality, efficacious, effective, accessible and affordable vaccines are available...”.¹¹⁰ The Council of Europe’s Committee on Social Affairs, Health and Sustainable Development adopted in December 2020 a resolution supporting the UN’s asserting that vaccines “must be a global public good”¹¹¹.

To enact this resolution certain measures must be taken. Products and processes do not become global public goods by declaring them so. The creation of global public goods requires global funding for scaling up manufacturing of COVID-19 vaccines, conditions on this funding to ensure sharing of knowledge and know-how to enable production in all regions of the world and a fair global distribution plan.

108 <https://www.un.org/press/en/2021/sgsm20620.doc.htm>

109 <https://www.euractiv.com/section/health-consumers/opinion/a-covid-19-vaccine-must-have-a-global-public-good-guarantee/>

110 <https://documents-dds-ny.un.org/doc/UNDOC/GEN/N20/101/42/PDF/N2010142.pdf?OpenElement>

111 <https://pace.coe.int/en/news/8145/covid-19-vaccines-must-be-a-global-public-good-available-to-everyone-everywhere->

There is no doubt that the Commission and EU Member States had agreed to the public policy objective to pursue Covid-19 vaccines as global public goods. The Annex to the Agreement between the Commission and Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures (C(2020)4192 final), which is annexed to some of the APAs, includes the following negotiating directive:

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 [meet] 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.

One cannot find out whether the Commission has indeed promoted Covid-19 vaccines as a global public good during the negotiations with pharma companies. But should it have done so, there is no evidence of this in the actual agreements the Commission concluded with the companies. As far as we have been able to verify, the term global public good is not mentioned in the APAs, including in the agreements available in full. As to the question of who owns the intellectual property, all agreements with the EC are clear: the IP, including know-how and data, remains in the hands of the company. By contrast, the US R&D contract retains rights in all data the generation of which was funded under the contract (see section 3.8 on IP). Such data might include: results of pre-clinical and early phase clinical trials; chemistry, manufacturing and control development; or data related to scale-up and validation of manufacturing capacity (see section 3.1).

In conclusion, the agreements between the Commission and vaccine manufacturers assessed in this study, as far as they are disclosed, do not provide any evidence that the Commission pursues its negotiating objective of “promoting Covid-19 vaccine as a global public good”, as agreed with the Member States in June 2020. The focus of the APAs seem to be more on de-risking investments and increasing manufacturing capacity of the companies and less on the protection of public interest and public investments through open sharing of IP and knowledge.

3.8. INTELLECTUAL PROPERTY

Summary table: Intellectual property

EU- AstraZeneca	EU- CureVac	EU- Moderna	UK- AstraZeneca	US- Moderna
<p>AZ sole owner of all IPRs generated during the development, manufacture, and supply of the Vaccine, including all Know-How (AZ BRE to share all clinical trial data with EC, but no obligation if not permitted). Acknowledgement of AZ obligations to its upstream licensor.</p> <p>EC right to a licence for vaccines IPRs to continue development if AZ abandons the development.</p>	<p>CureVac owns all IP generated during the development, manufacture and supply of the product (including know-how) and is entitled to exclusively exploit those rights. No licence right granted to the EC or MS.</p>	<p>Moderna is sole owner of all IP, including know-how, and results of the APA. No licence or right granted to EC or MS. Moderna to provide a list of pre-existing rights owners, or declaration of no pre-existing rights with the last invoice.</p>	<p>No rights granted under this agreement. Certain pre-existing rights of OUI granted to UK Gov. AZ either sole owner of all pre-existing IPR in the Product or has licence to manufacture and supply.</p>	<p>USG owns all material and products (e.g. vaccines, validated lots) manufactured and/or acquired with USG funds.</p> <p>USG limited IP rights¹¹² in data generated prior to contract and in data developed exclusively with private funds (exact data redacted);</p> <p>USG unlimited IP rights¹¹³ in data funded under the contract, though Moderna owns inventions developed during the performance of the contract¹¹⁴.</p>

The vaccines being purchased (or in some cases, developed) under the contracts may be subject to a range of intellectual property rights held by the manufacturer and/or other parties. An overview of which IP rights are concerned and how they influence vaccine availability and affordability is available elsewhere^{115 116}. APAs may establish who holds the rights to the knowledge that is generated through the execution of the APA, such as data generated during the clinical development (i.e. testing) and manufacturing of the vaccine.

This study found that all EU APAs permit the company to retain all rights, including the intellectual property rights that are generated as a result of the EC funding, even if the funding served to finance clinical trials or to scale up production.

¹¹² Limited rights means data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Company, be used for purposes of manufacture nor disclosed outside the Government. <https://www.acquisition.gov/far/52.227-14>

¹¹³ Unlimited rights means the rights of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so. <https://www.acquisition.gov/far/52.227-14>

¹¹⁴ Acquisition.gov, 52.227-11 Patent Rights-Ownership by the Contractor. Available online: <https://www.acquisition.gov/far/52.227-11>

¹¹⁵ <https://theindependentpanel.org/wp-content/uploads/2021/05/Background-paper-6-Scaling-up-vaccination-legal-aspects.pdf>

¹¹⁶ <https://medicinespatentpool.org/what-we-do/disease-areas/vaxpal/>

• BOX 5: KEY INTELLECTUAL PROPERTY TERMS¹¹⁷

- **Intellectual property:**

Intellectual property (IP) refers to the legal rights that result from intellectual activity in the industrial, scientific, literary and artistic fields. Key intellectual property elements in medicine include patents, data and know how.

- **Patents:**

A patent is a form of IP granted to an inventor for the creation of something new, non-obvious to a person who is knowledgeable in the field, and useful. A patent gives the holder the right to prevent others from making, selling, or using a particular technology as long as it is in force. To use patented technologies, licences may be granted. Licences may be voluntary (as in, with the permission and participation of the patent holder) or compulsory. A compulsory licence is an authorisation by a competent government authority to use a patented invention by a third party without the consent of the patent holder, against a payment of "adequate remuneration." Governments have the right to issue compulsory licences when they deem it necessary for any reason, including for the use of the patent by the government. This is called "government use" or "public non-commercial use".

