

REGN-COV2 SUPPLY AGREEMENT FOR PANDEMIC PURPOSES

This Agreement is made as of 5 March 2021 ("**Effective Date**") between:

- (1) The Secretary of State for the Department for Business, Energy and Industrial Strategy ("**UK**") acting on behalf of Her Majesty's Government of the United Kingdom (including the Northern Ireland Executive Committee, the Scottish Executive and the Welsh Government) (the "**Crown**"); and
- (2) Roche Products Limited, a company established under the laws of England and Wales with its primary office at 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW and registered number 00100674 ("**Roche**").

Background

UK has informed Roche that it is taking preparatory measures to counter the COVID-19 pandemic. UK wishes to purchase a quantity of Units (as defined in Annex A) of the pharmaceutical product known as REGN-COV2 (being a casirivimab and imdevimab combo pack) ("**Product**") as part of its preparatory measures. As such, UK has agreed to purchase a number of Units of the Product from Roche, and Roche has agreed to deliver that quantity of Units of Product to hospitals in the Territory on behalf of UK, and to use Commercially Reasonable Efforts (defined below) to secure an appropriate Marketing Approval (defined below) and other necessary regulatory approvals in the United Kingdom of Great Britain and Northern Ireland (the "**Territory**") for the sale and supply of the Product to the UK. To the extent a Marketing Approval is initially secured through Regulation 174 of the Human Medicines Regulations 2012, it is acknowledged that any such authorisation will require the applicable Secretary of State's approval (the "**SoS Approval**").

THEREFORE, Roche and UK (each a "**Party**", collectively the "**Parties**") agree as follows:

1. Product Requirements, Pricing and Quantities

- (a) Roche will supply, and UK will purchase, the quantity of Units of Product identified as a Firm Quantity in accordance with the "Product Requirements" at Annex A.
- (b) Product will be sold by Roche and purchased by UK in accordance with the pricing, payment and other commercial terms set forth in this Agreement, including the provisions of Annex B and the Product will be accompanied with all information and notices required from time to time by the regulatory approval and laws in the Territory and the documents in Annex F ("**Documentation**").

2. Delivery

- (a) In this Agreement "**Delivery**" shall mean delivery of Units of the Product DDP (Incoterms 2020), QP-released and labelled for the Territory in accordance with the Marketing Approval (or, if applicable, Further Marketing Approval) to a warehouse or other storage facility within the Territory that is controlled by UK or a UK-contracted service provider (details of which service provider and storage facility to be notified by UK to Roche through the Working Committee as soon as practicable after the Effective Date (the "**UK Storage Facility**"). Subject to Roche obtaining a Marketing Approval, Roche shall Deliver the Firm Quantity of Products in accordance with Annex A in the applicable volumes and by the

dates set forth in Annex D (the "**Delivery Schedule**"). [REDACTED]

(b) Roche further agrees, following Delivery, to distribute Units of the Delivered stock of Product from UK Storage Facilities to (i) NHS hospitals and (ii) other locations agreed in good faith by Roche and UK in accordance with Roche's standard distribution terms as set forth in Annex C or as otherwise agreed by the parties ("**Distribution**"). Roche shall be responsible for any damage or loss to Units of Product during Distribution.

(c) If UK requires Units to be Distributed to other locations or on materially different terms [REDACTED] to those set forth in Annex C, then Roche shall use CRE to provide Distribution on those enhanced terms and shall have the right to invoice UK for any reasonable additional costs incurred by Roche in excess of the costs involved in a standard Distribution ("**Non Standard Distribution**").

(d) "**Commercially Reasonable Efforts**" or "**CRE**" shall mean (a) in the case of Roche, the activities and degree of effort that a group of a similar size with a similarly-sized infrastructure and similar resources as Roche's group would undertake or use in the development, manufacture, approval and supply of a therapeutic product (including having regard to one for treating patients to combat the current COVID-19 global pandemic) at the relevant stage of development or commercialization having regard to the urgent need for such products including taking into account efficacy and safety. Such efforts being subject to (i) those activities which are within the power or influence of Roche having regard to its arrangements with the licensor of the Product and such licensor's obligations and rights in relation to Roche seeking regulatory approval and (ii) the requirement for the SoS Approval; and (b) in the case of UK, the activities and degree of effort that governments would undertake or use in supporting their contractor in the supply of drugs having regard to the urgent need for drugs to treat patients in a global pandemic which is resulting in serious public health issues, restrictions on personal freedoms and economic impact, across the world.

