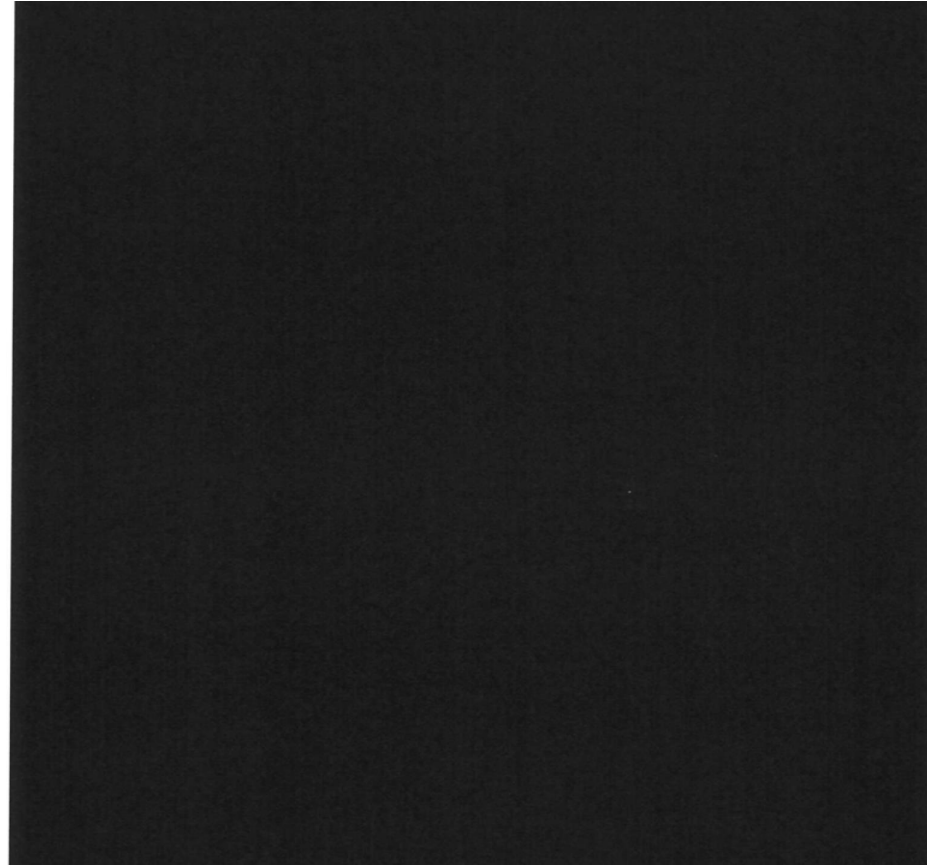


Access to information in COVID-19 contracts and agreements: Oxford/AstraZeneca vaccine case study



Oxford University/Jenner Institute ChAdOx1 nCoV-19 vaccine

27th April 2020

In Race for a Coronavirus Vaccine, an Oxford Group Leaps Ahead

“I personally don’t believe that in a time of pandemic there should be exclusive licenses,” Professor Hill said. “So we are asking a lot of them. Nobody is going to make a lot of money off this.”

Guidance for organisations seeking to licence or otherwise access University of Oxford IP relevant to the COVID-19 pandemic

1. OU and OUI will expedite access to Oxford IP to enable global deployment at scale of associated products and services to address the COVID-19 pandemic
2. The default approach of the University and OUI regarding (1) will be to offer non-exclusive, royalty-free licences to support free of charge, at-cost or cost+ limited margin supply as appropriate, and only for the duration of the pandemic, as defined by the WHO
3. Licence terms for supplying downstream (post-pandemic) commercial markets will be the subject of a separate agreement
4. The grant to a Licensee of access to IP under (1) does not guarantee it will be granted downstream commercial rights
5. Where relevant University IP is licensed to support commercial sales after the point at which the pandemic is declared by the WHO (or other appropriate body) to be over, such licences will carry appropriate financial terms to allow the University to reinvest proceeds in research and teaching.

The University and Oxford University Innovation Ltd will wherever possible adhere to the above principles, subject to our obligations to 3rd party funders and to cases where the overarching principle (1) can only be achieved by a different approach. All licences granted under these principles will preserve the University’s academic research freedoms to publish and use the IP for teaching and research purposes.

28th April 2020

Business | Jumping the gun

An Indian firm starts mass-producing an unproven covid-19 vaccine

It is gambling that one created in Oxford will work and be approved

He calls the decision a gut feeling and a personal kind of commitment to public health. The arrangement is not a contractual one, but a “gentleman’s agreement”, says Adrian Hill, head of the Jenner Institute. A number of other companies, as yet undisclosed, are working on agreements with Oxford to produce the vaccine. “No single company can produce the necessary doses and no company should have that authority,” Mr Poonawalla said. The Serum Institute is likely to be the provider of vaccines for low- and middle-income countries, says Dr Hill.