- **Data:**

Data refers to information relevant to the development or the manufacture of a medical product, its use, or to its status as marketable from drug regulatory authorities. Test data, frequently mentioned in the case of medical products, is data which has been generated in pre-clinical and clinical trials (and in other tests) which has to be submitted to regulatory authorities in order to demonstrate that the corresponding medical product meets the necessary efficacy, safety and quality requirements such that it can obtain marketing approval. Other relevant data might include information relevant to the chemistry, manufacturing and development of a product.

- **Know-how:**

Know-how is procedural knowledge and refers to practical knowledge on how to accomplish something. Know-how can include a broad body of information which, taken in aggregate, is also commercially valuable. In the case of vaccines for Covid-19, many of which are new-in-class technologies (see Box 2), know-how transfer, in addition to patent licensing will be critical to building manufacturing capacity and scale-up.

¹¹⁷ For a full explanation of this 'IP stack', see 'What is the 'know-how gap' problem and how might it impact scaling up production of Covid-19 related diagnostics, therapies and vaccines?' Available here: <https://medicineslawandpolicy.org/2020/12/what-is-the-know-how-gap-problem-and-how-might-it-impact-scaling-up-production-of-covid-19-related-diagnostics-therapies-and-vaccines/>

Under the UK-AstraZeneca agreement, the government is not granted any IP rights, although this agreement referenced the fact that rights were granted to the UK Government under agreements the government concluded with Oxford University Innovation for research, development and manufacturing of the vaccine. (More information about the IP path of the Oxford-AstraZeneca vaccine from development to commercialisation and the roles of public and private actors therein is available elsewhere¹¹⁸).

By contrast the US-Moderna agreement grants the US government limited IP rights to the data generated prior to the contract, and unlimited IP rights to the data generated under the contract.

The EU-AstraZeneca APA indicates that the company will make its best reasonable efforts (defined in section 3.5) to share all clinical data with the European Commission. Of note, this contract gives the European Commission the right to access the IP in order to continue developing the vaccine if the company abandons development during the contract.

¹¹⁸ <https://medicineslawandpolicy.org/wp-content/uploads/2020/10/How-the-Oxford-Covid-19-Vaccine-became-the-AstraZeneca-Covid-19-Vaccine-Final.pdf>

With the exception of the IP terms in the US-Moderna agreement, the IP provisions in the four other APAs are unlikely to support knowledge sharing for greater vaccine manufacturing and access.

The US-Moderna agreement shows that governments can negotiate better vaccine access terms when they establish APAs earlier in vaccine development and contribute financially to this development. This is because the ownership of vaccine IP is established early in the R&D process. The later governments invest in the vaccines R&D lifecycle, the less margin they have to negotiate favourable access terms. Public entities or other purchasers that invest in early-stage vaccine R&D are in a better position to negotiate IP and access conditions, including the potential for licensing and patent buy-outs. In the Covid-19 pandemic, the EU entered into APAs with manufacturers in the later stages of vaccine development (see section 3.4 for a brief explanation of the stages of vaccine development), compared to the US and the UK, which also financed large parts of vaccine R&D.

If clinical data, know-how, and other IP and knowledge is generated under an APA, it ought to be owned by or licensed to the purchasing government, or at least co-owned with the company. Having rights to the data would place the purchasing government in a better position to negotiate a fair price or share the data with a wider range of actors. The fact that IP sharing is not part of the agreement with CureVac is particularly noteworthy because this agreement supports the development of the product and the CEO of the company publicly stated¹¹⁹ in December 2020 that patents related to Covid-19 vaccines should be temporarily suspended and has called for much closer international collaboration in R&D of the new vaccines¹²⁰. This statement was welcomed by organisations campaigning for the People's Vaccine¹²¹.

Governments purchasing Covid-19 products can always demand companies collaborate with WHO C-TAP (see Box 4). These conditions were not located in the unredacted text of the five agreements studied.

A demand that companies engage with C-TAP would be consistent with the Commission's "Manifesto for EU COVID-19 Research" issued in October 2020, which calls on beneficiaries of EU funding, in order to maximise the accessibility of research results in the fight against COVID-19 to "Where possible, grant for a limited time, non-exclusive royalty free licences on the intellectual property resulting from EU-funded research. These non-exclusive royalty free licences shall be given in exchange for the licensees' commitment to rapidly and broadly distribute the resulting products and services under fair and reasonable conditions to prevent, diagnose, treat and contain COVID-19"¹²².

119 <https://www.stuttgarter-zeitung.de/inhalt.kampf-gegen-corona-curevac-patente-fuer-impfstoffe-aussetzen.568f0c24-6dd1-4724-a46f-8683d53c8444.html>

120 <https://www.stuttgarter-zeitung.de/inhalt.kampf-gegen-corona-curevac-patente-fuer-impfstoffe-aussetzen.568f0c24-6dd1-4724-a46f-8683d53c8444.html>

121 <https://www.one.org/international/press/one-welcomes-calls-suspension-patents-covid-vaccines/>

122 <https://op.europa.eu/en/publication-detail/-/publication/0dce5fc4-fc85-11ea-b44f-01aa75ed71a1/>

3.9. PAYMENT SCHEDULE & CONDITIONS (INCLUDING DOWN PAYMENT)

Summary table: Production location requirements

EU- AstraZeneca	EU- CureVac	EU- Moderna	UK- AstraZeneca	US- Moderna
<p>2/3 of 336 mil. down payment 5 days after signature; remaining 1/3 upon evidence of use of first payment and manufacturing progress report. MS payment for fill/ finish/ packaging, storage and distribution costs, due upon shipment.</p> <p>Payment schedule can be updated if AZ CoGs increase.</p> <p>Optional doses to be irrevocably ordered by EC based on the first safety and efficacy report of ph.III study.</p>	<p>EC and MS upfront payments to increase the speed of R&D, clinical trials and the preparation of the at-scale production capacity, to be made respectively after APA signature and submission of interim data to EMA.</p> <p>20% (\$360 mil) upfront payment from EC upon APA signature, 40% payment by each MS upon marketing approval, 40% by MS upon delivery of doses in country</p> <p>Mostly redacted. Mention of Price Reduction. Redacted.</p>	<p>20% (\$360 mil) upfront payment from EC upon APA signature, 40% payment by each MS upon marketing approval, 40% by MS upon delivery of doses in country</p> <p>Mostly redacted. Mention of Price Reduction. Redacted.</p>	<p>Mostly redacted. Mention of Price Reduction.</p>	<p>Redacted.</p>

