# Covid-19 Vaccine Advance Purchase Agreements – Compilation and categorisation of terms relevant to intellectual property rights

The information presented here is taken from eleven publicly accessible advanced purchase agreements which were signed in 2020, i.e. prior to an approved vaccine being available, five concluded by the UK government[[1]](#footnote-1) and six by the EU Commission.[[2]](#footnote-2) The agreements analysed are as follows (in chronological order of the date they were signed):[[3]](#footnote-3)

EU & AstraZeneca (27 August 2020) – unredacted.[[4]](#footnote-4)

UK & AstraZeneca (28 August 2020) – redacted.[[5]](#footnote-5)

UK & Valneva (13 September 2020) – redacted.[[6]](#footnote-6)

EU & Sanofi/GSK (16 September 2020) – redacted.[[7]](#footnote-7)

UK & Pfizer/BioNTech (12 October 2020) – redacted.[[8]](#footnote-8)

EU & Janssen (21 October 2020) – redacted.[[9]](#footnote-9)

UK & Novavax (22 October 2020) – redacted.[[10]](#footnote-10)

EU & Pfizer/BioNTech (11 November 2020) – redacted.[[11]](#footnote-11)

UK & Moderna (16 November 2020) – redacted.[[12]](#footnote-12)

EU & CureVac (17 November 2020) – redacted.[[13]](#footnote-13)

EU & Moderna (4 December 2020) – unredacted.[[14]](#footnote-14)

This data supports the analysis presented in the [insert title and citation of publication in due course]

[Table 1](#Table_1Return) – Matter forming the main subject of the APAs.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Parties | Key supply commitments | Date of APA  | Vaccine | Number of doses | Estimated delivery date | Cost & funding process.[[15]](#footnote-15) |
| EU & AstraZeneca (unredacted) | -To develop a safe and efficacious vaccine.[[16]](#footnote-16)-To build sufficient manufacturing capacity, including the transfer of technology to others.[[17]](#footnote-17)- To deliver doses to participating Member States.[[18]](#footnote-18) | 27 August 2020 | ChAdOx1 nCov-19[[19]](#footnote-19) | - Initial doses = 300 million - Optional doses = 100 million.[[20]](#footnote-20) | Initial doses = end of Q2 (June) 2021.[[21]](#footnote-21) | €870 million (estimate).Upfront costs of €336 million.[[22]](#footnote-22)Supplied on a “no profit no loss” basis.[[23]](#footnote-23) |
| UK & AstraZeneca (redacted) | -To develop a product that complies with specification and MA.[[24]](#footnote-24)-To manufacture at designated facilities (redacted)[[25]](#footnote-25)-To deliver according to proposed delivery schedule (redacted).[[26]](#footnote-26)  | 28 August 2020 | Recombinant viral suspension containing ChAdOx1 nVov-19.[[27]](#footnote-27) | 100 million.[[28]](#footnote-28) | Proposed delivery schedule is redacted.[[29]](#footnote-29) | Target ‘cost of goods’ per dose is redacted.[[30]](#footnote-30) Cost to be calculated on a “open book” basis.[[31]](#footnote-31)Supplied on a ‘no profit no loss’ basis.[[32]](#footnote-32)  |
| UK & Valneva (redacted) | -To develop the candidate.[[33]](#footnote-33)-To establish manufacturing facilities.[[34]](#footnote-34)-To supply product.[[35]](#footnote-35) | 13 September 2020 | VLA2001[[36]](#footnote-36) | Initial order of 30 million regimens (or 60 million doses)[[37]](#footnote-37) | Delivery schedule is redacted.[[38]](#footnote-38) | Price and payment schedule are redacted.[[39]](#footnote-39) |
| EU & Sanofi/GSK (redacted) | -To develop, manufacture and supply.[[40]](#footnote-40) -To ensure manufacturing preparedness. | 16 September 2020. | Adjuvanted pandemic vaccine.[[41]](#footnote-41) | 300 million doses.[[42]](#footnote-42)Sanofi/GSK will endeavour to provide at least 200 million doses to the global initiative “Access to COVID-19 Tools (act) Accelerator”, but specific details are to be subject to a separate agreement with relevant parties.[[43]](#footnote-43) | The timeline for availability is redacted. | -The cost per dose is redacted. This cost is a ‘ceiling’ price.[[44]](#footnote-44)-Down payment to support manufacturing preparedness.[[45]](#footnote-45)-Additional cost of post-marketing studies (if required) to be borne by participating Member States.[[46]](#footnote-46) |
| UK & Pfizer (redacted) | -To develop, manufacture, supply and distribute.-To build sufficient manufacturing capacity.[[47]](#footnote-47) | 12 October 2020.  | Name and specific details of proposed vaccine not included or redacted. | 40 million doses[[48]](#footnote-48)  | Delivery schedule is redacted. | Price per dose is redacted.[[49]](#footnote-49) |
| EU & Janssen (redacted) | -To progress accelerated clinical development plan;--To expand manufacturing capacity;-to purchase materials, supplies, manufacturing capacity etc.;-To manufacture vaccine candidate.[[50]](#footnote-50) | 21 October 2020 | SARS-CoV-2 vaccine, Ad26.COV2-S[[51]](#footnote-51) | Base volume commitment = 200 million vaccine regimens.Additional volume commitment = up to 200 million vaccine regimens.[[52]](#footnote-52) | Delivery schedule is redacted. | -Price per vaccine regimen is redacted. -APA acknowledges that Janssen is developing a ‘Global Not-for-Profit Framework to establish a global price for its vaccine during the emergency response period.[[53]](#footnote-53) |
| UK & Novavax (redacted) | -To develop, manufacture, and supply.[[54]](#footnote-54)-To establish a UK-located supply chain for the product.[[55]](#footnote-55) | 22 October 2020 | NVX-CoV2373. | Priority order of 60 million doses with option to purchase additional doses.[[56]](#footnote-56) Not an exclusive purchasing agreement.[[57]](#footnote-57) | Delivery date and schedule are redacted.[[58]](#footnote-58) | Price per dose for priority and additional doses is redacted.[[59]](#footnote-59) |
| EU & Pfizer (redacted) | -To develop, produce and deliver an authorised vaccine. - Vaccine in Phase 3 clinical development with authorisation expected in Dec 2020 at the earliest.[[60]](#footnote-60) | 11 Nov 2020[[61]](#footnote-61) | BNT162b2 a nucleoside-modified messenger RNA vaccine that encodes an optimised SARS-CoV-2 full-length spike glycoprotein.[[62]](#footnote-62) | -200 million doses with a possible ‘additional order’ for a maximum of 100 million doses.[[63]](#footnote-63) | Delivery schedules are redacted.[[64]](#footnote-64) | -Prices are redacted.[[65]](#footnote-65)-Advance payments made by EU but details on amount and timing are redacted.[[66]](#footnote-66) |
| UK & Moderna | -To develop mRNA-1273-To secure relevant marketing approval.-To manufacture a filled and finished mRNA-1273 that is labelled, released, and delivered.[[67]](#footnote-67) | 16 November 2020 | mRNA-1273 | 17 million doses.[[68]](#footnote-68) | Delivery schedule is redacted.[[69]](#footnote-69) | Price per dose is redacted. |
| EU & CureVac (redacted) | -To increase the speed of vaccine research, development, and clinical trials.[[70]](#footnote-70)-To obtain EU market authorisation for the product;[[71]](#footnote-71)-To establish sufficient manufacturing capabilities.[[72]](#footnote-72) | 17 Nov 2020.[[73]](#footnote-73) | mRNA-based CVnCoV COVID-19 vaccine.[[74]](#footnote-74) | -Initial doses = 225 million doses.-Optional doses (once market authorisation is granted) = 180 million.[[75]](#footnote-75) | Initial doses = end of Q1 (March) 2022. Optional doses = end of Q4 (December) 2022.[[76]](#footnote-76) | Cost per dose is redacted.[[77]](#footnote-77) Up-front payments made by both the Commission and the Member States, but the amount is redacted.[[78]](#footnote-78) |
| EU & Moderna (unredacted) | -To develop, manufacture and supply -To obtain marketing authorisation -To establish and expand manufacturing capacities.[[79]](#footnote-79) | 4 December 2020. | mRNA-1273 | 80 million initial doses.Option to purchase additional 80 million doses on or prior to 31 December 2020.[[80]](#footnote-80) | Initial doses = end of Q3 (June) 2021.[[81]](#footnote-81) | Cost per dose = $22.50.[[82]](#footnote-82) Down payment of 20% of the cost of the initial doses.[[83]](#footnote-83) |

[Table 2](#Table_2Return) – The clinical development of the vaccines examined.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Vaccine | Phase I | Phase II | Phase III | MHRA approval | EMA approval |
| AstraZeneca |  | April-May 2020[[84]](#footnote-84) | April-Nov 2020[[85]](#footnote-85) | 30 Dec 2020[[86]](#footnote-86) | 29 Jan 2021[[87]](#footnote-87) |
| Valneva |  | December 2020[[88]](#footnote-88) | April 2021[[89]](#footnote-89) | 14 April 2022[[90]](#footnote-90) | 23 June 2022[[91]](#footnote-91) |
| Pfizer | April 2020[[92]](#footnote-92) |  | July 2020[[93]](#footnote-93) | 2 Dec 2020[[94]](#footnote-94) | 21 Dec 2020[[95]](#footnote-95) |
| Moderna |  | May 2020[[96]](#footnote-96) | July 2020[[97]](#footnote-97) | 8 Jan 2021[[98]](#footnote-98) | 6 Jan 2021[[99]](#footnote-99) |
| Janssen (J&J) | July 2020[[100]](#footnote-100) |  | September 2020[[101]](#footnote-101) | 28 May 2021[[102]](#footnote-102) | 11 Mar 2021[[103]](#footnote-103) |
| Novavax |  | May 2020[[104]](#footnote-104) | Nov 2020[[105]](#footnote-105) | 3 Feb 2022[[106]](#footnote-106) | 20 Dec 2021[[107]](#footnote-107) |
| CureVac[[108]](#footnote-108) | June 2020 | Sept 2020 | Dec 2020 |  |  |
| Sanofi/GSK | Sept 2020[[109]](#footnote-109) | Feb 2021[[110]](#footnote-110) | May 2021[[111]](#footnote-111) |  |  |