(e) Title and, subject to the last sentence of Section 2(b), risk to the Units shall pass to UK on Delivery.

(f) As soon as practicable following the Effective Date the parties shall (and UK shall use CRE to procure that appropriate representatives from the NHS and Department of Health and Social Care shall meet to agree the detailed terms of Distribution for the Product.

(g) After the Effective Date, and through consultation via the Working Committee, [REDACTED]
[REDACTED], (ii) Roche shall keep UK updated with respect to progress towards securing the grant of a Marketing Approval, (iii) Roche shall keep UK updated with respect to progress towards Delivering the Units of Product in accordance with the Delivery Schedule [REDACTED], and (iv) if necessary and in accordance with this Section 2, discuss and refine and, to the extent possible as agreed by the parties taking into account what is within the reasonable control of that party, update the Delivery Schedule in good faith.

(h) Subject to Section 2(i), if Roche fails to Deliver Units of Product in the volume or by the dates provided for in the Delivery Schedule or as notified for the actual date of Delivery (as may be refined in accordance with this Section 2) (a "Delay" or "Delayed Product"), [REDACTED], and in any event Roche shall reimburse UK for any out of pocket expenses which UK has reasonably incurred as a consequence of such Delay and Delayed Product.

(i) Notwithstanding the provisions of Section 2(h), Units of Product will not be considered Delayed [REDACTED] of the Units due to be Delivered in a Delivery batch are not Delivered pursuant to the Delivery Schedule or by the date notified for actual Delivery.

(j) Roche shall promptly inform UK from time to time of any possibility to Deliver Units of Product earlier than the dates set forth in the Delivery Schedule, provided that Marketing Approval has been secured. Following such notification, if UK wishes to accept Product being Delivered earlier than the Delivery Schedule, the Parties shall discuss in good faith and Roche shall use Commercially Reasonable Efforts to Deliver those quantities of Product in accordance with the Delivery dates which are agreed between the Parties following notification pursuant to this Section 2(j). The provisions of Sections 2(h) and 2(i) shall apply *mutatis mutandis* to any revised Delivery dates for Product in accordance with this Section 2(j).

(k) Without prejudice to any other remedies, any rejection of or defect in the Product Delivered under this Agreement shall be addressed in accordance with Annex B.

(l) Until the Firm Quantity has been Delivered free of defects and in full to UK, Roche shall not and shall procure none of its affiliates shall supply any quantities of the Product to any third party in, or for use in or import to, the Territory.

3. Use; Regulatory

(a) The Product is sold [REDACTED] for use to treat COVID-19 patients during and potentially following the COVID19 pandemic (as declared by the WHO). UK agrees to ensure that Product shall not be re-sold, exported or used for any other purpose outside of the Territory, save that UK may donate, re-sell or export Product to the Crown Dependencies and UK Overseas Territories, being those territories listed in Annex G and UK shall be responsible for obtaining all applicable Regulatory Licences and Marketing Approvals for such re sales and exports ("**Re-Sold Product**"). By way of exception to the foregoing, UK may provide Product which would otherwise be wasted or destroyed as being surplus to UK's requirements on a not-for-profit basis to any other country or person (any such Product being "**Donated Product**") provided that the UK shall be responsible for obtaining all applicable Regulatory Licences and Marketing Approvals for such re sales and exports.

(b) As between the Parties, (a) Roche shall be responsible at its sole cost and risk for filing and prosecuting to grant or issuance all approvals, licenses, permits, certifications, registrations or authorizations necessary for the manufacture, packaging, import, storage, and transport of the Product for, after grant of a Marketing Approval, commercial use in the Territory ("**Regulatory Licenses**") and (b) UK shall and shall procure that its Authorised Agents shall be responsible at its or their sole cost and risk for filing and prosecuting to grant or issuance all approvals, licenses, permits, certifications, registrations

or authorisations necessary for, after grant of a Marketing Approval, storage of the Product but not for Distribution undertaken by or on behalf of Roche ("**UK Licenses**").