Payment schedules determine when (and under what conditions) money will be disbursed under the agreement. Most of the APAs for which information is unredacted contain significant payments upon signing of the agreement. This was specifically done to “decrease risks for companies while speeding up manufacturing” as a part of the EC’s Coronavirus vaccines strategy¹²³. This intention – often also clearly stated in the APAs themselves, as with the Curevac APA – was to speed R&D, clinical trials and the establishment of manufacturing capacity to bring vaccines to market as soon as possible.

¹²³ European Commission. Coronavirus vaccines strategy [Internet]. Brussels: European Union; 2020. https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/corona-virus-vaccines-strategy_en

Summary table: Payback obligations

EU- AstraZeneca	EU- CureVac	EU- Moderna	UK- AstraZeneca	US- Moderna
AZ to return all unused material and funding to EC if AZ abandons development.	MS right to reduce or recover payment if vaccines are not delivered in accordance with APA, based on financial statements detailing expense uses of upfront payments so that unspent amounts can be reimbursed to the EC and MS.	If termination, financial statement of costs/expenses covered with EC Down Payment and Unspent amounts to be reimbursed to EC	Termination clauses mostly redacted except the following: if the price paid exceeds the price per product delivered, AZ shall refund the amount of such excess.	Vaccine development progress is continually assessed for go/no go decisions so that funding is properly allocated to impact the COVID-19 public health emergency. If the contract is terminated, the parties negotiate an equitable distribution of all property produced or purchased under the contract based upon the share of costs incurred by each.

3.10. PAYBACK OBLIGATIONS

Payback obligations define what must be returned against non-delivery or abandonment of the subject of the agreement or in the case of unspent funds. They can be useful as accountability mechanisms, especially in cases where significant upfront financing has been provided to aid and speed R&D, as has been the case with Covid vaccines (see section 3.9).

The sections on payback obligations have been partly or entirely redacted in the available APAs. What is available does not appear to carry requirements other than the return of unspent funding and/or materials. The UK-AstraZeneca contract has a clause, requiring that if the price paid upfront exceeds the cost of goods (see section 3.3), AstraZeneca must refund the excess. The agreement between the US and Moderna specifies a constant re-evaluation of funding during the length of the agreement to ensure proper

allocation with a requirement to equitably distribute assets on contract termination.

What, in effect, these minimal payback obligations do is significantly de-risk company investment in Covid-specific R&D while essentially gifting any add-on benefits of that – i.e. the funding of increased manufacturing capacity, or the development of technologies (such as mRNA vaccines) that have applicability to Covid and potential applicability in other disease areas) – to the companies.

In case of failure, only unspent funds must be returned. In case of success, there are no requirements to pay back public money in case of high profit off of vaccines. The EU-Moderna agreement also includes in an annex that the EU will pay for transfer of technology related to the vaccines to Europe.

3.11. TOTAL PAYMENT AMOUNT

Summary table: Total payment amount

EU- AstraZeneca	EU- CureVac	EU- Moderna	UK- AstraZeneca	US- Moderna
€870 million divided in €336 million upfront paid by the EC and €534 million subsequent funding paid by MS.	Redacted	\$1.8 billion	Redacted	\$483 million

The total payment amount is the maximum payout of the APA. Based on the conditions that are unredacted, the total amount is equal to the number of doses multiplied by the price of the dose: For the EU-AstraZeneca APA, the price is listed as €2.90/dose, and the subject of the agreement is the delivery of 300 million doses, yielding a total payment amount of €870 million; for EU-Moderna, 80 million doses at \$22.50 a dose yield 1.8 billion total payment.

Based on this, some speculation can be made on the other agreements, though with redactions they are unconfirmed. The EU-CureVac APA promises 225 million doses, and information made available elsewhere sets the CureVac price at €10/dose¹²⁴, so the likely total price is €2.25 billion. The UK-AstraZeneca agreement commits to the supply of 100 million doses; the same source as CureVac sets the price per dose at £1.61, so total cost is likely in the vicinity of £161 million.

Embedded in these prices is a portion that will cover the scaling up of manufacturing capacity as well as technology transfer. The key takeaway on total price is that significant amounts of public money have been mobilised and promised to several companies without significant access requirements attached to it.

¹²⁴ <https://www.theguardian.com/world/2020/dec/18/belgian-minister-accidentally-tweets-eus-covid-vaccine-price-list>

3.12. ACCESS-RELATED PROVISIONS

Summary table: Access-related provisions

EU- AstraZeneca	EU- CureVac	EU- Moderna	UK- AstraZeneca	US- Moderna
<p>MS may donate excess doses to lower- or middle-income countries or public institutions and donate or resell, at no profit, such doses to other European countries that agree to be bound by similar terms and conditions.</p> <p>For additional orders beyond 400 million, no profit no loss price guaranteed only until 1st July 2021 (AZ to reassess in good faith if pandemic ceases after that date).</p>	<p>MS commit not to resell, distribute or donate, even to NGOs or WHO, without prior written consent of CureVac. Receiving country must first confirm to the satisfaction of CureVac that it will fully assume the indemnity obligations. However, CureVac is free to grant or withhold its consent at its own discretion. MS have an obligation to reimburse the Commission for the upfront payment per dose in case of resale.</p> <p>Price of additional orders subject to CureVac determination of end of the pandemic, taking into account WHO advice.</p>	<p>Resell or export possible to other EU/EEA countries if indemnification agreed by the receiving country.</p> <p>Donation outside EU/EEA possible upon approval of Moderna, including indemnification, responsibility of transport and authorisations.</p>	<p>No profit No loss Pricing + AZ BRE to mitigate and reduce CoGs for expedited supply in the context of a global pandemic during the term of the agreement.</p> <p>Right to donate or transfer products delivered, and in excess, to other countries and NGOs, including ACT-A (conditions redacted).</p>	<p>Out of scope.</p>

Access-related provisions refer to any provisions which may be expected to contribute to access globally. For instance, if excess doses might be shared with countries outside the agreement that are experiencing a shortage.