[Table 3](#Table_3Return) – Payback Obligations

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| --- | --- |
| Agreement |  |
| EU & AstraZeneca | -Following the completion of the agreement documentary evidence shows that the cost of the goods was less than the amount paid (for the initial, optional or additional doses) AstraZeneca shall work with the Alliance Manage to establish a fair and equitable way to return the amount of excess payments to the Commission/Member States.[[112]](#footnote-112)-In the event of termination due to abandonment, AstraZeneca shall use best reasonable efforts to transfer all purchase vials and stoppers to the Commission (or designee); assign the Commission (or designee) all purchase or reserved drug product manufacturing capacity from the applicable CMO; return to the Commission (or designee) within 30-days any portion of the funding that is unspent, if any, after deducting all incurred expenses.[[113]](#footnote-113)-In the event of termination due to abandonment, the Commission and Member States shall reimburse AstraZeneca for all reasonably incurred unpaid expenses and any non-cancellable expenses.[[114]](#footnote-114) |
| UK & AstraZeneca | -If following any audit the price charged exceeds the actual cost incurred the AstraZeneca shall within 30-days refund such overpayments plus interest. Commission to pay within 30 days any underpayment.[[115]](#footnote-115)-Following a material breach, terminating party can claim damages for breach of contract.[[116]](#footnote-116)- Effect of termination by AstraZeneca – redacted.[[117]](#footnote-117)-In the event that price paid exceeds the product delivered prior to the date of termination, AstraZeneca shall refund the purchaser the amount of such excess.[[118]](#footnote-118) |
| UK & Valneva | -The clause on Consequences of Termination is heavily redacted.[[119]](#footnote-119) -Clause 4.6 does state that Valneva shall be responsible for its own cost and expense for the development of the product, the implementation and execution of the development plan and for undertaking, and having undertaken, all activities required thereunder to develop the product and to file for and prosecute through to grant a marketing authorisation in the territory. “Development” is defined broadly to include ‘all research, discovery, characterisation, preclinical, clinical and regulatory activity with respect to the product’.[[120]](#footnote-120)-Clause 5.4 states that Valneva shall also be responsible at its own costs and expense for the manufacture of the Product.(The impact of these clauses on who bears the financial burden is not clear in light of the redactions in clause 26 (Consequences of termination) and the completely redacted price and payment clauses/schedules). |
| EU & Sanofi/GSK | -Should no delivery be made (for failure to satisfy milestones 1 and 2) and following formal notification by the Commission, Sanofi/GSK will transfer, upon formal request, to the Commission any raw materials and primary components not used but paid for with the Down Payment or money paid at milestone 1 and 2. -Sanofi/GSK will also facilitate the discussion of a transfer of reserved capacity with CMOs paid for with the Down Payment to a third party selected by the Commission (Subject to CMOs agreement and the CMOs negotiation with third-party about the financial terms of such a transfer.[[121]](#footnote-121)-Sanofi/GSK may be liable for damages to the Commission/MS if agreement terminated because of circumstances listed in clause II.15.2 (a)-(f) (but not (g)).[[122]](#footnote-122)-Commission or MS may be liable for damages to Sanofi/GSK – but the circumstances in which they may be liable has been redacted.[[123]](#footnote-123)- |
| UK & Pfizer | -The clause on the consequences of termination is heavily redacted.[[124]](#footnote-124) |
| EU & Janssen | -Apart from deductions made against the cost of the end product to Member States in accordance with clause I.6.2., the down payments are not refundable by Janssen, except if contractor decides to abandon its development of the vaccine (not clear if it also applies where Janssen have been unable to obtain regulatory approval. Also, it is not clear if expenses can be deducted).[[125]](#footnote-125) -On termination (*due* *inter* aliato Janssen abandoning development or it is unable to obtain regulatory approval) it must return all equipment, materials and property belonging to the other party that the other party supplied to it in connect with the APA.[[126]](#footnote-126)  |
| UK & Novavax | -Novavax shall refund [redacted].[[127]](#footnote-127) |
| EU & Pfizer | -The clause on the ‘Effects of termination’ is heavily redacted.[[128]](#footnote-128) Attachment 5 on the ‘Return and Disposal of Product Materials’ is also completely redacted.  |
| UK & Moderna | Significant sections in the clause covering ‘Termination’ and the “effects of Expiration or Termination’ have been redacted.[[129]](#footnote-129) |
| EU & CureVac | -On termination, CureVac to supply a financial statement outlining spent and unspent amounts. Unspent amounts are to be reimbursed within 30-days from receipt of the financial statement by the Commission. CureVac to transfer to the Commission or a nominated third-party any raw materials and primary components not used and paid for with the upfront payments. CureVac will also facilitate discussion of a transfer of reserved capacity with CMOs paid for with the upfront payments.-Where termination is for CureVac cause contrary to clause II.14.2(b)-(g), CureVac may be liable for damages incurred by Commission or MS (section redacted).-Commission/MS may be liable for damages in certain circumstances (redacted). |
| EU & Moderna |  -If the APA is automatically terminated pursuant to II.16.1 or terminated by the Commission pursuant to II.16.2(a) due to the fact that Moderna failed to obtain market authorisation for the product then the Commission will be entitled to a refund in accordance with II.16.5.[[130]](#footnote-130)-In the case of automatic termination or where Modern is unable to obtain market authorisation by 30 Sept 2021, the down payment shall not be refundable except Moderna will supply a financial states (within 60 days) detailing costs and expenses the down payment has been used for (detailed list of type of ‘expenses’). Unspent amounts will be reimbursed with 30 days.[[131]](#footnote-131)-In the case of automatic termination because market authorisation has not been granted at all or not granted before 30 Sept 2021, but Moderna is able to sell the vaccine to a third party because it has obtained market authorisation in a different country/territory then Modern will refund 50% of the Down payment with 90 days.[[132]](#footnote-132)- Where termination is for Moderna cause contrary to clause II.16.2(b)-(h), Moderna may be liable for damages incurred by Commission or MS.[[133]](#footnote-133)-If Modern terminates the agreement in the event of Force Majeure, Moderna is not entitled to any damages.[[134]](#footnote-134)-If Moderna terminates the agreement because the Commission or MS fail to meet their obligations, the Commission and Member States are liable for damages to Moderna.[[135]](#footnote-135) |

[Table 4](#Table_4Return) – Costs and expenses related to IP

|  |  |
| --- | --- |
| Agreement |  |
| EU & AstraZeneca | -Definition of ‘cost of goods’ includes ‘any other costs and expenses directly incurred for, or fairly allocable to, the Vaccine (e.g., legal, finance, reporting, compliance, and executive management oversight).[[136]](#footnote-136) |
| UK & AstraZeneca | -Cost of goods definition – significantly redacted.[[137]](#footnote-137) |
| UK & Valneva | Price and payment clauses/schedules are completely redacted. Clause 26 on ‘Consequences of Termination is also heavily redacted.  |
| EU & Sanofi/GSK |  |
| UK & Pfizer | -Price and payment heavily redacted. |
| EU & Janssen | -Provision on ‘Refundability’ and the principles applicable for the refund of down payments have been redacted.[[138]](#footnote-138) |
| UK & Novavax | -Cost of product heavily redacted.[[139]](#footnote-139) |
| EU & Pfizer | -The provision on the ‘Effects of Termination’ and ‘Prices’ are heavily redacted making it impossible to determine if this has been provided for in the APA.[[140]](#footnote-140) |
| UK & Moderna | -Provisions related to ‘Purchaser Obligations’, ‘Payment’ and ‘Effects of Expiration or Termination’ are heavily redacted.[[141]](#footnote-141) |
| EU & CureVac | -The costs of IP are an ‘expense’ to be accounted for in the financial statement on termination of the APA.[[142]](#footnote-142) |
| EU & Moderna | -The costs of IP are an ‘expense’ that is to be accounted for in the financial statement on the termination of the APA.[[143]](#footnote-143) |

[Table 5](#Table_5Return) – Definitions of ‘IP Rights’

|  |  |
| --- | --- |
| Agreement |  |
| EU & AstraZeneca | “Vaccine IP Rights” – All IP rights generated during the development, manufacture and supply of the vaccine, including all know-how.[[144]](#footnote-144) |
| UK & AstraZeneca | “IP Rights” means all patent rights, supplementary protection certificates and patent term extensions, trademarks, copyrights, design rights, database rights, domain names, rights in inventions, confidential information, know-how, trade names, business names, get-up, logos, trade dress, and all other rights in the nature of IP rights (whether registered or unregistered) and all applications and rights to apply for the above, anywhere in the world in each case for their full term and any extension thereto.[[145]](#footnote-145) |
| UK & Valneva | “Intellectual Property Rights” means all patent rights, supplemental protection certificates and patent term extensions, trademarks, copyrights, design rights, database rights, domain names, rights in inventions, confidential information, know-how, trade names, business names, get-up, logos and trade dress, and all other rights in the nature of intellectual property rights whether registered or unregistered) and all applications and rights to apply for the above, anywhere in the world in each case for their full term and any extension thereto.[[146]](#footnote-146) |
| EU & Sanofi/GSK | “Vaccine IP Rights” – All IP rights generated during the development, manufacture, and supply of the vaccine, including all know-how.[[147]](#footnote-147) |
| UK & Pfizer | “IP Rights” means all patents, copyright, design rights, registered designs, trade marks, know-how, database rights, confidential formulae and any other IP rights and the rights to apply for patents and trade marks and registered designs.[[148]](#footnote-148) |
| EU & Janssen | “Intellectual Property Rights” means patents, utility models, rights to inventions, copyright and neighbouring and related rights, moral rights, trademarks and service marks, business names and domain names, rights in get-up and trade dress, goodwill, and the right to sue for passing off or unfair competition, rights in designs, right in computer software, database rights, rights to use, and protect the confidentiality of, Confidential Information (including know-how and trade secrets) and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsists or will subsist now or in the future in any part of the world. |
| UK & Novavax | “IP Rights” means all patent rights, supplementary protection certificates and patent term extensions, trademarks, copyrights, design rights, database rights, domain names, rights in inventions, confidential information, know-how, trade names, business names, get-up, logos, trade dress, and all other rights in the nature of IP rights (whether registered or unregistered) and all applications and rights to apply for the above, anywhere in the world in each case for their full term and any extension thereto.[[149]](#footnote-149) |
| EU & Pfizer | -The definition of ‘Vaccine IP Rights’ has been redacted.[[150]](#footnote-150) |
| UK & Moderna | -”Intellectual Property Rights” means all patent rights, supplementary protection certificates and patent term extensions, trademarks, copyrights, design rights, database rights, domain names, rights in inventions, confidential information, know-how, trade names, business names, get-up, logos, trade dress, and all other rights in the nature of IP rights (whether registered or unregistered) and all applications and rights to apply for the above, anywhere in the world in each case for their full term and any extension thereto.[[151]](#footnote-151)-Exhibit B lists the ‘product marks’ -”Trademark” means trademarks, service marks, certification marks, trade dress, internet domain names, trade names, identifying symbols, designs, product names, company names, slogans, logos or insignia, whether registered or unregistered, and all common law rights, applications and registrations therefore, and all goodwill associated therewith.[[152]](#footnote-152) |
| EU & CureVac | “Product IP rights” – All IP rights generated during the development, manufacture, and supply of the product, including all know-how.[[153]](#footnote-153) |
| EU & Moderna | “Vaccine IP rights” – All IP generated during the development, manufacture, and supply of the product, including all know-how.[[154]](#footnote-154) |