(c) Roche shall use CRE to seek an emergency use authorization, accelerated approval, conditional approval, temporary approval under Regulation 174 of the Human Medicines Regulations 2012 (subject to SoS Approval), conditional or full marketing approval or any other similar approval required under Law in the Territory for the commercial supply of the Product in the Territory for an indication covering the treatment of SARS-CoV-2 (the "**Therapeutic Indication**") but excluding any pricing or reimbursement approvals from the UK Medicines and Healthcare products Regulatory Agency ("**MHRA**") (the "**Marketing Approval**"). [REDACTED]

(d) [REDACTED]

(e) [REDACTED]

[REDACTED] Subject to any obligations on Roche in relation to the label for the Product under the Further Marketing Approval all Units Delivered on or after the date of the Further Marketing Approval shall be licensed under the Further Marketing Approval. Roche shall keep UK informed as to progress towards the Further Marketing Approval through the Working Committee. In conjunction with seeking the Further Marketing Approval, Roche shall use CRE to seek guidance from the MHRA that any Product Delivered under the original Marketing Approval prior to the granting or issuance of the Further Marketing Approval may from the date of the Further Marketing Approval be used under the Further Marketing Approval.

(f) Roche shall use CRE to maintain the grant or issuance of a Marketing Approval (and, if applicable, a Further Marketing Approval), including fulfilling any conditions attached to such approval(s) by the MHRA. Furthermore, if the initial Marketing Approval granted is by way of Regulation 174 of the Human Medicines Regulations 2012 subject to SoS Approval, then Roche shall use CRE to continue to pursue a Marketing Approval on a conditional or full basis for the Product. This obligation shall continue to apply after the expiry or termination of this Agreement until such time as the shelf life of all Product supplied hereunder has expired.

(g) In addition to using CRE to seek a Marketing Approval for the Product, Roche shall be responsible for and shall procure that all those involved in the manufacturing and supply chains concerning the Product hold and maintain all other licenses, consents, permissions and authorizations

required for the development, manufacture, testing, packaging, labelling, storage and transport of the Product through to Delivery.

(h) Roche acknowledges and agrees that UK may delegate any of its responsibilities under this Agreement to one or more authorised agents to act on its behalf, including for the receipt and handling of Product, inspection and reporting of any defects or issues concerning the Product and/or any Documentation provided therewith. Roche shall work and co-operate reasonably with each authorised agent notified to it by UK in connection with this Agreement ("**Authorised Agents**").

(i) Nothing in this Agreement shall amount to an exclusive purchasing obligation on UK or preclude or restrict UK from purchasing any products whatsoever from third parties, including any products that are complementary to, competitive to, equivalent to, or substitutable for the Product or that are indicated for or expected to be beneficial in or are indicated for use in the Therapeutic Indication.

4. Term and Termination

(a) This Agreement shall become effective and binding on the Parties upon the Effective Date and shall remain in effect until fully performed unless earlier terminated as permitted below (the "**Term**").

(b) Either party may terminate this Agreement upon [REDACTED] in the following circumstances:

(i) the other party commits a material breach of this Agreement and has not remedied such breach within [REDACTED] from receipt of written notice of such breach;

(ii) if following the Expected Approval Date and consultation within the Working Committee, either (A) an adverse safety signal exists in any population in which the Product is being or has been tested which would be reasonably and objectively likely to cause the Product not to have a safety profile suitable for the grant or issuance of a Marketing Approval; or (B) there is reasonable and objective evidence, or opinion from the MHRA, that the Product will not secure a Marketing Approval.

(c) UK may terminate this Agreement upon written notice to Roche in the following circumstances:

(i) an Excusable Delay (defined below) has continued for [REDACTED];

(ii) if Delivery of the whole of the Firm Quantity has [REDACTED] after the date on which the final tranche of the Firm Quantity is required under the Delivery Schedule and the reasons for the delays have been discussed by the Working Committee (or such later date agreed by the parties) (the "**Longstop Date**");

(iii) if the Marketing Approval is subsequently after grant or issuance withdrawn, suspended or conditioned in such a manner to cause material delay in [REDACTED];

(iv) if Roche purports to assign, sub-contract, novate, create a trust in or otherwise transfer or dispose of this Agreement in breach of its terms, including those at Section 15;

(v) the Agreement has been substantially amended to the extent that the Public Contracts Regulations 2015 require a new procurement procedure in circumstances where UK has given notice to Roche of such consequences of the amendment;