As the world stood still in lockdown in April 2020, a group of Oxford researchers packed the cell cultures needed to make their experimental coronavirus vaccine and quietly shipped them to India’s Serum Institute.

ChAdOx1 nCoV-19 becomes AZD122

30th April 2020

AstraZeneca 

AstraZeneca and Oxford University announce landmark agreement for COVID-19 vaccine

☰

KHN

COVID-19

They Pledged to Donate Rights to Their COVID Vaccine, Then Sold Them to Pharma

A few weeks later, Oxford—urged on by the Bill & Melinda Gates Foundation—reversed course. It signed an **exclusive** vaccine deal with AstraZeneca that gave the pharmaceutical giant sole rights and no guarantee of low prices—with the less-publicized potential for Oxford to eventually make millions from the deal and win plenty of prestige.

Bloomberg UK Covid Vaccine Front-Runner Is Months Ahead of Her Competition

announced a £2.2 million grant to Gilbert's team to support testing and manufacturing. Her colleague Sandy Douglas got £400,000 to figure out how to ramp up the manufacturing process to a million-dose scale.

During the search for money, Bill Gates pushed Gilbert and Hill to partner with a big pharmaceutical company, and as a CEPI founder he had leverage. "We went to Oxford and said, you are doing brilliant work," Gates recalled in a call with reporters in early June. "You really need to team up, and we told them a list of people to go and talk to."

The Oxford team was initially reluctant, Hill says, because they'd run plenty of trials on their own. "What we struggle against all the time is the perception from funders that we

Public funding and access commitments

- £85.5 million UK public funding (which secured 30m doses “by September for people in the UK” and 100m doses altogether)
- \$1.2 billion from US BARDA (secured 300m doses)
- \$750 million agreement with CEPI and Gavi (first ACT-A/COVAX AMC) - 300m doses for LMICs
- No agreements or contracts made public despite access implications
- AZ commits to providing the vaccine on a “not-for-profit basis for the duration of the pandemic, and in perpetuity to low- and middle-income countries” – but no transparency on their costs, prices, timelines, definitions etc.

Global development

This article is more than 3 months old

Oxford AstraZeneca vaccine to be sold to developing countries at cost price

Jab that is part of global initiative to distribute doses will remain at low price 'in perpetuity'

PUBLISHED
21 May 2020

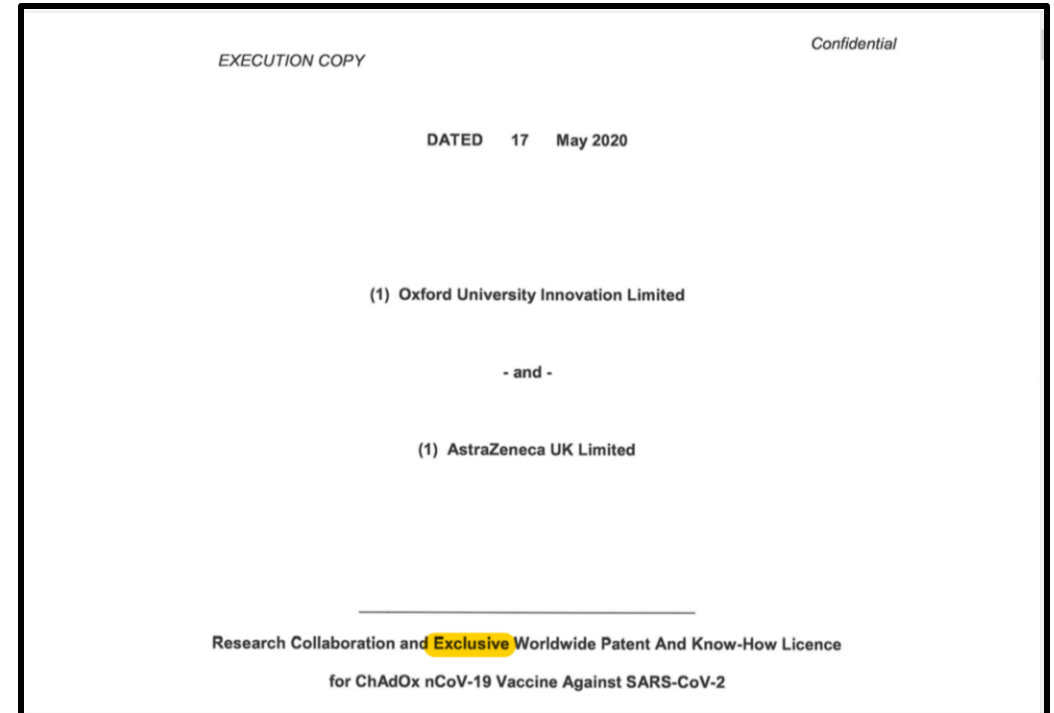
AstraZeneca takes next steps towards broad and equitable access to Oxford University's potential COVID-19 vaccine

Financial considerations

Today's announcement is not anticipated to have any significant impact on the Company's financial guidance for 2020; expenses to progress the vaccine are anticipated to be offset by funding by governments.