[Table 6](#Table_6Return) – Confidential Information

|  |  |
| --- | --- |
| Agreement |  |
| EU & AstraZeneca | -Confidential information means any and all know-how, software, algorithms, designs, plans, forecasts, analyses, evaluations, research, business information, financial information, business plans, strategies, customer lists, marketing plans, or other information whether oral, in writing, in electronic form, or in any other form, any physical items, compounds, components, samples or other materials disclosed by or on behalf of a party to the other party before or after the date of the agreement.-Exclusion from confidential information include information that becomes public knowledge through no improper conduct by the receiving party; information already lawfully possessed by the receiving party without any obligations of confidence; information obtained from a third party without any obligations of confidence (third party must be in lawful possession and not in violation of a contractual or legal obligation to maintain confidentiality); where the disclosing party has agreed to release the receiving party from the obligation of confidence.[[155]](#footnote-155)-Exceptions for legally required disclosures.[[156]](#footnote-156)-Receiving party must ensure the same level of protection afforded to its own confidential information; use the information solely to the extent necessary to fulfil the agreement; disclosures to third parties must place the third party under the same level of confidential obligation to ensure no further disclosure is made.[[157]](#footnote-157) -Obligation to maintain confidential information in a secure fashion by taking reasonable steps to protect from theft and unauthorised use/disclosure; and to notify the disclosing party immediately if any unauthorised use, disclosure, theft, unauthorised access or loss occurs.[[158]](#footnote-158)-Obligation survives for so long as either party has knowledge of any confidential information and shall survive termination or expiry of the APA for a period of 5 years.[[159]](#footnote-159) |
| UK & AstraZeneca | - 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. It includes information in relation to the product and/or services provided hereunder (including know-how, processes, techniques, specifications, reports, analyses, sources of supply, marketing plans, sales strategies, and pricing information).[[160]](#footnote-160)-Each party shall treat the confidential information of the other party as strictly confidential and not disclose it to any third party for any purpose without obtaining prior written consent form the other party.-Each party agrees not to use the confidential information other than as permitted under the agreement.- Each party agrees to treat the confidential information of the other party with at least the same care and in the same manner as its own secret and valuable information.[[161]](#footnote-161)-Each party reserves the right to disclose confidential information to its affiliates/representatives as necessary to enable performance of the APA. Such affiliates/representatives must comply with the confidentiality obligations of the APA.[[162]](#footnote-162)-Confidentiality obligations don’t apply to information that lawfully enters the public domain; information already available to the other party on a non-confidential basis; information obtained from a third party without any obligations of confidence (third party must be in lawful possession and not in violation of a contractual or legal obligation to maintain confidentiality; information developed independently.-Exceptions are provided for FOIA, the 'Codes of Practice’, Environmental Regulations, regulatory authorities, courts, Parliament etc.[[163]](#footnote-163)- Parties agree to publish APA but with exceptions and/or redactions as necessary according to the extensive provisions listed in the agreement (including for reasons of national security, personal data, confidential information protected by IPRs, third party confidential information, IT security, or prevention of fraud). Purchaser shall have final decision regarding exemptions and redactions.[[164]](#footnote-164)-Confidentiality obligations shall last for the term of the agreements and for a period of 10 years thereafter.[[165]](#footnote-165) |
| UK & Valneva | - Confidential information means any business, commercial or technical information (in whatever form or media) of either party that is confidential or of a confidential nature that is provided by one party to the other prior to or after the date of signing the agreement or as a consequence of entering into or performing this agreement. It includes any information or materials possessed or developed (including know-how, processes, techniques, specifications, reports, analyses, sources of supply, marketing plans, sales strategies and pricing information, except for information that is demonstratably non-confidential in nature. The terms of the APA are to be regarded as confidential information.[[166]](#footnote-166)- Each party shall treat the confidential information of the other party as strictly confidential and not disclose it to any third party for any purpose without obtaining prior written consent form the other party.-Each party agrees not to use the confidential information other than as permitted under the agreement.-Each party agrees to treat the confidential information of the other party with at least the same care and in the same manner as its own secret and valuable information.[[167]](#footnote-167)-Each party reserves the right to disclose confidential information to its affiliates/representatives as necessary to enable performance of the APA. Such affiliates/representatives must comply with the confidentiality obligations of the APA.[[168]](#footnote-168)- Confidentiality obligations don’t apply to information that lawfully enters the public domain; information already available to the other party on a non-confidential basis; information obtained from a third party without any obligations of confidence (third party must be in lawful possession and not in violation of a contractual or legal obligation to maintain confidentiality; information developed independently.-Exceptions are provided for FOIA, the 'Codes of Practice’, Environmental Regulations, regulatory authorities, courts, Parliament etc.[[169]](#footnote-169)-Parties agree to publish APA but with exceptions and/or redactions as necessary according to the extensive provisions listed in the agreement (including for reasons of national security, personal data, confidential information protected by IPRs, third party confidential information, IT security, or prevention of fraud). Purchaser shall have final decision regarding exemptions and redactions.[[170]](#footnote-170)-Press releases about the agreement, its subject matter, or any transactions without the prior written consent of the other party (the other party will cooperate in good faith).[[171]](#footnote-171)-Survival clause requires personal data to be remain confidential indefinitely, but the survival term for other confidential information has been redacted.[[172]](#footnote-172) |
| EU & Sanofi/GSK | -Confidential information, material or document means any and all information of any kind (including know-how, software, algorithms, designs, plans, forecasts analyses, evaluations, research, business information, financial information, business plans, strategies, customer lists, marketing plans or other information) and any physical items, compounds, components, samples or other materials disclosed directly or indirectly by one Party and/or any of its affiliates or representatives to the other Party and/or any of its affiliates or representatives, in written, oral, electronic or in any other form.[[173]](#footnote-173)-Confidentiality must be maintained for a period of 5 years following termination or expiry of the APA.[[174]](#footnote-174)-Exception provided for legally required disclosure of confidential information or material. Recipient of confidential information must provide prompt written notice to the ‘disclosing’ other party so that they may seek a protective order or other appropriate remedy to prevent disclosure. The recipient of the confidential information will reasonably cooperate with disclosing party’s counsel in their efforts to obtain a protective order or similar remedy.[[175]](#footnote-175)-The party receiving the confidential information must afford it the same level of protection as its own confidential information; only use and disclose solely to the extent necessary to perform the contract.[[176]](#footnote-176)-Confidential information must be maintained in a secure fashion by taking reasonable steps to protect from theft and unauthorised use and disclosure. Any unauthorised use, disclosure, access or theft or loss must be notified to the disclosing party immediately.[[177]](#footnote-177) |
| UK & Pfizer | -Confidential information means all confidential or proprietary information in any form concerning the contract, its conclusion and/or operation, including any procurement process, irrespective of the manner in which it is disclosed, whether marked confidential or not. Failure to mark as confidential shall not cause the information to be non-confidential and the discloser will not have the burden of proving that a reasonable person in the circumstances would understand the information to be confidential, provided that the discloser has made good faith efforts to clearly mark confidential information as such.[[178]](#footnote-178)-Disclosure requires prior written consent of the other party.[[179]](#footnote-179)-Use of confidential information only for purpose of the contract.-Exceptions provided, *inter alia*, for judicial, administrative, governmental or regulatory process in connection with any action, suit, proceedings or claim or otherwise by Laws, including FOIA, Codes of Practice or Environmental information Regulations.-Confidentiality clause survives expiry or termination for any reason.[[180]](#footnote-180)-Confidentiality clause remains in force without limit in respect of personal data or information related to national security; for all other confidential information for a period of 3 years after expiry or termination of the contract unless otherwise agreed in writing.[[181]](#footnote-181) |
| EU & Janssen | -Confidential Information means any information or document received by either party from the other, or accessed by either party, in the context of and/or related to the APA, including the text of this APA.-It does not include information known to the receiving party; information lawfully obtained from a third party without an obligation of confidence; information that is in the public domain (other than through an act of the receiving party); is independently developed by the receiving party without use of the information of the disclosing party.-All information that was provided, or is to be provided, by Janssen to the Commission or Member States with regards to the vaccine candidate, COVID vaccines and/or vaccine volume shall be deemed Janssen’s confidential information. [[182]](#footnote-182)-Receiving can use confidential information to perform its obligations under the APA.[[183]](#footnote-183) Disclosure for any other purpose and to third parties requires prior written consent (including disclosure in a press release or other public statement[[184]](#footnote-184)). Receiving party shall be responsible for the actions and omissions of third parties to whom the information is disclosed.-Each party agrees to treat the confidential information of the other party with at least the same care and in the same manner as its own secret and valuable information.[[185]](#footnote-185)- Confidentiality obligations are binding during the performance of the APA and for as long as the information or documents remain confidential unless the receiving party is released from its obligation or the information becomes public (except as a result of a breach).[[186]](#footnote-186)- Exceptions provided where the applicable law requires disclosure. Unless prohibited by law, the disclosing party must be notified, provide the disclosing party an opportunity to intervene, and use reasonable efforts to obtain assurances that confidentiality will be respected.[[187]](#footnote-187) -Exceptions provided for FOI. Commission must take all reasonable steps under the applicable laws to prevent disclose of Janssen’s confidential information. Prior to any disclosure Janssen must be notified.[[188]](#footnote-188) |
| UK & Novavax | -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. It includes information in relation to the product and/or services provided hereunder (including know-how, processes, techniques, specifications, reports, analyses, sources of supply, marketing plans, sales strategies, and pricing information).-It also includes information disclosed pursuant to a confidentiality agreement signed on 1 June 2020. -Confidential information cannot be disclosed to a third party for any purpose without obtaining prior written consent from the other party.-Confidential information of the other party can only be used as permitted under the APA.-Each party agrees to treat the confidential information of the other party with at least the same care and in the same manner as its own secret and valuable information.-Each party reserves the right to disclose confidential information to its affiliates/representatives as necessary to enable performance of the APA. Such affiliates/representatives must comply with the confidentiality obligations of the APA.[[189]](#footnote-189)-Exceptions are provided for FOIA, the 'Codes of Practice’ and Environmental Regulations.-Parties agree to publish APA but with exceptions and/or redactions as necessary according to the extensive provisions listed in the agreement. |
| EU & Pfizer | -Some short, but significant, sections are redacted.[[190]](#footnote-190)-Confidential information means any information disclosed or obtained by one party to the other party, either directly or indirectly, or which the disclosing party indicates in writing at the time of disclosure is considered confidential or proprietary, or which the recipient knows or ought to know is such.[[191]](#footnote-191)-It does not include information known to the receiving party; information lawfully obtained from a third-party without an obligation of confidence; information that is in the public domain (other than through an act of the receiving party); is independently developed by the receiving party without use of the information of the disclosing party.[[192]](#footnote-192)-Disclosure of confidential information of the other party to a third party requires prior written consent.[[193]](#footnote-193)-Confidential information shall be used solely for the purposes for which it was provided.[[194]](#footnote-194)-Each party must take all reasonable precautions to prevent unauthorised use or disclosure.[[195]](#footnote-195)-Receiving party may disclose if required or requested by a governmental authority pursuant to applicable law in connection with legal or administrative proceedings. Provided that the receiving party notifies the disclosing party as soon as practicable; furnishes only information in the opinion of the receiving party (or legal counsel) is responsive to the requirement or request; asks a court or other public body to treat the confidential information as confidential.[[196]](#footnote-196)-May only disclose to such of its representatives who have a need to know to fulfil its obligations under the APA. Such representatives must be bound by a written agreement of confidentiality, at least as restrictive as that contained in the APA. Receiving party responsible for all actions of its representatives whether employed or in contractual privity with the receiving party.[[197]](#footnote-197)-Pfizer retains right to disclose confidential information to affiliates without prior written consent of the Member States.-Neither this APA or performance under it shall transfer to the receiving party any proprietary right, title, interest or claim in or to any of the disclosing party’s confidential information (including but not limited to any intellectual property) or be construed as granting a license in its confidential information.[[198]](#footnote-198)-The period in which the confidentiality obligation survives the termination or expiration of the APA has been redacted. Notwithstanding this survival clause, any information which constitutes a trade secret shall be bound by the obligation of confidence for as long as such information constitutes a trade secret, but in no event for a period of less than [redacted].[[199]](#footnote-199) |
| UK & Moderna | -Confidential Information means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, specifications, data, results and other material, pre-clinical and clinical trial results, manufacturing procedures, test procedures and purification and isolation techniques, and any tangible embodiments of any of the foregoing, and any scientific, manufacturing, marketing and business plans, any financial and personnel matters relating to a Party or its present or future products, sales, licensors, licensees, suppliers, purchasers, employees, investors or businesses, that have been disclosed including in connection with the discussions and negotiations pertaining to this Agreement or in the course of performing this Agreement. Without limiting the foregoing, (a) this Agreement and its terms as well as all information pertaining to the relationship between the Parties will be deemed Confidential Information of each Party,(b) the Moderna Technology is Confidential Information of Moderna; and (c) the Product, including the Specifications, Marketing Approvals for the Product, and all data, results and other information relating to the Product (including the safety, immunogenicity or efficacy of the Product) is Confidential Information of Moderna. -Each party must keep the confidential information of the other completely confidential and take proper and reasonable measures to prevent public disclosure, treating such information with at least the same care and in the same manner as its own secret and valuable information.-Neither party will use the confidential information of the other except as is necessary to perform obligations and rights under the APA.-Moderna must not disclose any information that identifies the purchaser or its related parties.[[200]](#footnote-200)- Exclusions cover information known to the receiving party; information lawfully obtained from a third party without an obligation of confidence; information that is in or becomes part of (through no fault of the receiving party) the public domain; is subsequently disclosed to the receiving party without restrictions by a third party who is lawfully entitled to possession and disclosure; is independently developed by the receiving party without use of the information of the disclosing party.[[201]](#footnote-201)-Authorised disclosures cover disclosures authorised in writing in advance; to receiving party’s professional advisors; if required by applicable including the FOIA, by order of Parliament or National Audit Office, a court (several conditions/requirements attached to such disclosures); disclosures to parties necessary for performance of the APA (any receiving party to be legally bound to keep information confidential); disclosures for specific government administrative purposes (as listed in the agreement).[[202]](#footnote-202)- Modern gives consent for publication of the APA (but with information exempt from disclosure in accordance with the FOIA redacted). Subject to giving Moderna 7-days written notice of publication and proposed redactions. Government will consult with Moderna to inform its decision regarding any exemptions or redactions and shall act reasonably in considering redaction requests from Moderna. Modern shall cooperate to enable the purchaser to publish the APA.[[203]](#footnote-203)-Press releases about the agreement, its subject matter, or any transactions without the prior written consent of the other party (the other party will cooperate in good faith).[[204]](#footnote-204)-Provision on security filings with United States Securities and Exchange Commission cover the APA.[[205]](#footnote-205)-Parties agree that damages alone may not be an adequate remedy. Thus, clause provides that parties will be entitled to seek injunctive relief or other equitable remedies.[[206]](#footnote-206)-Obligations of confidence shall remain in force without limit for personal data or patient treatments or medical records. Other obligations shall last for the term of the APA and for a further 10 years.[[207]](#footnote-207) |
| EU & CureVac | -Confidential information or document means 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. -It does not include information known to the receiving party; information lawfully obtained from a third party without an obligation of confidence; information that is in the public domain (other than through an act of the receiving party); is independently developed by the receiving party without use of the information of the disclosing party.[[208]](#footnote-208)-All confidential information must be treated with strict confidentiality-Confidential information only to be used to perform obligations under the APA.-Each party agrees to treat the confidential information of the other party with the same level or protection as its their confidential information and in any case with due diligence.-Confidential information can only be disclosed to third parties with prior written consent of the other party.[[209]](#footnote-209)-May disclose to necessary parties -e.g., subcontractors, directors, employees, etc provided such company or individual is legally bound to comply with the confidentiality obligations of the APA.[[210]](#footnote-210)-Confidentiality obligations are binding during the performance of the APA and for as long as the information or documents remain confidential.[[211]](#footnote-211)-Each party may disclose the total contract volume and value of the APA and/or the Vaccine order form.[[212]](#footnote-212) |
| EU & Moderna | -Confidential information is any information or document received by either party from the other or accessed by either party in the context of the implementation of the APA, that any of the parties has identified in writing as confidential, or, if not so identified, that would be reasonably understood in the biopharmaceutical industry to be confidential. It does not include information in the public domain.[[213]](#footnote-213) |