(vi) UK has become aware that Roche should have been excluded under Regulation 57(1) or (2) of the Public Contracts Regulations 2015 from the procurement procedure leading to the award of this Agreement;

(vii) there has been a failure by Roche and/or any other person involved in the development, manufacture, packaging, storage, transport or supply of the Product to comply with legal obligations in the fields of environmental, social or labour Law, where such failure to comply materially adversely affects the performance by Roche of its obligations under this Agreement. Where such failure to comply with legal obligations in the fields of environmental, social or labour Law is a failure by a party other than Roche, UK may request the replacement of such party and Roche shall use Commercially Reasonable Efforts to comply with such request as an alternative to UK terminating this Agreement under this section 4(c)(vii);

(viii) if a breach of the representations and warranties in Section 10 occurs on or after the Effective Date; or

(ix) Roche becomes insolvent or bankrupt or makes an assignment in favor of its creditors or a proposal under applicable bankruptcy legislation, or if the business or property of Roche shall be placed in the hands of a receiver or trustee in bankruptcy, by voluntary act or otherwise.

5. Limited Warranty; Indemnity; Limitation of Liability

(a) Roche warrants, represents and undertakes to UK that:

(i) at the time of Delivery, Product shall have been manufactured, labelled, handled, stored, transported, sold and packaged in accordance with (A) the relevant Marketing Approval; (B) all applicable Laws including Good Manufacturing Practice (GMP) (including record and sample keeping, deviation reporting, testing and quality requirements), Good Distribution Practices (GDP), Good Pharmacovigilance Practices (GVP); (C) all other Regulatory Licenses applicable to the Product; and (D) the specifications set forth in the approved Product monograph and Annex A;

(ii) all Product supplied and Delivered pursuant to this Agreement shall be new, unadulterated and have not (A) previously left the control of Roche or an affiliate or licensor of Roche at any time prior to Delivery; (B) been rejected or returned by any other entity; or (C) been reprocessed or reworked;

(iii) all Product Delivered shall have [REDACTED] of remaining shelf life left by reference to the expiry date (the "**Minimum Shelf Life**") calculated from the actual date of Delivery;

(iv) all Documentation supplied with Product pursuant to this Agreement shall be complete and accurate in all respects and the Product to which such Documentation relates shall comply with such Documentation;

(v) it shall, in fulfilling its obligations hereunder and supplying Product to UK, comply with (and ensure the Products comply with) all applicable Law in the Territory;

(vi) following grant of a Marketing Approval, all Product prior to Delivery shall be finally quality released for supply by an entity established in the Territory;

(vii) it and any parties or persons involved in the manufacture, packaging, labelling, storage, transport and supply of Product have manufacturing and warehousing capacity and facilities other than UK Storage Facilities for which UK shall be responsible that are sufficient for the manufacture and holding of Product compliant with the requirements under this Agreement and licensed by the MHRA for such activities;

(viii) it has and shall maintain a properly documented system of quality controls and processes (including quality management systems) that, at a minimum, meet requirements under applicable Laws and which cover all aspects of its obligations under this Agreement (including those it may subcontract to others) and shall at all times comply with such quality controls, systems and processes;

(ix) as at the Effective Date it has the right and authority to enter into this Agreement and it has the capability and capacity to fulfil its obligations under this Agreement;

(x) as at the time of their Delivery, title to the Product Delivered under this Agreement will pass to UK as provided in this Agreement free and clear of any security interest, lien, charge or other encumbrance;

(xi) as at the Effective Date there are no pending or threatened actions or proceedings before any court or administrative agency which would materially adversely affect the financial condition, business or operations of Roche;

(xii) as at the Effective Date there are no material agreements existing to which Roche is a party which prevent Roche from entering into or performing this Agreement;

(xiii) as at the Effective Date all necessary actions to authorise the execution of and performance of its obligations under this Agreement have been taken by Roche before such execution;

(xiv) it shall: (i) comply with all applicable Law and guidance to ensure that there is no slavery or human trafficking in its supply chains; and (ii) notify UK immediately if it becomes aware of any actual or suspected incidents of slavery or human trafficking in its supply chains;

(xv) it shall at all times conduct its business in a manner that is consistent with any anti-slavery policy of UK;