The Oxford-AZ licence agreement

- No access to the licence, despite repeated requests from multiple CSO groups both to Oxford and AstraZeneca directly and publicly (not even a redacted version).
- UAEM submitted multiple FOI requests to the University of Oxford for the license agreement:
 - Request was for “all agreements, including contracts, licence agreements and MOUs, since 1 January 2018, between: (1) the University of Oxford and Vaccitech; (2) the University of Oxford and AstraZeneca; and (3) the University of Oxford, Vaccitech and AstraZeneca, which reference the ChAdOx1 nCoV-19 Vaccine or ChAdOx1 vector technology.”
- There was a total of 31 agreements in the scope of this request – none public: All rejected. UAEM submitted formal complaint on the basis of public interest and importance.
- Complaint was successful and redacted version published:
https://www.whatdotheyknow.com/request/668542/response/1802897/attach/3/Oxford%20AZ%20Covid19%20Vaccine%20Licence%20Redacted%20Version%20FINAL.pdf?cookie_passthrough=1



The Oxford-AZ agreement

- No un-redacted mentions of definition of cost of goods, pricing requirements, or definition of “pandemic period” to determine how public “at cost during the pandemic” statements will be upheld
- Also very broad definition of confidentiality – could be linked to heavy redactions/difficulty accessing the licence

4. GRANT OF LICENCES

4.1 OUI grants to AstraZeneca an exclusive (but subject to the provisions of Clause 4.3, 4.4, 16.17 and 16.19) worldwide, royalty-bearing licence under the Licensed Rights to Exploit Licensed Products subject to and in accordance with the provisions of this Agreement.

6.3 AstraZeneca shall enter into a written agreement with each Sub-Licensee (that is not an Affiliate of AstraZeneca) and shall ensure that:

6.3.1 the provisions of each Sub-licence Agreement are not inconsistent with the provisions of this Agreement;

- Clause 4.3, 4.4 and the whole of 16 redacted – i.e. we don’t know what conditions Oxford included in the agreement, or what is required of sub-licensees (i.e. on price, timelines etc.)

1.17 "Cost Of Goods"

12. PRICING OF LICENSED PRODUCTS

4.2 AstraZeneca shall not use and/or exploit the Licensed Rights except as expressly authorised in this Agreement.

16. LICENSEE'S OBLIGATIONS TO EXPLOIT

The AZ-Fiocruz licence leak

Coronavirus treatment

+ Add to myFT

10/7/20, 7:29 PM

AstraZeneca vaccine document shows limit of no-profit pledge

AstraZeneca, which has promised not to profit from its Covid-19 vaccine “during the pandemic”, has the right to declare an end to the pandemic as soon as July next year, according to a document seen by the Financial Times.

Several drugmakers have already signed sales agreements with governments but the terms of the contracts are confidential and few details have been released.

The document states that for the purposes of the MoU and the “Definitive Agreements” the pandemic will be considered over on July 1, 2021. The so-called “Pandemic Period” could be extended but only if “AstraZeneca acting in good faith considers that the SARS-COV-2 pandemic is not over”, it says.

2.1.7 The sublicensing of the commercialization rights for the Covid-19 Vaccine shall comply with the commitments on drugs destination in connection with the pandemic, assumed by AZUK in the AZUK-OUI Agreement.

2.1.7 O sublicenciamento dos direitos de comercialização da Vacina Covid-19 obedecerá aos compromissos de destinação dos medicamentos no contexto da pandemia assumidos pela AZUK no Contrato AZUK-OUI.

2.1.8 For the purposes of this MoU and the Definitive Agreements, the Pandemic Period will be considered as provided for in the AZUK-OUI Agreement, namely, 1 July 2021 unless AstraZeneca acting in good faith considers that the SARS-CoV-2 pandemic is not over as at 1 July 2021, in which case, it shall be such later date as AstraZeneca, acting in good faith, considers the SARS-CoV-2 pandemic to be over.