[Table 7](#Table_7Return) – IP Ownership & Exploitation

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| Agreement |  |
| EU & AstraZeneca | -AstraZeneca shall be the sole owner of all IP rights generated during the development, manufacture, and supply of the vaccine, including all know-how – the ‘vaccine IP rights’.-AstraZeneca shall be entitled to exclusively exploit any such vaccine IP rights, except as set forth in this agreement. AstraZeneca does not grant to the Commission (by implication, estoppel or otherwise) any rights, title, license or interest in the vaccine IP rights.[[214]](#footnote-214)-Provision on IP rights survives termination or expiration of the APA.[[215]](#footnote-215)-Note above on sharing of clinical data. |
| UK & AstraZeneca | -UK government is a third-party beneficiary of certain rights granted in its favour under the Licence Agreement concluded between AstraZeneca and Oxford University Innovation ltd effective 17 May 2020.[[216]](#footnote-216)-AstraZeneca grants a perpetual, non-exclusive, royalty free license to use and exploit such product information and IP rights therein solely for the purpose of illustrating and describing the vaccine in product catalogues.[[217]](#footnote-217)-Neither party will gain any rights of ownership to or use of property or IP owned by the other (by virtue of this supply agreement, by implication or otherwise).[[218]](#footnote-218) |
| UK & Valneva | - Neither party will gain any rights of ownership to or use of property or IP owned by the other (by virtue of this supply agreement, by implication or otherwise)[[219]](#footnote-219)-Other than the warranty related to ownership of IP and licensing of third-party IPRS, the other six subclauses on IP rights and usage have been redacted.[[220]](#footnote-220) |
| EU & Sanofi/GSK | -Sanofi/GSK shall be the sole owner of all IP rights generated during the development, manufacture, and supply of the vaccine, including all know-how -i.e., the ‘Vaccine IP Rights’.-Sanofi/GSK shall be entitled to exclusively exploit any such vaccine IP rights.-Sanofi/GSK does not grant to the Commission (by implication, estoppel or otherwise) any right, title, license or interest in the Vaccine IP Rights (except as expressly set out in the APA).[[221]](#footnote-221) |
| UK & Pfizer | -Neither party will gain any rights of ownership to or use of any property or IP owned by the other.-Pfizer grants to the UK, for the life of the use of the goods, an irrevocable, royalty-free, non-exclusive license of any IPRs controlled by Pfizer for the purpose of receiving and using the goods (to include any associated technical or other information supplied to the UK in any media).[[222]](#footnote-222)-Large section of text redacted.  |
| EU & Janssen | - Neither party gains any rights of ownership to or use of any property or IP rights owned by the other.-Under no circumstances does Janssen grant to the Commission, the Member States or any other third party by transfer, implication, estoppel or otherwise, any right, title, license or interest in any intellectual property rights it or any of its affiliates owns or controls in relation to or resulting from the vaccine candidate, the COVID vaccine or the Vaccine Volume.[[223]](#footnote-223) |
| UK & Novavax | -Neither party gains any rights of ownership to or use of any property or IP rights owned by the other.[[224]](#footnote-224) |
| EU & Pfizer | -The provision on the ‘Exploitation of the Results of the APA’ is heavily redacted. -All rights not expressly granted by the Contractor hereunder are reserved by the Contractor. As the provision is mostly redacted it is impossible to know what if any rights have been granted under this provision.[[225]](#footnote-225)- Neither this APA or performance under it shall transfer to the receiving party any proprietary right, title, interest or claim in or to any of the disclosing party’s confidential information (including but not limited to any intellectual property) or be construed as granting a license in its confidential information.[[226]](#footnote-226)-Each party shall not use the name, trade name, service marks, trademarks, trade dress or logos of the other party in publicity releases, advertising or any other publication without prior written consent in each instance (except public announcements pursuant to subclause (ii) of II.10.). |
| UK & Moderna | -All right, title and interest in and to all Moderna technology will be the exclusive property of Moderna and no right or interest therein s transferred or granted to the purchaser under the APA. Purchaser only acquires the right to use the product.[[227]](#footnote-227)-Moderna grants the purchaser a perpetual, non-exclusive, royalty free license to use product information and any IPRs therein solely for the purpose of illustrating and describing the product in product catalogues.[[228]](#footnote-228)-Purchase does not claim any rights in the product marks, and will not hold itself out as owner of any product marks.[[229]](#footnote-229)-Purchaser will not attempt to register or aid any third party in using or attempting[[230]](#footnote-230)-Purchaser will discontinue any use of product marks to which Moderna reasonably objects and not use any marks in a manner that diminishes the value of any product marks or Moderna.[[231]](#footnote-231)- Purchaser will not modify, distort, change remove or obscure any product marks.[[232]](#footnote-232)Except as provided in the APA, no party will be deemed by estoppel, implication or otherwise to have granted the other party any licenses or other right with respect to any IPRs.[[233]](#footnote-233) |
| EU & CureVac | -CureVac shall be the sole owner of all IP rights generated during the development, manufacture, and supply of the product, including all know-how (the ‘product IP rights’).-CureVac shall be entitled to exclusively exploit any Product IP Rights.-CureVac does not grant to the Commission or Member states (by implication, estoppel or otherwise) any right, title, license or interest in the Vaccine IP Rights (except as expressly set out in the APA).[[234]](#footnote-234) |
| EU & Moderna | -Moderna shall be the sole owner of all IP rights generated during the performance of the agreement.-Moderna shall be entitled to exclusively exploit the results of the APA and any such vaccine rights.-Moderna does not grant to the Commission or the Member States (by implication, estoppel or otherwise) any right, title, license or interest in or to the results of the APA, the Vaccine IP Rights or Moderna’s pre-existing rights.-All rights not expressly granted by Moderna under the APA are reserved to Moderna.***Product marks and related rights.***-Product marks and goodwill are the exclusive property of Moderna/affiliates.-Nothing in the APA grants any right, title or interest therein.-All use by the Commission and Member States will inure (be to the benefit) of Moderna.-Any use of product marks to which Moderna objects must be discontinued.-Any use by the commission and Member States must not diminish the value of the marks or disparage Moderna and/or its affiliates.-The Commission and Member States must not modify, overprint, distort, change, remove or obscure any product marks on the delivered product.  |

[Table 8](#Table_8Return) – Access to Test Data

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| Agreement |  |
| EU & AstraZeneca | -If post-launch safety or risk management studies are required (by EMA, another regulatory authority and relied on by the EMA, or otherwise conducted for the benefit of the Member States) AstraZeneca shall introduce all such costs to the ‘cost of goods’ and include it in the payments to be made by the Member states.[[235]](#footnote-235)-In no event shall AstraZeneca be obligated to disclose vaccine development project results or other information concerning development of the vaccine that AstraZeneca is not legally or contractually permitted to share (including information which AstraZeneca me be required to first disclose to Oxford University. AstraZeneca shall explain the basis on which it is not permitted to share.[[236]](#footnote-236)-On reasonable notice, AstraZeneca shall enable the Commission to access all clinical trial data (including communications with Regulatory authorities and bodies) and all data relevant to the manufacturing of the vaccine (provided it is permitted to share such information; and if not permitted, it shall use its best reasonable efforts to obtain permission to share).-If Commission chooses to access such information through a third party, the third party must be independent expert in the applicable field. The Commission shall notify AstraZeneca of such expert in advance. The Commission shall choose another expert if AstraZeneca provides reasonable justifications.[[237]](#footnote-237)-AstraZeneca shall promptly inform the Commission if, in reviewing the progress of clinical trials, it reasonably determines that the ongoing or planned clinical trials are not likely to be sufficient for approval of the vaccine by the Commission.[[238]](#footnote-238) |
| UK & AstraZeneca | -No dedicated provision – see confidentiality clauses.-This may be covered under the ‘Licence Agreement’ between AZ and OUI effective as of 17 May 2020. In the introduction clauses it does note that the UK Gov has acquired some rights under this agreement. This may include rights to access clinical data.-Also, provision on indemnities is excluded, so any access rights granted for this purpose are not visible. |
| UK & Valneva | -Upon request from the UK government, Valneva shall respond to all reasonable enquiries and requests for information made by the UK regarding the development of the product. The UK is to be kept promptly informed of all material events and issues that impact the development and/or manufacture of the product and its delivery.[[239]](#footnote-239)-Rest of provision is redacted. |
| EU & Sanofi/GSK | -Sanofi/GSK commit to provide the Commission, as soon as available, the data of ‘Milestone 1’ including, preclinical studies results, key phase I/II clinical study results. Phase III clinical study final design and protocol, anticipated deliver schedule.[[240]](#footnote-240)-Member States agree to pay Sanofi/GSK Milestone 1 in two equal payments after signature of the vaccine order form and upon receipt of the following – *Instalment 1 -* Phase III clinical trial authorisation submission proof and Phase III clinical trial approvals by regulatory authority in relevant countries; Sanofi/GSK progress report showing “first visit first subject”.*Instalment 2 – ‘*Milestone 1 Progress Report’ on the phase III clinical trial progress showing “first visit last subject”. The report will substantiate the activities performed and progress made during phase III clinical trial – some redaction.[[241]](#footnote-241)-Post-marketing studies that the APA anticipates will be required by the EMA, are to be paid for by the Member states. The cost and lump sum payment for these studies have been redacted. -Regular expected post licensure activities (e.g., lowering age indication, regular pharmacovigilance etc) are to be borne by Sanofi/GSK.[[242]](#footnote-242)-In case liability has been incurred by Sanofi/GSK, Sanofi/GSK shall give the Member state, or an independent expert, reasonable access to information necessary for Member state to indemnify and to verify whether conditions are fulfilled. This information shall include clinical trial and other data generated to demonstrate safety, efficacy and quality of vaccines, as well as all data relevant to the manufacturing of the vaccine including quality control data.[[243]](#footnote-243)  |
| UK & Pfizer | -Parties agree to discuss at Governance meetings – an update on progress towards grant or otherwise of the authorisation; an update on progress made in relation to clinical trials and manufacturing; any communication from the licensing authority (MHRA/EMA) relating to safety or efficacy including any actual or suspected adverse reaction and any known health and safety hazard of the goods.[[244]](#footnote-244)-Clause on indemnity is completely redacted, so unable to see if access to clinical trial data is a condition of indemnification. |
| EU & Janssen | -Janssen shall report on progress made in clinical development of the vaccine candidate.[[245]](#footnote-245)-Information shall only be provided to Commission and Member States’ experts who, where appropriate, will have entered into confidentiality arrangements to ensure strict confidentiality and non-disclosure.[[246]](#footnote-246)-Janssen shall provide information to the Member States reasonably required for indemnification purposes. Subject to strict confidentiality obligations and under no circumstances shall the contractor be required to provide any information (including trade secrets) which it reasonably believes would cause material harm to it if disclosed.[[247]](#footnote-247) |
| UK & Novavax | -The UK government shall use commercially reasonable efforts to assist Novavax’ conduct of UK based phase III clinical trial by facilitating access to the National Institute of Health Research to facilitate access to clinical trial sites in the UK, principal investigators, immunology lab testing facilities and personnel, and IRBs; and to streamlined regulatory approvals.[[248]](#footnote-248)-All provisions on indemnities are redacted, so unable to see if access to clinical trial data is a condition of indemnification. |
| EU & Pfizer | -Clause I.6.6. on ‘Clinical trials and licensure’ is short and mostly redacted. -Clause I.6.7. on ‘Waiver’ is heavily redacted making it impossible to determine if access to test data is a condition of the waiver. -Clause I.12 on ‘Indemnification’ is almost completely redacted making it impossible to determine if access to test data is a condition of indemnification. -Clause II.6. on ‘Liability’ is also heavily redacted. |
| UK & Moderna | -Subject to applicable laws and any restrictions imposed by NIH or other governmental authorities, Moderna shall share summaries of available interim and final data from phase 2 and 3 studies.[[249]](#footnote-249) |
| EU & CureVac | -CureVac to provide updates on progress of clinical development of product including interim and final results of clinical studies of the product.[[250]](#footnote-250)-CureVac shall keep the Commission and Member states informed about any signal detected during the pharmacovigilance or vaccine monitoring programs in relation to the vaccine within 5 working days from notifying the EMA.[[251]](#footnote-251)-In case liability has been incurred by CureVac or its affiliates etc, CureVac shall give the Member State or independent expert access to all information reasonably necessary to indemnify CureVac or its affiliates etc. and to verify whether the stated conditions are satisfied.[[252]](#footnote-252) |
| EU & Moderna | -Moderna to provide the following information as part of and until its submission for market authorisation and full production – key updates on progress made in clinical development; final reports of clinical studies and safety evaluations submitted to the EMA.[[253]](#footnote-253) -Indemnified party to give the relevant Member State access to documents and information as are reasonably necessary and appropriate for the state to indemnify and to verify whether the conditions pursuant to clause II.5.1. are fulfilled.[[254]](#footnote-254) |