Access-related provisions may also relate to specific pricing arrangements in favour of access, such as the fact that AstraZeneca commits to mitigate and reduce the costs of vaccines during the term of the UK agreement, even though the agreement acknowledges that this would be done in the context of

urgent need for expedited supply in the context of a global pandemic. This could mean that in non-pandemic circumstances, the prices could be reduced.

All of the APAs contain provisions that allow Member States to resell, donate or otherwise export unused doses, though conditions may vary. Some companies such as CureVac and Moderna require permission from the company for resale outside the EU to ensure the receiving country will assume indemnity obligations in case of liability (see section 3.4).

Interestingly, two of the APAs specifically mention the 'end of the pandemic', in particular as regards dose pricing of future orders. AstraZeneca's pandemic price (and thus no profit pricing commitment) may end 1 July 2021 pending a good faith reassessment by the company; CureVac will "take into account" WHO's advice.

There is limited evidence that states have conditioned their financial contributions on guarantees that developers will fairly or equitably provide access to the resulting medicines. This was a missed opportunity considering the unprecedented scale of state financing mobilised for Covid-19 vaccine R&D.

The contracts analysed in this study aim to provide funding for companies to cover R&D costs and/or establish sufficient manufacturing capacities in advance of the marketing approval of vaccines. APAs offer the company the assurance of a market for the product under development by placing purchase orders. The EC has been entitled to negotiate APAs on behalf of Member States. The EC committed to promoting Covid-19 vaccines as global public goods in the agreement with Member States that established this entitlement (see also section 3.7). It was expected that the EC, negotiating for the entire bloc, would likely be able to obtain better terms and conditions than individual MS could have. Whether this is indeed the case one cannot assess.

• BOX 6: BRAZIL-ASTRAZENECA

- In 2020 Brazilian Oswaldo Cruz Foundation entered into a Memorandum of Understanding with AstraZeneca for the production of Covid-19 vaccines¹²⁵. The agreement contains AstraZeneca's public commitment to not profit from its Covid-19 vaccine during the pandemic. However, the agreement also determines that the company may, as soon as July 2021, unilaterally determine that the pandemic has ended. The Financial Times was the first to report about the clause, which drew attention to the fact that companies have sole say over where and under which conditions vaccines

are made available¹²⁶. In addition to the right to determine when the pandemic is ending, AstraZeneca also limited the supply of vaccines produced by Fiocruz to Brazil only, making it impossible to export to other countries, including in the Latin American region.

- The EU-AstraZeneca APA has a similar clause whereby the company "determines in good faith that the COVID-19 Pandemic has ceased". At that point, AstraZeneca retains the right to abandon its not for profit pricing. The AstraZeneca "not for profit" price is €2.90/dose. Full vaccination requires two doses.

¹²⁵ Memorandum of Understanding between AstraZeneca and Fiocruz, dd. 31 July 2020. Available here: https://medicineslawandpolicy.org/wp-content/uploads/2021/06/MOU_Fiocruz_AZUK_sigilo2.pdf
¹²⁶ <https://www.ft.com/content/c474f9e1-8807-4e57-9c79-6f4af145b686>

CONCLUSIONS AND RECOMMENDATIONS

This chapter summarises some key conclusions that can be drawn from the agreements, and offers some policy recommendations on basis of them. The agreements analysed were heavily redacted and these conclusions should be read with that in mind. In general, the lack of transparency around the APAs is problematic on many fronts.

4.1. SUMMARY POINTS AND POLICY RECOMMENDATIONS

The APAs are part of a strategy to provide upfront financing for Covid-19 vaccines and to accelerate their development and availability. Since the beginning of the pandemic, governments have spent at least €93 billion on COVID-19 vaccines and therapeutics globally¹²⁷. It is the correct public policy response to use public financing to ensure pandemic products are developed rapidly and become available equitably. But there should be strings attached to public financing to more vigorously pursue the objective to make Covid-19 vaccines and access to them Global Public Goods. Below are some other summary considerations and recommendations that could enhance equitable access to Covid-19 vaccines.

Intellectual property sharing

The APAs focussed on de-risking company investments which offered the companies significant benefits. For example, the production capacity that has been created with this funding is a permanent benefit because it will stay with the company after the APA expires. Also the financing for development costs, if spent, does not have to be paid back in case a product is not successful (nor is compensation due in case of massive success and profits). In exchange, there is no demand to share the data and knowledge generated. These assets also stay with the company without requiring they be shared, licensed for use, or co-owned in the public interest.

Sharing of intellectual property, including know-how, data and technology is critical to bring in additional manufacturers. This is particularly necessary in countries and regions that are being underserved as a result of vaccine hoarding by wealthy nations. One of the IPPPR's findings was that "Concentration of manufacturing capacity, and of trials and knowledge generation, for vaccines, therapeutics, diagnostics and other essential supplies in a small number of countries has been a major contributor to inequity"¹²⁸.

Recommendation: APAs and other financial contributions to vaccine development should require the proactive sharing of IP and technology with producers elsewhere. To implement sharing strategies the European Union should fully support the WHO C-TAP and other vaccine technology transfer initiatives that will help increase and diversify production of Covid-19 vaccines globally. Doing so will contribute to the objective to promote Covid-19 vaccines and access to them as Global Public Goods.

Supporting the TRIPS Waiver as proposed by South Africa and India has merit, in particular for health technologies such as therapeutics and diagnostics that do not require technology transfer. The European Union therefore should also support the TRIPS Waiver.