2.1.8 Para fins deste ME e dos Contratos Definitivos, o Período de Pandemia será considerado aquele previsto no Contrato AZUK-OUI, a saber, 1º de julho de 2021 exceto no caso de a AstraZeneca, em boa-fé, considerar que a pandemia 2019-nCoV ainda não terminou nesta data, caso em que, a AstraZeneca, em boa-fé, determinará data posterior a ser considerada como final da pandemia



FINANCIAL TIMES

HOME WORLD UK COMPANIES TECH MARKETS CLIMATE OPINION WORK & CAREERS LIFE & ARTS HOW TO SPEND IT

Become an FT subscriber to read:

Vaccine deal allows AstraZeneca to take up to 20% on top of costs

The UK-AZ Supply Agreement

- Signed 28th August 2020 - Redacted version published online on 30th September 2020:
<https://www.contractsfinder.service.gov.uk/notice/2ce928f2-0e8b-48cd-b0e7-bccff514d281?origin=SearchResults&p=1>

"Cost of Goods" means the fully burdened aggregate reasonable direct and indirect costs and expenses incurred by AstraZeneca (on a "no profit no loss" basis) to manufacture the Product, consisting solely of:

[REDACTED]

"Confidential Information" means any business, commercial or technical information (in whatever form or media) of either Party that is marked or otherwise indicated as confidential when disclosed or would otherwise be regarded as confidential by a reasonable business person relating to the business, affairs, technologies, products, customers, clients or suppliers

SCHEDULE 3 PROPOSED DELIVERY SCHEDULE PRELIMINARY AND SUBJECT TO CHANGE

| DATE DRUG PRODUCT IS AVAILABLE FOR DELIVERY | NUMBER OF DOSES |
|---|-----------------|
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |

11. PRICE AND CHARGES

- 11.1 AstraZeneca shall supply Product to Purchaser pursuant to the Order at a price equal to the Cost of Goods of such Product excluding VAT (the "Price"). As at the Effective Date the Cost of Goods for such Product is estimated at the Target Cost of Goods per dose.

- 11.3 AstraZeneca shall charge the Price and calculate the Cost of Goods on an Open Book Basis and provide transparency to the Purchaser as to the calculation of the same. "Open Book Basis" shall mean providing the Purchaser with access to information (i) in respect of the costs of the Product and (ii) as necessary to demonstrate its calculation is consistent with its approach in respect of other vaccine products, in each case solely to the extent necessary for the Purchaser to be able to verify that Cost of Goods has been calculated in accordance with the methods and principles set out in this Supply Agreement. Open Book Basis shall not require AstraZeneca to disclose detailed information with regard to its cost of goods for other products.

16. INTELLECTUAL PROPERTY

- 16.1 Neither Party will gain any rights of ownership to or use of any property or Intellectual Property Rights owned by the other (whether by virtue of this Supply Agreement, by implication or otherwise).

UK have no leverage in this agreement – despite paying twice (R&D/purchasing)/no accountability for AZ if they don't deliver

Impacts of secret contracts

- Being kept in the dark: no information. Information is power: AZ retained both.
- Timewasting in a pandemic: Took months to try and uncover what was in these agreements (incl. from investigative journos, news, press releases, leaks and meetings etc.)
- Leaks of other secret vaccine contracts have shown problematic terms (liability and indemnification, donations and prices) – all important factors in creating global inequities
- No foundations for informed policy assessments for best practices
- Undermines "right to know", access to information and public trust
- No accountability:
 - Prices varied between \$2.50 - \$8 depending on country and manufacturer (incl. SII)
 - Figures cited for AZ "at cost pricing" ranged from \$2.50 - \$5
 - AZ ended "non-profit" period in October 2021 (for all except Gavi 58 countries)
 - Timelines and delivery schedules – who would get what, when

South Africa paying more than double EU price for Oxford vaccine

Health ministry quotes says premium is because government did not pay into research and development effort

Each person will receive two doses separated by 28 days and Uganda is purchasing the vaccine from the manufacturer at \$7 per dose, it said.

NEWS | February 10, 2022

AstraZeneca revenues soar with nearly \$4bn in Covid-19 vaccine sales

The drugmaker, which is just beginning to profit from its Covid-19 vaccine, has recorded \$37.4bn in revenue.

What is needed

- Despite being secret, the OX/AZ/UK agreements have some good conditions in esp. around price. Making them public would have set public interest benchmark for the pandemic – and why not if “no profits”?
- Making contracts and licence agreements public can help the development of best practices (e.g. as has been started through MPP)
- Without transparency – no full picture of what went wrong/right. Full transparency would help build a picture of what a voluntary licence that is good for public health looks like - "model clauses" vs. "harmful clauses".
 - Governments establish or strengthen laws to ensure that contracts and license agreements are published promptly and in full.
 - Conditions should be attached to public funding of biomedical R&D projects to ensure all contracts and license agreements associated with any final products are published in full.
 - Governments establish and strengthen public interest principles in legal decisions, laws and policies on freedom of information, confidential information and trade secrets. This could allow public interest override on claims of confidentiality for voluntary licensing terms concerning health products.

<https://msfaccess.org/voluntary-licenses-access-medicines>

TRANSPARENCY MATTERS: SECRETS COST LIVES