[Table 9](#Table_9Return) – Access to IPRs following abandonment

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| Agreement |  |
| EU & AstraZeneca | -The Commission or any third party designated by the Commission, shall have the right to obtain a license or sublicense from AstraZeneca for the vaccine IP rights to the extent necessary to enable the Commission to continue the development efforts for the vaccine for the EU market in the event that AstraZeneca determines to abandon the development efforts hereunder (subject to the upstream license).-The Commission or any third party who obtains any license, sublicense from AstraZeneca shall be solely liable for all royalties, costs and other expenses incurred by AstraZeneca and payable to a third party in consideration for such license or sublicense (including, but not limited to, payment obligations AstraZeneca has to its upstream licensor for the Vaccine).[[255]](#footnote-255) |
| UK & AstraZeneca |  |
| UK & Valneva |  |
| EU & Sanofi/GSK | -Section on abandonment has been redacted.[[256]](#footnote-256) |
| UK & Pfizer |  |
| EU & Janssen |  |
| UK & Novavax |  |
| EU & Pfizer |  |
| UK & Moderna |  |
| EU & CureVac |  |
| EU & Moderna |   |

[Table 10](#Table_10Return) – Location of manufacture

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| Agreement |  |
| EU & AstraZeneca | -AstraZeneca shall use its Best Reasonable Efforts to manufacture the Vaccine at manufacturing sites located within the EU (which for the purposes of this provision includes the UK).-AstraZeneca may manufacture the vaccine in non-EU facilities, if appropriate, to accelerate supply of the Vaccine in Europe *provided* that AstraZeneca provides prior written notice of such non-EU manufacturing facilities to the Commission and an explanation for using non-EU manufacturing facilities.-If AstraZeneca is unable to deliver on its intention to use EU manufacturing facilities, the Commission or Member States may present to AstraZeneca CMOs within the EU capable of manufacturing the vaccine doses and AstraZeneca shall use its best reasonable efforts to contract with those CMOs to increase the available manufacturing capacity within the EU.[[257]](#footnote-257)-Drug *substance* manufacturing at Novasep (FR/BE), Halix Biologics (I/IL), Oxford Biomedica (UK), Cobra Biologics (UK).[[258]](#footnote-258)-AstraZeneca also in discussion with Advent (ITL). Catalent (US) may serve as a back-up supply site.[[259]](#footnote-259)-Drug *product* manufacturing at Catalent (ITL), IDT Biologika (DE), Wockhardt (UK) and potential other suppliers.[[260]](#footnote-260)-Following execution of the manufacturing arrangements for the initial Europe doses, AstraZeneca will provide the names of the contracted suppliers.[[261]](#footnote-261) |
| UK & AstraZeneca | -Definitions include ‘UK Supply Chain’ which means facilities identified in Schedule 2 – Schedule 2 redacted.-AstraZeneca to ensure that market authorisation granted will cover the UK supply chain and *‘the other manufacturing facilities in Europe’* as Facilities qualified and validated for manufacture of the vaccine.[[262]](#footnote-262) |
| UK & Valneva | -The Facility Plan (which is redacted in the Schedules to the Agreement) requires Valneva to ‘be consistent with the provisions of this Agreement to achieve a Manufacturing facility with the Territory (defined as ‘the United Kingdom of Great Britain and Northern Ireland) that is suitable for and has sufficient capacity for the manufacture and delivery of the product in the territory in accordance with the delivery schedule’.[[263]](#footnote-263)  |
| EU & Sanofi/GSK | -The doses for the Member States would be predominantly manufactured at GSK and Sanofi sites in the European territory and additional manufacturing sites could be leveraged to accelerate production and/or to provide a back-up solution for security and expansion.[[264]](#footnote-264)-Sanofi/GSK cannot subcontract beyond the third parties already mentioned in the APA without prior written consent.[[265]](#footnote-265) The list of third-party contractors has been redacted. |
| UK & Pfizer | -The supply of good will be made from Supplier sites within the EEA (which shall include the UK, irrespective of the UK’s withdrawal from the EU), unless express prior written approval has been granted by the UK. -Clause 8.6 hints that supplies from alternative sites outside the EEA may be sought where there is insufficient volume in the EEA – but relevant sentence is redacted.-Pfizer may subcontract to the parties set out in Schedule 8[[266]](#footnote-266) – Schedule 8 redacted. May sub-contract to others with prior written consent of UK authority (not to be unreasonably withheld or delayed).[[267]](#footnote-267) |
| EU & Janssen | -No express requirement for local manufacture.-In the ‘Tentative Availability Schedule’ it states that Janssen is scaling up manufacturing capacity in various European Member States with a view to make available vaccine volume from its European manufacturing sites. But the Commission and Member States acknowledge and agree that Janssen will rely on additional capacity established (and to be established) within its worldwide manufacturing network (in particular in the United States) in order to support availability of vaccine volume under this APA. Janssen will inform the Commission if other manufacturing outside the EU Member states will be required for making available the vaccine volume.[[268]](#footnote-268) |
| UK & Novavax | -Novavax to be responsible for establishing a UK located supply chain.[[269]](#footnote-269)-Intended that Fujifilm facilities in the UK shall undertake manufacturing and finish and fill activities. -Novavax shall have ultimate decision-making authority regarding all matter related to the facilities, to be assisted by the relevant government authority if alternative facilities are required.[[270]](#footnote-270)-List of all facilities provided in original agreement but redacted. -Evident from clause 3.3 that Novavax’s validation commitment for manufacturing facilitates extends to those outside of the UK but within the EEA. -Any use of facilities outside the EEA is subject to redacted condition/s.[[271]](#footnote-271)-Prior to full-scale manufacturing by Fujifilm, or other CMOs secured by Novavax, an interim supply of the vaccine may be sought from Novavax’s existing manufacturing facilities. Subject to Novavax’s obligations to COVAX and its funding entitles.[[272]](#footnote-272)-In the event that the order cannot be fulfilled in the UK, Novavax shall use commercially reasonable efforts to secure manufacturing from other facilities within its EEA supply chain, or facilities in its supply chain outside of the EEA (some information redacted).-Novavax to supply to the UK on a priority basis – e.g., must meet the total quantity to the UK (60 million doses) before supplying any product to any other person in, or for use within, the territory; cannot use any ‘secured facilities’ to supply any third-party until the priority order has been satisfied (subject to some exceptions). |
| EU & Pfizer | -Clause I.6.3. on ‘Supply Mechanism’ does cover the primary manufacturing sites and sites operated by subcontractors, but the relevant information is redacted. -Pfizer may not subcontract beyond the parties already identified in its tender. However, sections of text have been redacted making it impossible to establish if location is expressly stated. -Annex IV on ‘Subcontractors’ and Annex V on ‘Participating Contractor Affiliates’ are completely redacted.  |
| UK & Moderna | -Provision on ‘Manufacturing Location’ is heavily redacted, but does require Moderna to keep purchaser informed promptly of all manufacturing sites and facilities in which manufacturing activities are undertaken.[[273]](#footnote-273)-Moderna may subcontract all or any part of its manufacturing of the product provided Moderna informs the government in writing of the details and identities and Moderna remains responsible for performance under the APA. |
| EU & CureVac | -CureVac may not manufacture or have manufactured the product at manufacturing sites located outside the territory of the EU, the UK and the EEA or Switzerland without prior consent of the Commission (consent may not be unreasonably withheld or delayed if the manufacturing site is required to accelerate the production of the initial doses).[[274]](#footnote-274)-A list of pre-approved CMOs is annexed to the APA but is redacted.[[275]](#footnote-275)-CureVac may not subcontract without prior written consent of the Commission (not to be unreasonably withheld or delayed).[[276]](#footnote-276) |
| EU & Moderna | -To produce initial doses, Moderna may not manufacture or have manufactured the product at sites outside the EU, the EEA or Switzerland without prior consent of Commission (not to be unreasonably withheld, conditioned or delayed if the purpose is to accelerate the production of the initial doses).[[277]](#footnote-277)-Moderna to undertake tech transfer to ROVI in Madrid, Spain to facilitate expertise and capacity building for finish and fill.-Lonza in Basel, Switzerland selected as contract manufacturing partner with Lonza employees being trained at a Moderna manufacturing site[[278]](#footnote-278)-Moderna to ensure subcontracting does not affect the contractual rights of Commission and Member states and to be solely responsible for the implementation of the APA. -Cannot subcontract beyond those mentioned in the agreement without written consent of the Commission (such consent cannot be unreasonably withheld, conditioned or delayed). -Moderna has the right to extend the rights, licenses and obligations under the APA to one or more of its affiliates. All applicable terms of the APA will apply to such affiliates. Contractor remains primarily liable for acts/omissions and financial liabilities of its affiliates.[[279]](#footnote-279) |