¹²⁷ <https://healthpolicy-watch.news/81038-2/>

¹²⁸ https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf

Transparency

The lack of transparency of the agreements is significant. For example, none of the agreements disclose the price the EU's health systems will pay for the vaccines. The public is asked to trust that these agreements are for the public's benefit but independent scrutiny of that claim is not possible. The same is true for the companies' stated commitments. For example, AstraZeneca has committed to "no-profit, no loss" for the duration of the pandemic (but retained the right to decide when the pandemic ends). It would be important for the Commission to verify this claim and communicate the result to the public.

Public accountability is best served when the public has access to clear information on how governments are allocating funds. Much of what has been redacted in the APAs analysed would not qualify as a necessary business secret (such as who owns the intellectual property created under the agreements). Transparency is also critical in markets for health products outside the APAs. A WHO resolution has called on Member States to share publicly key health data, such as: the net prices of health products, sales revenue, prices, marketing costs, subsidies and incentives, and updated patent status¹²⁹. Several EU Member States have adopted legislation or regulation supporting the disclosure of the R&D costs and public investments in new medicines¹³⁰.

Recommendation: Take action to ensure greater transparency. Governments should insist on greater transparency when negotiating contracts in the public interest. All EU Member States should implement the World Health Assembly resolution¹³¹ on pharmaceutical transparency which includes commitments to greater price transparency. Transparency on this type of information can help health product procurers make informed decisions on fair pricing.

Global Public Goods

The European Commission and a number of EU Member States have made public commitments to pursue Covid-19 vaccines as global public goods. The promotion of Covid-19 vaccines as a global public good as a 'negotiating directive' was included in the agreement between the Commission and the Member States, which is attached to some of the APAs. However, as far as we have been able to verify, the term global public good does not appear in the

APAs, including in the agreements available in full. As to the question of who owns the IP, all agreements with the EC are clear that the IP – including know-how and data – remains in the hands of the company. Therefore, the Commission either has not attempted to follow the negotiating directive or was rejected in its efforts by the companies. Either way, the result represents a breach of lofty public promises, with consequences not just for Europe but globally.

Recommendation: The European Commission should go beyond words and develop a strategy to pursue its stated objective to promote Covid-19 vaccines as a global public good.

Financing cost of R&D

The growing inequity in vaccine access around the world has been described by the head of the WHO as 'vaccine apartheid'¹³². Nine companies are expected to turnover \$190 billion in Covid vaccine sales in 2021 with products that have been mostly developed with public financing¹³³. It would therefore also be important for the private sector to disclose their contribution to the development of the vaccines. As the agreements analysed in this paper demonstrate, the public sector has made significant upfront contributions to the development and availability of Covid-19 vaccines. It would be good to be able to assess if the private sector contributed their fair share.

Recommendation: The European Commission should demand from companies to disclose the breakdown of the research and development cost of Covid-19 vaccines and which entities contributed to paying these costs.

129 WHA 72.8 Resolution on Improving the transparency of markets for medicines, vaccines, and other health products. 28 May 2019. https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf

130 Medicines Law & Policy has a forthcoming report on the importance of transparency in medical markets for the World Health Organization's Health Evidence Network (HEN), which will be made available here: <https://www.euro.who.int/en/data-and-evidence/evidence-informed-policy-making/health-evidence-network-hen>

131 WHA 72.8 Resolution on Improving the transparency of markets for medicines, vaccines, and other health products. 28 May 2019. https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf

132 WHA 72.8 Resolution on Improving the transparency of markets for medicines, vaccines, and other health products. 28 May 2019. https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf

133 <https://www.bloomberg.com/news/newsletters/2021-05-29/a-190-billion-covid-vaccine-bonanza>

ANNEX A: KEY PROVISIONS IN THE APAS: SUMMARY TABLE

Below are the key conditions along 12 themes relevant to vaccines and global public goods. In the sections below, each theme is expanded upon and explained in detail. Abbreviations used in this summary table are defined at the beginning of the report.

1. Subject of the agreement

EU- AstraZeneca (27 Aug. 2020) <i>Full agreement available</i>	EU- CureVac (19 Nov. 2020)	EU- Moderna (25 Nov. 2020) <i>Full agreement available</i>	UK- AstraZeneca (28 Aug. 2020)	US- Moderna (16 April 2020)
Production, purchase and supply of 300 million doses at no profit/no loss for distribution within EU by end June 2021 ¹³⁴ , with an option to order an additional 100 million doses.	Advance purchase of 225 million doses and an option to order up to a total of 180 million additional doses, the latter once MA is granted. CureVac BRE (i) to obtain EU marketing authorisation and (ii) to establish sufficient manufacturing capacities.	80 million doses + option to order an additional 80 million (an option to be exercised before the end of 2020).	100 million doses manufacture and supply agreement (contemplated in exclusive licence of Oxford University Innovation (OUI) to AZ) - without exclusive purchase obligation.	Financial support for pre-clinical, phase 2 & 3 clinical, chemistry, manufacturing and control (CMC) development, scale up and validation of manuf. capability for 100 million doses by 2021.

¹³⁴ See Jillian Deutsch, "Commission's vaccine contract with AstraZeneca ties EU's hands on lawsuits," Politico, 19 February 2021. Available online: <https://www.politico.eu/article/coronavirus-vaccine-europe-commission-contract-astrazeneca-ties-hands-lawsuits/>

2. Transparency

<p>EU- AstraZeneca (27 Aug. 2020) <i>Full agreement available</i></p>	<p>EU- CureVac (19 Nov. 2020)</p>	<p>EU- Moderna (25 Nov. 2020) <i>Full agreement available</i></p>	<p>UK- AstraZeneca (28 Aug. 2020)</p>	<p>US- Moderna (16 April 2020)</p>
<p>Confidential Information broadly defined as any information disclosed by one party to the other party and which is not public knowledge.</p> <p>No obligation for AZ to disclose Vaccine development results that AZ is not legally or contractually permitted to share and may be required to first disclose to Oxford University.</p>	<p>Strict confidentiality of any information or document disclosed or given between the Parties or on their behalf in the context of the negotiation and conclusion of the APA (including the terms of the APA and the Vaccine Order Forms) and/ or the performance of the APA.</p>	<p>Confidentiality of any info or doc related to the implementation of the APA.</p>	<p>AZ to provide transparency to UK Gov on calculation of CoGs on an "Open Book Basis" (though details of CoGs redacted). AZ consents to UK publication of Supply Agreement in its entirety (but with any information which is exempt from disclosure in accordance with the provisions of the FOIA ... redacted) to the general public. UK Gov. sole discretion to redact prior to publication for reasons of national security, personal data, IP, confidentiality, etc.</p>	<p>Confidential information to be identified by the Parties.</p> <p>Moderna's obligation to acknowledge USG funding in any publications and publicity, including the percentage and dollar amount of the total costs of the programme financed by USG.</p>

3. Pricing

<p>EU- AstraZeneca (27 Aug. 2020) Full agreement available</p>	<p>EU- CureVac (19 Nov. 2020)</p>	<p>EU- Moderna (25 Nov. 2020) Full agreement available</p>	<p>UK- AstraZeneca (28 Aug. 2020)</p>	<p>US- Moderna (16 April 2020)</p>
<p>Price equal to Cost of Goods (CoGs) (€2.90 / dose) which shall not be at a loss for AZ.</p> <p>AZ has right to increase Price per Dose if increase of CoGs by less than 20%. If CoGs increase by 20% or more, AZ and EC to agree on increase of price or reduction of doses number. Fair and equitable way to return excess payments of EC/MS to AZ if CoGs less than estimated price.</p> <p>EC right to audit up to 5 years after agreement expires to protect EU financial interests.</p>	<p>Redacted. EC can audit performance of APA for 5 years.</p>	<p>\$22.5/dose EC can audit performance of APA for 5 years.</p>	<p>Redacted. Price equal to Cost of Goods (excluding VAT), e.g. fully burdened aggregate reasonable direct and indirect costs and expenses incurred by AZ (on no profit no loss basis) to manufacture the Product (full def. redacted). AZ to automatically pass on any increase or decrease in CoGs as compared to the Target Costs of Goods (redacted). If audit determines price exceeds actual CoGs, AZ to refund overpayment with interests.</p>	<p>Redacted. Excess of cost/price ceiling agreed upon is at the Company's own risk Cost-Plus-Fixed-Fee¹³⁵. Subject to audit by the EC.</p>

¹³⁵ According to acquisitions.gov, "A cost-plus-fixed-fee contract is a cost-reimbursement contract that provides for payment to the contractor of a negotiated fee that is fixed at the inception of the contract. The fixed fee does not vary with actual cost, but may be adjusted as a result of changes in the work to be performed under the contract. This contract type permits contracting for efforts that might otherwise present too great a risk to contractors, but it provides the contractor only a minimum incentive to control costs." See here for more information: <https://www.acquisition.gov/far/16.306>

4. Indemnification for liability

<p>EU- AstraZeneca (27 Aug. 2020) <i>Full agreement available</i></p>	<p>EU- CureVac (19 Nov. 2020)</p>	<p>EU- Moderna (25 Nov. 2020) <i>Full agreement available</i></p>	<p>UK- AstraZeneca (28 Aug. 2020)</p>	<p>US- Moderna (16 April 2020)</p>
<p>MS to indemnify AZ for any loss relating to or arising from the use or administration of the Vaccine regardless of where the Vaccine is administered, where the claim is brought, and whether the claim of a Defect originates from the distribution, administration and use, clinical testing or investigation, manufacture (except if not GMP), labelling, formulation, packaging, donation, dispensing, prescribing or licensing of the Vaccine in its jurisdiction.</p>	<p>Administration of the Products conducted under the sole responsibility of MS. No warranty from CureVac about the efficacy to prevent COVID 19 or lack of unacceptable side-effects of the vaccine. Obligation of MS to indemnify CureVac and its subcontractors in case of liability incurred, settlements paid and certain costs relating to third party claims. (several provisions redacted).</p>	<p>Products used under sole responsibility of MS. MS obligation to indemnify Moderna and its contractors. Indemnification "to be interpreted broadly" for any claim of loss, including Product testing and development - except in cases of willful misconduct, gross negligence, non-compliance with marketing authorisation (MA) specifications or GMP product deficiency.</p>	<p>All provisions related to Indemnities are redacted.</p> <p>AZ solely responsible for manufacturing Products in accordance with applicable laws, GMP and marketing authorisation.</p>	<p>Product use in the US protected from liability under a declaration issued under PREP Act 42 U.S.C. 247d-6d¹³⁶.</p>

¹³⁶ <https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>

5. Delivery conditions

<p>EU- AstraZeneca (27 Aug. 2020) <i>Full agreement available</i></p>	<p>EU- CureVac (19 Nov. 2020)</p>	<p>EU- Moderna (25 Nov. 2020) <i>Full agreement available</i></p>	<p>UK- AstraZeneca (28 Aug. 2020)</p>	<p>US- Moderna (16 April 2020)</p>
<p>Estimated delivery schedule: 120 million doses by Q1 2021, reminder by Q2 2021.</p> <p>MS payment obligation suspended in case of non-delivery or late delivery past the firm delivery date.</p> <p>Capacity limitation foreseen and subject to AZ BRE. Delays due to performance of competing agreements is not deemed a contract breach.</p>	<p>225 million doses in 2021/Q1 2022. Additional 180 doses as of Q2 2022.</p> <p>Risk of delay in EU marketing authorisation and production scale-up acknowledged. CureVac to submit a revised delivery schedule.</p>	<p>Delivery dates acknowledged to be “best estimates and subject to change”, based on the expected approval date. 10 mil Q1 2021, 35 mil Q2 2021, 35 mil, Q3 2021. In case of delays, Moderna submits an updated delivery schedule after prior consultation with the EC. If more than 90 days later than originally scheduled, MS may cancel their order and will be fully reimbursed.</p>	<p>Details redacted.</p> <p>AZ Best Reasonable Efforts (BRE) to keep as close to original Proposed Delivery Schedule. No adjustment (without written prior consent) to firm and final Delivery Schedule.</p> <p>If AZ experiences capacity limitations or shortages, Parties discuss in good faith how to resolve the issues. UK right to cancel or refuse Delivery not conformed to Schedule, with no obligation to pay, unless... redacted text.</p>	<p>Redacted</p>