[Table 11](#Table_11Return) – Redistribution of Excess doses

|  |  |
| --- | --- |
| Agreement |  |
| EU & AstraZeneca | -In the event there is an excess of supply of the initial Europe doses and optional doses, the Member States shall keep their shared rights in the initial Europe doses and shall determine their best use of such excess doses, reserving the possibility to donate them to lower or middle income countries or public institutions and to donate or resell, at no profit, such doses to other European countries that agree to be bound by the terms and conditions of this APA applicable to participating Member States.[[280]](#footnote-280)-Member States may also resell, at no profit, Initial Europe doses and/or optional doses to European countries that are not Member states if such countries agree to be bound by the terms and conditions of the APA.[[281]](#footnote-281)--Selling EU state to reimburse to the Commission the ‘initial funding’ paid for the doses concerned. |
| UK & AstraZeneca | -AstraZeneca agrees and acknowledges that the UK may donate or transfer, at no profit, excess vaccine to other countries, governments and charitable organisation including the ACT Accelerator.[[282]](#footnote-282)-Most of the paragraph is redacted. This either contains conditions on donation or transfer and/or detail about ‘resale’ of excess product. |
| UK & Valneva | -The only unredacted provision that touches upon this issue is Clause 28 on ‘International Access’. Clause states that the product may be made available to developing countries around the world to help control the pandemic. This does not appear to be subject to any conditions imposed by Valneva.There is a further reference to ensure some form of access to the product. The nature of the access and who it is for is redacted, but this would be subject to discussion between Valneva, the UK government and other national governments.[[283]](#footnote-283) |
| EU & Sanofi/GSK | - Commission or Member States can donate or redistribute doses between Member states or other countries or other international entities that have concluded a Vaccines Order Form with Sanofi/GSK.[[284]](#footnote-284)-Such redistribution to EEA countries is allowed if those countries agree to be bound by equivalent liability protection as set out in the APA.-Redistribution or donation to other countries or international entities is subject to prior notification and approval of Sanofi/GSK (not to be unreasonably withheld). And subject to the other countries or international entities agreeing to liability protection at least as protective as the terms of the APA.[[285]](#footnote-285)-Sanofi/GSK will endeavour to provide at least 200 million doses of the vaccine to the global initiative ‘Access to COVID-19 Tools (act) Accelerator’ so as to ensure availability for all, especially vulnerable countries (subject to the inclusion of satisfactory liability protection). Details to be agreed under a separate agreement with the relevant parties.[[286]](#footnote-286)--Selling EU Member State to reimburse the Commission the ‘down payment’ for the doses concerned. |
| UK & Pfizer | -UK will have the right to ‘donate’ excess doses to in-need third countries or public institutions, contributing to the global and fair access to the goods across the world.-Large section redacted which hints at a list of conditions on donation and resale. - Section concludes - ‘Otherwise, and to the extent permitted by law, the [UK] shall not be permitted to resell or donate the Goods to other countries or third parties.[[287]](#footnote-287) |
| EU & Janssen | -Member States may ‘resell’ to:[[288]](#footnote-288)* A Member States who has opted out of the APA, or to Norway, Liechtenstein and Iceland without prior consent, on condition that:
	+ Regulatory approval has been granted in the receiving state
	+ Doses are not to be sold at a profit.
	+ Commission is reimbursed by the selling Member State
	+ Janssen and the reselling state must agree on the volume that is to be resold in order to optimise the worldwide allocation of COVID vaccine.
	+ Receiving state must agree to be bound by the terms of the APA including the indemnification clauses.
	+ Reselling state accepts responsibility for all logistics and costs thereof (unless agreed otherwise with the receiving state).
* Another participating EU Member State without prior consent, on condition that:
	+ Regulatory approval has been granted in the receiving state
	+ Doses are not to be sold at a profit.
	+ Receiving state must agree to be bound by the terms of the APA including the indemnification clauses.
	+ Reselling state accepts responsibility for all logistics and costs thereof (unless agreed otherwise with the receiving state).
* Any other third party, provided that:
	+ The selling state informs Janssen of its intention to resell.
	+ Both Janssen and the Member State mutually agree on the appropriate terms and conditions of such resale (taking into account the need to optimise the worldwide allocation of COVID vaccine).

-If a Member State contemplates ‘donation’ of any vaccine to a third party the state must inform Janssen and discuss whether this would be possible (taking into account the need to optimise the worldwide allocation of COVID vaccine). If possible, the Member State and Janssen must mutually agree on appropriate terms and conditions, including:* The recipient country (which shall be a low income or middle-income country), where donations are made to a supranational/international organisation or governmental or non-governmental entities
* Appropriate regulatory approval having been granted in each donation recipient country to the satisfaction of Janssen.
* Janssen and the Member State agreeing on the volume of vaccine to be donated (in order to optimise the worldwide allocation of COVID vaccine).
* Section redacted
* Reselling state accepts responsibility for all logistics and costs thereof (unless agreed otherwise with the receiving state).
 |
| UK & Novavax | -Novavax agrees and acknowledges that the UK may donate or resell excess product to other countries, governments and charitable organisations, including the ACT Accelerator. Subject to several conditions. -In relation to donations or resale outside the territory the UK government to be solely responsible for shipping, transporting to such countries; for initiating and implementing recalls; product warranties apply solely to the sale of the product to the UK gov; Novavax shall have no indemnification obligation in respect of the product once it is donated or resold. - Certain obligations under the agreement to not extend to donated/resold product, and no confidential information of Novavax shall be disclosed.[[289]](#footnote-289) |
| EU & Pfizer | --The parties acknowledge that should any resale to a third country take place, the participating member state reselling doses has an obligation to reimburse the Commission.[[290]](#footnote-290)-The sections of text that appear to cover redistribution of excess doses has been redacted.[[291]](#footnote-291) |
| UK & Moderna | -(Subject to section 3.11 and the following restrictions being compliant with applicable law) the purchaser will not sell, resell, transfer, hypothecate, assign, export, import or distribute the product outside the territory. If the purchaser receives any order or request for product outside the territory (territory is not defined or is redacted in the definitions – assumed to be the UK) it must be referred to Moderna for acceptance or rejection. Moderna will use reasonable efforts to stop any redistribution it becomes aware of. If the purchaser is unable to stop such redistribution, Moderna will take steps to cease further distribution by itself to such third party.[[292]](#footnote-292)-Clause 3.11 on the ‘Right to Support other Government Authorities’ provides an exception to the territory restrictions above. Purchase may provide the product to (I)NGOs (such as CEPI or GAVI), charitable foundations (such as the Gates Foundation) or the WHO or other international humanitarian body; (ii) any Crown dependencies and UK overseas territories; (iii) any Government Authority outside of the territory, and not identified under (ii) or as a ‘restricted person’ ( e.g. the target of sanctions, is identified by the US as not to be engaged with in any transaction, or a government authority to which Moderna provides any product[[293]](#footnote-293)).-Any provision of the product must be made on a not-for-profit basis and must comply with terms in Exhibit E (redactions in remaining part of clause 3.11 suggest additional conditions):* UK must supply Moderna with any information reasonably requested in relation to the redistribution to establish compliance with the following conditions,
* It must be lawful to supply product according to the applicable laws of the UK and donation country in relation to packaging, storing, transporting, exporting, importing, insuring or distribution of vaccines,
* The donation recipient confirms in writing to the UK that the vaccines will be used and administered in accordance with the label and applicable laws,
* The product has been stored and transported in accordance with GDP,
* The product has sufficient shelf life remaining to reasonably enable administration of the product prior to its expiry.
 |
| EU & CureVac | -Member states are entitled to re-sell, export and/or distribute to any other EU or EEA Member State and Switzerland. Provided that before re-sale, export, distribution, the recipient state agrees in writing to fully assume the indemnity obligations set out in the APA.[[294]](#footnote-294)-Member states must ensure that the vaccine will not be re-sold, exported, distributed or donated for free to another country outside the EU, EEA and Switzerland, including for donation via NGOs or the WHO, without prior consent of CureVac.[[295]](#footnote-295)-CureVac is free to grant or withhold consent to resale to non-EU, EEA and Switzerland countries. -In any event, no resale shall take place at a price higher than the purchase price agreed in the APA.-no resale may take place unless the receiving country assumes the indemnity obligations set out in the APA or they provide alternative protection arrangements that CureVac accepts as adequate.[[296]](#footnote-296)-Member State has an obligation to reimburse the Commission for the up-front payments made in relation to the doses being sold. -CureVac shall not unreasonably withhold consent to export, distribute or donate to third counties (subject to same indemnity requirement).-The Members state or receiving country shall assume responsibility for the expense required for regulatory/quality/GMP/GDP processes to be satisfied to allow for resale etc.[[297]](#footnote-297)-In the case of donation or resale to another EU, EEA state or Switzerland, the contractor may (at its discretion, and without additional cost) support or execute implementation of regulatory/quality/GMP/GDP requirements.[[298]](#footnote-298) |
| EU & Moderna | -Each Member State is entitled to re-sell, export and/or distribute the Product to any other EU or EEA Member state. Subject to the product being paid for in full prior to resale/donation; and the other EU/EEA state expressly agrees in writing to assume the indemnity and other rights and obligations hereunder.-When selling to an EEA or non-EEA state the EU member state must reimburse the Commission for the upfront payments made in relation to those doses.-Cannot resell at a price higher than the purchase price.-Member states can only resell, export, distribute or donate to a country outside the EU/EEA (either directly or indirectly through NGOs, WHO or other public organisation) with the written consent of Moderna (which cannot be unreasonably withheld, subject to the Member States and third country’s compliance with Moderna’s reasonable requests). -It will be reasonable to withhold consent where Moderna would be required to obtain market authorisation in the jurisdiction. -The donation/resale country will only be permitted to use the product within its own territory.[[299]](#footnote-299)-Member state must donate ‘at no cost’ to the donation country Further substantive and administrative obligations imposed on Member State and third country, including the requirement that Member states resale at cost. |

[Table 12](#Table_12Return) – Third-party IP rights

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| --- | --- |
| Agreement | Third-Party IP Rights |
| EU & AstraZeneca | -No direct warranty that will deliver free of IP rights. Clause 11.1 does acknowledge that AstraZeneca has pre-existing obligations to its upstream licensor. |
| UK & AstraZeneca | -Effective 17 May 2020, AstraZeneca secured an exclusive license from Oxford University Innovation Ltd to use OUI’s vaccine technology to research, develop, commercialise, sublicense and otherwise exploit a vaccine for the prevention of SARS-CoV-2 in humans.[[300]](#footnote-300)-AstraZeneca warrants, represent and undertakes that either it is the sole proprietor and legal and beneficial owner of all IP rights in the product, or it is licensed by the relevant owners to manufacture and supply the product in accordance with the APA. It will use its best reasonable efforts to ensure that it remains the owner and/or licensee of the IPRs in the vaccine throughout the term of the agreement.[[301]](#footnote-301)-AstraZeneca warrants that any receipt, keeping, sale and use of the vaccine by the purchaser (or affiliate) in accordance with the agreement shall not infringe any IPRs of any third party.[[302]](#footnote-302) |
| UK & Valneva | Valneva represents and warrants that as of the date of the agreement it owns all IPRs in the product or it is licensed by the relevant owners to, and has the rights to use the cell line used for, the manufacture of the product.[[303]](#footnote-303) |
| EU & Sanofi/GSK | -Sanofi/GSK warrant that to the best of their knowledge they will have all necessary IPRs for the supply of the vaccine.[[304]](#footnote-304) |
| UK & Pfizer | -Pfizer warrants that receipt and use of goods or any other item or information supplied, or made available, to the UK will not infringe…. (detail redacted).[[305]](#footnote-305)-Pfizer warrants that it has and shall maintain all rights, consents, authorisations, licenses and accreditations (other than those provided for pursuant to the above clause) required to manufacture and supply the goods.[[306]](#footnote-306)-IP clause survives expiry or termination for any reason.[[307]](#footnote-307) |
| EU & Janssen | -No express clauses evident, but Janssen is leveraging its own AdVac and high yielding manufacturing platforms as well as its experience and capabilities from the development of its Ebola vaccine and investigational HIV, RSV and Zika vaccine candidates.[[308]](#footnote-308) |
| UK & Novavax | -Novavax warrants that it is either the sole proprietor and legal and beneficial owner of all IPRs in the product or it is licensed by the relevant owners to manufacture and supply the product in accordance with the agreement.-Novavax warrants that it is not aware that any receipt, keeping, sale and use of the product in accordance with this agreement would infringe any third-party IPRs.[[309]](#footnote-309) |
| EU & Pfizer | -In clause II.8.2. on ‘Warranties of either party’ the warranties provided by Pfizer have been redacted. |
| UK & Moderna | -Title to the product supplied under this agreement will pass to the purchaser free and clear of any security interest, lien, charge or other encumbrance.[[310]](#footnote-310) |
| EU & CureVac | -CureVac warrants that at the time of delivery, it has good title to the products and will deliver them free and clear of any security interests, liens, or other incumbrances, including having obtained any necessary IP rights.[[311]](#footnote-311) |
| EU & Moderna | -Moderna to warrant that any newly created parts and pre-existing material incorporated into the results produced under the APA are free of claims from creators or any third parties and that all necessary pre-existing rights have been obtained or licensed.-Moderna to provide a list of pre-existing rights and the identification of the rights’ owners and provide evidence that it has the ownership or the right to use all rights listed.-If there are no pre-existing rights, Moderna must provide a declaration to that effect.  |