6. Production location requirements

<p>EU- AstraZeneca (27 Aug. 2020) <i>Full agreement available</i></p>	<p>EU- CureVac (19 Nov. 2020)</p>	<p>EU- Moderna (25 Nov. 2020) <i>Full agreement available</i></p>	<p>UK- AstraZeneca (28 Aug. 2020)</p>	<p>US- Moderna (16 April 2020)</p>
<p>AZ BRE to manufacture in the EU (which includes the UK). 30-40 mil by end 2020, 80-100 by Q1 2021, remainder end Q2 2021. Manufacture outside of the EU subject to prior written notice and explanation to the EC. AZ BRE to contracts with EU contract manufacturing organisations, proposed by EC, if AZ does manufacture in the EU. EC/MS BRE to assist AZ in supply of materials.</p>	<p>Manufacture outside of the territory of the European Union, the UK, the EEA or Switzerland is subject to prior consent of the EC.</p>	<p>API manufacture in Lonza, Switzerland. Fill and finish in Rovi Pharma, Spain. Manufacture of initial doses outside of the EU only upon EC approval.</p>	<p>AZ commitment to use supply chain manufacturers listed in Schedule 2 (redacted) for API and product.</p>	<p>Requirement for domestic production and assurance of material sourcing.</p>

7. Global Public Good

<p>EU- AstraZeneca (27 Aug. 2020) <i>Full agreement available</i></p>	<p>EU- CureVac (19 Nov. 2020)</p>	<p>EU- Moderna (25 Nov. 2020) <i>Full agreement available</i></p>	<p>UK- AstraZeneca (28 Aug. 2020)</p>	<p>US- Moderna (16 April 2020)</p>
<p>EC/MS Agreement on COVID-19 procurement is not annexed to the EC/AZ APA.</p>	<p>Mentioned as a negotiation objective in the Annex of the EC/MS Agreement on COVID-19 vaccine procurement on behalf of MS, the latter being included as an annex to the APA, ("in negotiations... EC shall...promote COVID 19 vaccine as global public good, including access for LMICs... sharing of IP especially developed with public support").</p>	<p>Mentioned as a negotiation objective in the Annex of the EC/MS Agreement on COVID-19 vaccine procurement on behalf of MS, the latter being included as an annex to the APA, ("in negotiations... EC shall...promote COVID 19 vaccine as global public good, including access for LMICs... sharing of IP especially developed with public support").</p>	<p>n/a</p>	<p>n/a</p>

8. Intellectual property

<p>EU- AstraZeneca (27 Aug. 2020) <i>Full agreement available</i></p>	<p>EU- CureVac (19 Nov. 2020)</p>	<p>EU- Moderna (25 Nov. 2020) <i>Full agreement available</i></p>	<p>UK- AstraZeneca (28 Aug. 2020)</p>	<p>US- Moderna (16 April 2020)</p>
<p>AZ sole owner of all IPRs generated during the development, manufacture, and supply of the Vaccine, including all Know-How (AZ BRE to share all clinical trial data with EC, but no obligation if not permitted). Acknowledgement of AZ obligations to its upstream licensor.</p> <p>EC right to a licence for vaccines IPRs to continue development if AZ abandons the development.</p>	<p>CureVac owns all IP generated during the development, manufacture and supply of the product (including know-how) and is entitled to exclusively exploit those rights. No licence right granted to the EC or MS.</p>	<p>Moderna is sole owner of all IP, including know-how, and results of the APA. No licence or right granted to EC or MS. Moderna to provide a list of pre-existing rights owners, or declaration of no pre-existing rights with the last invoice.</p>	<p>No rights granted under this agreement. Certain pre-existing rights of OUI granted to UK Gov. AZ either sole owner of all pre-existing IPR in the Product or has licence to manufacture and supply.</p>	<p>USG owns all material and products (e.g. vaccines, validated lots) manufactured and/or acquired with USG funds.</p> <p>USG limited IP rights¹³⁷ in data generated prior to contract and in data developed exclusively with private funds (exact data redacted); USG unlimited IP rights¹³⁸ in data funded under the contract, though Moderna owns inventions developed during the performance of the contract¹³⁹.</p>

¹³⁷ Limited rights means data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Company, be used for purposes of manufacture nor disclosed outside the Government. <https://www.acquisition.gov/far/52.227-14>

¹³⁸ Unlimited rights means the rights of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so. <https://www.acquisition.gov/far/52.227-14>

¹³⁹ Acquisition.gov, 52.227-11 Patent Rights-Ownership by the Contractor. Available online: <https://www.acquisition.gov/far/52.227-115>

9. Payment schedule and conditions (including down payment)

<p>EU- AstraZeneca (27 Aug. 2020) <i>Full agreement available</i></p>	<p>EU- CureVac (19 Nov. 2020)</p>	<p>EU- Moderna (25 Nov. 2020) <i>Full agreement available</i></p>	<p>UK- AstraZeneca (28 Aug. 2020)</p>	<p>US- Moderna (16 April 2020)</p>
<p>2/3 of 336 mil. down payment 5 days after signature; remaining 1/3 upon evidence of use of first payment and manufacturing progress report. MS payment for fill/ finish/ packaging, storage and distribution costs, due upon shipment.</p> <p>Payment schedule can be updated if AZ CoGs increase.</p> <p>Optional doses to be irrevocably ordered by EC based on the first safety and efficacy report of ph.III study.</p>	<p>EC and MS upfront payments to increase the speed of R&D, clinical trials and the preparation of the at-scale production capacity, to be made respectively after APA signature and submission of interim data to EMA.</p>	<p>20% (\$360 mil) upfront payment from EC upon APA signature, 40% payment by each MS upon marketing approval, 40% by MS upon delivery of doses in country</p>	<p>Mostly redacted. Mention of Price Reduction.</p>	<p>Redacted.</p>

10. Payback obligations

<p>EU- AstraZeneca (27 Aug. 2020) <i>Full agreement available</i></p>	<p>EU- CureVac (19 Nov. 2020)</p>	<p>EU- Moderna (25 Nov. 2020) <i>Full agreement available</i></p>	<p>UK- AstraZeneca (28 Aug. 2020)</p>	<p>US- Moderna (16 April 2020)</p>
<p>AZ to return all unused material and funding to EC if AZ abandons development.</p>	<p>MS right to reduce or recover payment if vaccines are not delivered in accordance with APA, based on financial statements detailing expense uses of upfront payments so that unspent amounts can be reimbursed to the EC and MS.</p>	<p>If termination, financial statement of costs/expenses covered with EC Down Payment and Unspent amounts to be reimbursed to EC.</p>	<p>Termination clauses mostly redacted except the following: if the price paid exceeds the price per product delivered, AZ shall refund the amount of such excess.</p>	<p>Vaccine development progress is continually assessed for go/no go decisions so that funding is properly allocated to impact the COVID-19 public health emergency.</p> <p>If the contract is terminated, the parties negotiate an equitable distribution of all property produced or purchased under the contract based upon the share of costs incurred by each.</p>

11. Total payment amount

EU- AstraZeneca (27 Aug. 2020) <i>Full agreement available</i>	EU- CureVac (19 Nov. 2020)	EU- Moderna (25 Nov. 2020) <i>Full agreement available</i>	UK- AstraZeneca (28 Aug. 2020)	US- Moderna (16 April 2020)
€870 million divided in €336 million upfront paid by the EC and €534 million subsequent funding paid by MS.	Redacted	\$1.8 billion	Redacted	\$483 million

12. Access-related provisions

<p>EU- AstraZeneca (27 Aug. 2020) <i>Full agreement available</i></p>	<p>EU- CureVac (19 Nov. 2020)</p>	<p>EU- Moderna (25 Nov. 2020) <i>Full agreement available</i></p>	<p>UK- AstraZeneca (28 Aug. 2020)</p>	<p>US- Moderna (16 April 2020)</p>
<p>MS may donate excess doses to lower- or middle-income countries or public institutions and donate or resell, at no profit, such doses to other European countries that agree to be bound by similar terms and conditions.</p> <p>For additional orders beyond 400 million, no profit no loss price guaranteed only until 1st July 2021 (AZ to reassess in good faith if pandemic ceases after that date).</p>	<p>MS commit not to resell, distribute or donate, even to NGOs or WHO, without prior written consent of CureVac. Receiving country must first confirm to the satisfaction of CureVac that it will fully assume the indemnity obligations. However, CureVac is free to grant or withhold its consent at its own discretion. MS have an obligation to reimburse the Commission for the upfront payment per dose in case of resale.</p> <p>Price of additional orders subject to CureVac determination of end of the pandemic, taking into account WHO advice.</p>	<p>Resell or export possible to other EU/EEA countries if indemnification agreed by the receiving country.</p> <p>Donation outside EU/EEA possible upon approval of Moderna, including indemnification, responsibility of transport and authorisations.</p>	<p>No profit No loss Pricing + AZ BRE to mitigate and reduce CoGs for expedited supply in the context of a global pandemic during the term of the agreement.</p> <p>Right to donate or transfer products delivered, and in excess, to other countries and NGOs, including ACT-A (conditions redacted).</p>	<p>Out of scope.</p>

ANNEX B: LINKS TO APAS

Links to APAs analysed in this document can be found below.

EU-AstraZeneca [redacted, from the EC]:
https://ec.europa.eu/info/sites/default/files/apa_as-trazeneca.pdf

EU-AstraZeneca [unredacted, from Italian news outlet RAI]:
https://www.rai.it/dl/doc/2021/02/19/1613725900577_AZ_FIRMATO_REPORT.pdf

EU-CureVac [redacted, from the EC]:
https://ec.europa.eu/info/sites/default/files/cure-vac_-_redacted_advance_purchase_agreement_0.pdf

EU-Moderna [redacted, from EC]: https://ec.europa.eu/info/sites/default/files/redacted_advance_purchase_agreement_moderna_0.pdf

EU-Moderna [unredacted, from Italian news outlet RAI]:
https://www.rai.it/dl/doc/2021/04/17/1618676613043_APA%20Moderna_.pdf

UK-AstraZeneca [redacted, from the UK]:
<https://www.contractsfinder.service.gov.uk/Notice/SupplierAttachment/77bb967f-0194-452a-bdae-9999aecc753d>

US-Moderna [redacted, from the US HHS]:
<https://www.hhs.gov/sites/default/files/moderna-75a50120c00034.pdf>

Brazil-AstraZeneca [unredacted, from Fiocruz]:
https://medicineslawandpolicy.org/wp-content/uploads/2021/06/MOU_Fiocruz_AZUK_sigilo2.pdf

ANNEX C: GLOSSARY

Intellectual property: Intellectual property (IP) refers to the legal rights that result from intellectual activity in the industrial, scientific, literary and artistic fields. Key intellectual property elements include patents, data and know how. A patent is a form of IP granted to an inventor for the creation of something new, non-obvious to a person who is knowledgeable in the field, and useful.

Licence: A licence grants permission for a third party to make use of a patent, for example, to sell a technology under patent and often requires the payment of a royalty. Licences may be voluntary (as in, with the permission and participation of the patent holder) or compulsory. A compulsory licence is an authorisation by a competent government authority to use a patented invention by a third party without the consent of the patent holder, against a payment of “adequate remuneration.” Governments have the right to issue compulsory licences when they deem it necessary for any reason.

Product liability: Product liability is the area of law that holds accountable those who make products available to the public should those products result in injury or damage to consumers or their property¹.

The Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS): Administered by the World Trade Organization, TRIPS sets out minimum standards for the protection of several forms of IP that all World Trade Organization members need to implement. TRIPS also contains several important flexibilities to preserve the rights of members to protect the public interest.

¹ https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/liability-defective-products_en



The Left in the European Parliament

Rue Wiertz 43 B-1047 Brussels

www.left.eu