1. According to the report undertaken by the National Audit Office published on the 14 December 2020, the UK the UK government had concluded, as of the 8 December 2020, five agreements with potential vaccine suppliers. National Audit Office, ‘Investigation into Preparations for Potential COVID-19 Vaccines’ (14 December 2020) <https://www.nao.org.uk/reports/investigation-into-preparations-for-potential-covid-19-vaccines/> accessed 30 September 2022. [↑](#footnote-ref-1)
2. For access to relevant documents related to the EU Vaccines Strategy see <https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en> accessed 30 September 2022. [↑](#footnote-ref-2)
3. Links have been provided to each agreement below. Copies of each agreement are also on file with the authors of this dataset and available on request. [↑](#footnote-ref-3)
4. This agreement has been unofficially made available in unredacted form via several media outlets and is currently accessible here <https://www.rai.it/dl/doc/2021/02/19/1613725900577_AZ_FIRMATO_REPORT.pdf> accessed 30 September 2022. The authors also retain a copy on file, which is available on request. [↑](#footnote-ref-4)
5. <https://www.contractsfinder.service.gov.uk/Notice/SupplierAttachment/77bb967f-0194-452a-bdae-9999aecc753d> accessed 30 September 2022. [↑](#footnote-ref-5)
6. <https://www.contractsfinder.service.gov.uk/notice/cd5013be-e8b8-4e57-82bc-d40301e55ab5?origin=SearchResults&p=1> accessed 30 September 2022. [↑](#footnote-ref-6)
7. <https://ec.europa.eu/info/sites/default/files/apa_with_sanofi_gsk.pdf> accessed 30 September 2022. [↑](#footnote-ref-7)
8. <https://www.contractsfinder.service.gov.uk/notice/f6adf3ca-59a4-4976-95e6-27a62a2a4c6e?origin=SearchResults&p=2> accessed 30 September 2022. [↑](#footnote-ref-8)
9. <https://ec.europa.eu/info/sites/default/files/jj_apa_202005071550.pdf> accessed 30 September 2022. [↑](#footnote-ref-9)
10. <https://www.keionline.org/misc-docs/UK-Novavax-Supply-Agreement-22Oct2020.pdf> accessed 30 September 2022. [↑](#footnote-ref-10)
11. <https://ec.europa.eu/info/sites/default/files/redacted_advance_purchase_agreement_biontech-pfizer_0.pdf> accessed 30 September 2022. [↑](#footnote-ref-11)
12. <https://www.contractsfinder.service.gov.uk/notice/a3df05e8-9916-4c12-90c3-0c28611cf48e?origin=SearchResults&p=1> accessed 30 September 2022. [↑](#footnote-ref-12)
13. <https://ec.europa.eu/info/sites/default/files/curevac_-_redacted_advance_purchase_agreement_0.pdf> accessed 30 September 2022. [↑](#footnote-ref-13)
14. This agreement has been unofficially made available in unredacted form and is currently accessible here <https://www.rai.it/dl/doc/2021/04/17/1618676613043_APA%20Moderna__.pdf> accessed 30 September 2022. The authors of this paper also retain a copy on file, which is available on request. [↑](#footnote-ref-14)
15. There are many media sources that disclose the redacted pricing for most of these agreements. However, there is inconsistency between those reports and thus we have chosen not to reference them. Details of the various reports on pricing can be found on the UNICEF, ‘COVID-19 Vaccine Market Dashboard’ <https://www.unicef.org/supply/covid-19-vaccine-market-dashboard> accessed 30 September 2022 [↑](#footnote-ref-15)
16. Clause 4.1. [↑](#footnote-ref-16)
17. Recital 8 and clause 7. [↑](#footnote-ref-17)
18. Clause 8.1. [↑](#footnote-ref-18)
19. Preamble. [↑](#footnote-ref-19)
20. Recital 8. [↑](#footnote-ref-20)
21. Clause 5.1 and schedule A [↑](#footnote-ref-21)
22. Clauses 7.2, 9.1 and Schedule A. ‘Upfront costs’ are defined in Schedule A to include ‘necessary starting materials and drug product manufacturing line capacity.’ [↑](#footnote-ref-22)
23. Recital 8 and clause 7.4. [↑](#footnote-ref-23)
24. Clauses 3.5 and 10. [↑](#footnote-ref-24)
25. Clause 4.1. There is an exception provided in clause 3.2.3 but this is redacted in the copy available. [↑](#footnote-ref-25)
26. Clause 6. [↑](#footnote-ref-26)
27. Schedule 1. [↑](#footnote-ref-27)
28. Clause 5.1. [↑](#footnote-ref-28)
29. Schedule 3 (redacted). [↑](#footnote-ref-29)
30. ‘Cost of goods’ is defined as the ‘fully burdened aggregate reasonable direct and indirect costs and expenses incurred to manufacture the product. The exact detail of direct and indirect costs has been redacted, Clause 1.1. [↑](#footnote-ref-30)
31. ‘Open book basis’ requires AstraZeneca to provide the purchaser with access to information to verify that costs have been calculated in accordance with the terms specified in the APA, Clause 11.3. [↑](#footnote-ref-31)
32. Clause 1.1. [↑](#footnote-ref-32)
33. Clause 4. [↑](#footnote-ref-33)
34. Clause 3. [↑](#footnote-ref-34)
35. Clause 5. [↑](#footnote-ref-35)
36. Clause 1.1. ‘Definitions’ [↑](#footnote-ref-36)
37. Clause 8.1. A ‘Regimen’ is defined as comprising two doses per patient (Clause 1.1 ‘Definitions). [↑](#footnote-ref-37)
38. Clause 9. [↑](#footnote-ref-38)
39. In a press release, Valneva announced that under the agreement the UK government had secured supply of 60 million doses at a cost of €470 million. <https://valneva.com/press-release/valneva-announces-major-covid-19-vaccine-partnership-with-u-k-government/> accessed 30 September 2022. [↑](#footnote-ref-39)
40. Clause I.2. [↑](#footnote-ref-40)
41. Recital 1. [↑](#footnote-ref-41)
42. Clause I.4.1 [↑](#footnote-ref-42)
43. Clause I.10. [↑](#footnote-ref-43)
44. Clause I.5. [↑](#footnote-ref-44)
45. Clause I.6.1 [↑](#footnote-ref-45)
46. Clause I.6.6. [↑](#footnote-ref-46)
47. Schedule 2 [1.1] [↑](#footnote-ref-47)
48. The relevant section in the APA is redacted, but information is available in the Policy Paper provided by the Department of Health and Social Care, Policy Paper: UK COVID-19 Vaccines Delivery Plan (13 January 2021) https://www.gov.uk/government/publications/uk-covid-19-vaccines-delivery-plan/uk-covid-19-vaccines-delivery-plan accessed 30 September 2022. [↑](#footnote-ref-48)
49. Schedule 2 [10.1] [↑](#footnote-ref-49)
50. Clause I.2 [↑](#footnote-ref-50)
51. AI.1 ‘Definitions’, ‘Vaccine Candidate’ [↑](#footnote-ref-51)
52. Clause I.4.1. The definition of ‘vaccine regime’ has been redacted, but we take this to mean a prescribed course (being one or more doses) rather than individual doses. [↑](#footnote-ref-52)
53. Clause I.5.2.1. [↑](#footnote-ref-53)
54. Clauses 3, 4 and 5. [↑](#footnote-ref-54)
55. Introduction (B) and clause 3. [↑](#footnote-ref-55)
56. Clause 7. [↑](#footnote-ref-56)
57. Clause 5.16. [↑](#footnote-ref-57)
58. Clause 8 [↑](#footnote-ref-58)
59. Clause 13. [↑](#footnote-ref-59)
60. Clause I.3 ‘Subject Matter’. Commission acknowledges that clinical development might not be successful or regulatory approval may not be obtained, and thus an authorised vaccine may not be available. [↑](#footnote-ref-60)
61. The date the agreement was signed has been redacted. However, according to the Pfizer press release, the APA was signed on or just before the 11 November 2020 <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-reach-agreement-supply-eu-200-million> accessed 30 September 2022. [↑](#footnote-ref-61)
62. Clause I.2 ‘Definitions’. [↑](#footnote-ref-62)
63. Clause I.6.2. [↑](#footnote-ref-63)
64. Clause I.6.3. [↑](#footnote-ref-64)
65. Clause I.7. [↑](#footnote-ref-65)
66. Clause I.8. [↑](#footnote-ref-66)
67. Preamble [↑](#footnote-ref-67)
68. The relevant section in the APA is redacted, but information is available in the Policy Paper provided by the Department of Health and Social Care, Policy Paper: UK COVID-19 Vaccines Delivery Plan (13 January 2021) https://www.gov.uk/government/publications/uk-covid-19-vaccines-delivery-plan/uk-covid-19-vaccines-delivery-plan accessed 29 September 2021. [↑](#footnote-ref-68)
69. Clause 5.6 and Exhibit [↑](#footnote-ref-69)
70. Recital I. [↑](#footnote-ref-70)
71. Clause 1.3. [↑](#footnote-ref-71)
72. Clause 1.3. [↑](#footnote-ref-72)
73. Commission, ‘Coronavirus: Commission approves contract with CureVac to ensure access to potential vaccine’ (Brussels, 17 November 2020) <https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2136> accessed 30 September 2022. [↑](#footnote-ref-73)
74. Clause 1.6. [↑](#footnote-ref-74)
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77. Clause 1.16.2. [↑](#footnote-ref-77)
78. Clause 1.17. [↑](#footnote-ref-78)
79. Clause I.2. [↑](#footnote-ref-79)
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109. <https://www.clinicaltrials.gov/ct2/show/NCT04537208> [↑](#footnote-ref-109)
110. <https://www.clinicaltrials.gov/ct2/show/NCT04762680> [↑](#footnote-ref-110)
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112. Clause 7.4(d) [↑](#footnote-ref-112)
113. Clause 12.2(c). [↑](#footnote-ref-113)
114. Clause 12.2(d). [↑](#footnote-ref-114)
115. Clause 11.9 [↑](#footnote-ref-115)
116. Clause 22.5.1. [↑](#footnote-ref-116)
117. Clause 23.2.2. [↑](#footnote-ref-117)
118. Clause 23.2.3. [↑](#footnote-ref-118)
119. Clause 26. [↑](#footnote-ref-119)
120. Clause 1.1 ‘Definitions. [↑](#footnote-ref-120)
121. Clauses I.6.2, I.6.3, I.6.4 and II.15.5(a). [↑](#footnote-ref-121)
122. Clause !!.15.5(b). [↑](#footnote-ref-122)
123. Clause II.15.5(c) & II.15.3. [↑](#footnote-ref-123)
124. Clause 17. [↑](#footnote-ref-124)
125. Clause I.6.4. [↑](#footnote-ref-125)
126. Clause II.16.3. [↑](#footnote-ref-126)
127. Clause 26.1.3. [↑](#footnote-ref-127)
128. Clause II.17.4. [↑](#footnote-ref-128)
129. Clause 11. [↑](#footnote-ref-129)
130. Clause I.8.5. [↑](#footnote-ref-130)
131. Clause II.16.5(a)(ii). [↑](#footnote-ref-131)
132. Clause II.16.5(a)(iii). [↑](#footnote-ref-132)
133. Clause II.16.5(c). [↑](#footnote-ref-133)
134. Clause II.16.5(d)(i) [↑](#footnote-ref-134)
135. Clause II.16.5(d)(ii) [↑](#footnote-ref-135)
136. Clause 1.15. [↑](#footnote-ref-136)
137. Clause 1 ‘Definitions’ [↑](#footnote-ref-137)
138. Clause I.6.4.1 [↑](#footnote-ref-138)
139. Clause 13 & 14. [↑](#footnote-ref-139)
140. Clauses I.7 & II.17.4. [↑](#footnote-ref-140)
141. Clauses 3, 4 & 11.3. [↑](#footnote-ref-141)
142. Clause II.14.5. [↑](#footnote-ref-142)
143. Clause II.16.5 [↑](#footnote-ref-143)
144. Clause 11. [↑](#footnote-ref-144)
145. Clause 1 ‘Definitions’ [↑](#footnote-ref-145)
146. Clause 1.1 ‘Definitions’ [↑](#footnote-ref-146)
147. Clause I.9 [↑](#footnote-ref-147)
148. Schedule 4, clause 1.1. [↑](#footnote-ref-148)
149. Clause 1 ‘Definitions’. [↑](#footnote-ref-149)
150. Clause I.2 ‘Definitions’ and clause I.11. [↑](#footnote-ref-150)
151. Clause 1.41 [↑](#footnote-ref-151)
152. Clause 1.86 [↑](#footnote-ref-152)
153. Clause I.21. [↑](#footnote-ref-153)
154. Clause I.10. [↑](#footnote-ref-154)
155. Clause 16.2. [↑](#footnote-ref-155)
156. Clause 16.3. [↑](#footnote-ref-156)
157. Clause 16.5. [↑](#footnote-ref-157)
158. Clause 16.6 & 16.7. [↑](#footnote-ref-158)
159. Clause 16.8. [↑](#footnote-ref-159)
160. Clause 1 ‘Definitions’. [↑](#footnote-ref-160)
161. Clause 17.1. [↑](#footnote-ref-161)
162. Clause 17.2. [↑](#footnote-ref-162)
163. Clause 17.3, 17.4, 17.5, 17.11, 17.12 & 17.13. [↑](#footnote-ref-163)
164. Clause 17.6, 17.7 & 17.8. [↑](#footnote-ref-164)
165. Clause 17.17. [↑](#footnote-ref-165)
166. Clause 1.1 ‘Definitions’. [↑](#footnote-ref-166)
167. Clause 20.1. [↑](#footnote-ref-167)
168. Clause 20.2. [↑](#footnote-ref-168)
169. Clauses 20.3-20.5, 20.11-20.13. [↑](#footnote-ref-169)
170. Clause 20.6-20.8. [↑](#footnote-ref-170)
171. Clause 20.14. [↑](#footnote-ref-171)
172. Clause 20.17. [↑](#footnote-ref-172)
173. Clause II.1 ‘Definitions’. [↑](#footnote-ref-173)
174. Clause II.8.1 & II.8.8. [↑](#footnote-ref-174)
175. Clause II.8.3. [↑](#footnote-ref-175)
176. Clause II.8.5. [↑](#footnote-ref-176)
177. Clause II.8.6. & II.8.7. [↑](#footnote-ref-177)
178. Schedule 4 ‘definitions’. [↑](#footnote-ref-178)
179. Schedule 3, clause 1. [↑](#footnote-ref-179)
180. Schedule 2, clause 18.2. [↑](#footnote-ref-180)
181. Schedule 3, clause 1.6 [↑](#footnote-ref-181)
182. AI.1 ‘Definitions’. [↑](#footnote-ref-182)
183. Clause II.8.4. [↑](#footnote-ref-183)
184. Clause II.8.5. [↑](#footnote-ref-184)
185. Clause II.8.2. [↑](#footnote-ref-185)
186. Clause II.8.3(a) & (b). [↑](#footnote-ref-186)
187. Clause II.8.3(c). [↑](#footnote-ref-187)
188. Clause II.8.6. [↑](#footnote-ref-188)
189. Clause 20. [↑](#footnote-ref-189)
190. See Clauses II.9.5 and II.9.9. [↑](#footnote-ref-190)
191. Clause I.2 ‘Definitions’. [↑](#footnote-ref-191)
192. Ibid. [↑](#footnote-ref-192)
193. Clauses II.9.1 & II.9.2(c). [↑](#footnote-ref-193)
194. Clause II.9.2(a). [↑](#footnote-ref-194)
195. Clause II.9.2.(b). [↑](#footnote-ref-195)
196. Clause II.9.3. [↑](#footnote-ref-196)
197. Clause II.9.4. [↑](#footnote-ref-197)
198. Clause II.9.8. [↑](#footnote-ref-198)
199. Clause II.9.9. [↑](#footnote-ref-199)
200. Clause 7.1. [↑](#footnote-ref-200)
201. Clause 7.2. [↑](#footnote-ref-201)
202. Clause 7.3(i)-(ix). [↑](#footnote-ref-202)
203. Clause 7.3(x). [↑](#footnote-ref-203)
204. Clause 7.4. [↑](#footnote-ref-204)
205. Clause 7.5. [↑](#footnote-ref-205)
206. Clause 7.6. [↑](#footnote-ref-206)
207. Clause 7.7. [↑](#footnote-ref-207)
208. Clause 1.2 ‘Definitions’. [↑](#footnote-ref-208)
209. Clause 11.6.2. [↑](#footnote-ref-209)
210. Clause 11.6.3. [↑](#footnote-ref-210)
211. Clause 11.6.4. [↑](#footnote-ref-211)
212. Clause 11.6.7. [↑](#footnote-ref-212)
213. Clause I.13 ‘definitions’ and II.7. [↑](#footnote-ref-213)
214. Clause 11.1. [↑](#footnote-ref-214)
215. Clause 12.4. [↑](#footnote-ref-215)
216. Introduction (B). [↑](#footnote-ref-216)
217. Clause 10.7. [↑](#footnote-ref-217)
218. Clause 16.1. [↑](#footnote-ref-218)
219. Clause 19.1. [↑](#footnote-ref-219)
220. Clauses 19.3-19.8. [↑](#footnote-ref-220)
221. Clause I.9. [↑](#footnote-ref-221)
222. Schedule 2, clause 12.1. [↑](#footnote-ref-222)
223. Clause II.13. [↑](#footnote-ref-223)
224. Clause 19. [↑](#footnote-ref-224)
225. Clause I.11. [↑](#footnote-ref-225)
226. Clause II.9.8. [↑](#footnote-ref-226)
227. Clause 8.1. [↑](#footnote-ref-227)
228. Clause 8.3(i). [↑](#footnote-ref-228)
229. Clause 8.3(ii). [↑](#footnote-ref-229)
230. Clause 8.3(iii). [↑](#footnote-ref-230)
231. Clause 8.3(iii). [↑](#footnote-ref-231)
232. Clause 8.3(iv). [↑](#footnote-ref-232)
233. Clause 8.4. [↑](#footnote-ref-233)
234. Clause I.20.1. [↑](#footnote-ref-234)
235. Clause 10.3. [↑](#footnote-ref-235)
236. Clause 4.2(a). [↑](#footnote-ref-236)
237. Clause 4.2.(b). [↑](#footnote-ref-237)
238. Clause 10.2. [↑](#footnote-ref-238)
239. Clause 4.18. [↑](#footnote-ref-239)
240. Clause I.6.2. [↑](#footnote-ref-240)
241. Clause I.6.2.(i). [↑](#footnote-ref-241)
242. Clause I.6.6. [↑](#footnote-ref-242)
243. Clause II.6.6. [↑](#footnote-ref-243)
244. Clause 9.4. [↑](#footnote-ref-244)
245. Clause I.4.3(c), I.10.2(a) & (c). [↑](#footnote-ref-245)
246. Clause I.10.2.2. [↑](#footnote-ref-246)
247. Clause II.5.4(b)(2)(iii). [↑](#footnote-ref-247)
248. Clause 4.7. [↑](#footnote-ref-248)
249. Clause 5.11. [↑](#footnote-ref-249)
250. Clause 1.22.1. [↑](#footnote-ref-250)
251. Clause 1.22.2. [↑](#footnote-ref-251)
252. Clause 1.23.7. [↑](#footnote-ref-252)
253. Clause I.12.8. [↑](#footnote-ref-253)
254. Clause II.5.2. [↑](#footnote-ref-254)
255. Clause 11.2. [↑](#footnote-ref-255)
256. Clause I.6.5. [↑](#footnote-ref-256)
257. Clause 5.4. [↑](#footnote-ref-257)
258. Schedule A. [↑](#footnote-ref-258)
259. Schedule A. [↑](#footnote-ref-259)
260. Schedule A. [↑](#footnote-ref-260)
261. Schedule A. [↑](#footnote-ref-261)
262. Clause 4.5. [↑](#footnote-ref-262)
263. Clause 3.2.2. [↑](#footnote-ref-263)
264. Clause I.4.1. [↑](#footnote-ref-264)
265. Clause II.10. [↑](#footnote-ref-265)
266. Schedule 2, clause 29.2. [↑](#footnote-ref-266)
267. Schedule 2, clause 29.1. [↑](#footnote-ref-267)
268. Exhibit A ‘Tentative Availability Schedule’, (a). [↑](#footnote-ref-268)
269. Introduction (B). [↑](#footnote-ref-269)
270. Clause 3 and 5. [↑](#footnote-ref-270)
271. Clause 5. [↑](#footnote-ref-271)
272. Clause 5.11. [↑](#footnote-ref-272)
273. Clause 5.2. [↑](#footnote-ref-273)
274. Clause 1.9. [↑](#footnote-ref-274)
275. Annex V. [↑](#footnote-ref-275)
276. Clause I.1.8.1. [↑](#footnote-ref-276)
277. Clause I.4.5. [↑](#footnote-ref-277)
278. Annex IV & V. [↑](#footnote-ref-278)
279. Clause II.9. [↑](#footnote-ref-279)
280. Clause 8.3(b). [↑](#footnote-ref-280)
281. Clause 8.3(c). [↑](#footnote-ref-281)
282. Clause 3.9. The APA does not expressly refer to ‘resale’ of excess doses. The agreement uses the phrase ‘transfer, at no profit’ which we take to mean ‘resale’ (at not profit). [↑](#footnote-ref-282)
283. Clause 28.1. [↑](#footnote-ref-283)
284. The APA does not expressly refer to ‘resale’ of excess doses. The agreement adopts the phrase ‘donate or redistribute’. We assume ‘redistribute’ to mean ‘resale’. [↑](#footnote-ref-284)
285. Clause I.6.2. [↑](#footnote-ref-285)
286. Clause i.10. [↑](#footnote-ref-286)
287. Schedule 2, clause 1.7. [↑](#footnote-ref-287)
288. Clause I.4.7.1. [↑](#footnote-ref-288)
289. Clause 9. [↑](#footnote-ref-289)
290. Clause I.6.2. [↑](#footnote-ref-290)
291. Clause I.6.2. [↑](#footnote-ref-291)
292. Clause 3.8. [↑](#footnote-ref-292)
293. Clause 1.75. [↑](#footnote-ref-293)
294. Clause I.10.1. [↑](#footnote-ref-294)
295. Clause I.10.2. [↑](#footnote-ref-295)
296. Clause I.10.3. [↑](#footnote-ref-296)
297. Clause I.10.6. [↑](#footnote-ref-297)
298. Clause I.10.6. [↑](#footnote-ref-298)
299. Clause I.4.6. [↑](#footnote-ref-299)
300. Introduction (A). See also AstraZeneca, ‘AstraZeneca and Oxford University announce landmark agreement for COVID-19 vaccine’ (Press release, 30 April 2020) [https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-and-oxford-university-announce-landmark-agreement-for-covid-19-vaccine.html#](https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-and-oxford-university-announce-landmark-agreement-for-covid-19-vaccine.html) accessed 30 September 2022. [↑](#footnote-ref-300)
301. Clause 16.2. [↑](#footnote-ref-301)
302. Clause 16.3. [↑](#footnote-ref-302)
303. Clause 19.2. [↑](#footnote-ref-303)
304. Clause I.12. [↑](#footnote-ref-304)
305. Schedule 2, clause 11.1.7. [↑](#footnote-ref-305)
306. Schedule 2, clause 11.1.8. [↑](#footnote-ref-306)
307. Schedule 2, clause 18.2. [↑](#footnote-ref-307)
308. Preamble. [↑](#footnote-ref-308)
309. Clause 19. [↑](#footnote-ref-309)
310. Clause 10.2(vi). [↑](#footnote-ref-310)
311. Clause I.14.2. [↑](#footnote-ref-311)