(xvi) throughout the Term, it shall maintain, review, update and implement a business continuity plan that is reasonably adequate and effective to provide for the continuity of supply to UK of the Product during events or issues that could adversely impact on the operations of Roche, its affiliates and contractors and other parties involved in the manufacture, packaging, labelling, storage, transport and supply of Product, and the ability of Roche to make available and Deliver Product, and it shall update its business continuity plan from time to time as reasonably appropriate and necessary;

(xvii) it shall not enter into any agreement with any third party that would by its terms conflict with or would be reasonably expected to prevent Roche from meeting its obligations with respect to Delivery in accordance with this Agreement;

Except for the warranties set forth in this Agreement, to the maximum extent permitted by applicable Law Roche expressly excludes all other remedies or warranties, expressed or implied, statutory or otherwise, in relation to the Product, including, without limitation, any warranty or condition of merchantability or of fitness for a particular purpose.

(b) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(c) [REDACTED]

[REDACTED]

(d) [REDACTED]

6. Intellectual Property

The Parties acknowledge that this Agreement does not in any way confer upon them any rights to the current, future or prior intellectual property of another Party, or to rights arising from, or pertaining to, the Confidential Information that may be conveyed to them within the scope of this Agreement, provided that Roche shall not assert or use any intellectual property rights to interfere in UK's or its agent's use or disposal of the Product supplied hereunder.

7. Confidentiality

(a) For this purposes of this Section 7, "**Confidential Information**" means, without limitation, all technical, business, financial, legal, marketing, business process, intellectual property, security, procurement or strategic information and data and related information, or any part or portion of information that:

- (i) is non-public and confidential, privileged or proprietary in nature;
- (ii) may have actual or potential economic value, in part, from not being publicly known;
- (iii) is in any form (i.e. fixed, stored, expressed or embodied);
- (iv) is disclosed in writing, orally, or otherwise;
- (v) is treated as confidential, but not required to be marked or identified as confidential at the time of disclosure; and
- (vi) is owned or controlled by Roche, UK or a third party.

For clarity, "Confidential Information" includes this Agreement and any discussions and correspondence relating thereto which shall be deemed Confidential Information of each Party.

(b) Subject to the remaining provisions of this Section 7, each Party agrees that with respect to the other Party's Confidential Information it shall not, during and for [REDACTED], [REDACTED], (i) use the other Party's Confidential Information except for the purposes contemplated by or authorised by this Agreement, unless otherwise authorized in writing by the other Party; (ii) disclose or transfer the other Party's Confidential Information to third parties without the express written permission of the other Party. Provided, however, that the Parties are authorized to disclose

Confidential Information to their directors, officers, employees, agents or representatives and those of their affiliates (which in the case of UK includes the UK Affiliates as defined in Section 5(b)) including their respective solicitors, accountants, financial advisors and other consultants who require said Confidential Information for the purposes contemplated by this Agreement (hereinafter referred to as "**Advisors**"), provided that such Advisors are made aware of and agree to be bound by the provisions of this Agreement. Notwithstanding the foregoing, each Party agrees to be responsible for any breach of this Section by any of its Advisors, whether or not they have agreed to be bound by the terms of this Agreement.

(c) It is expressly understood and agreed by each Party that the obligations of confidentiality herein shall not apply to any Confidential Information disclosed to a Party (a "**receiving Party**") which: (i) the receiving Party can demonstrate by written records was known to the receiving Party before the date of disclosure hereunder; (ii) is now, or becomes in the future, publicly available other than by breach of this Section 7 by the receiving Party or its Advisors; (iii) is lawfully disclosed to receiving Party on a non-confidential basis by a third party who is not obligated to the disclosing Party or any other party obligated to the disclosing Party to retain such Confidential Information in confidence; (iv) is independently developed by receiving Party in the course of work by employees or consultants of receiving Party or its affiliates (which, in the case of UK, includes the UK Affiliates) who have not had access to such Confidential Information; (v) receiving Party is required by any Law, regulation, or legal process to disclose, in which event receiving Party shall, where lawful and reasonably possible, provide the disclosing Party with prompt notice of such requirement and provide the disclosing Party (at the disclosing Party's cost) with reasonable assistance should the disclosing Party seek a protective order or other appropriate remedy to prevent or limit disclosure. In addition to the foregoing, Roche agrees that the obligations of confidentiality herein shall not apply to the extent Confidential Information of Roche is required to be disclosed (but with any information which is exempt from disclosure in accordance with the provisions of the FOIA or the Environmental Regulations redacted) in order to ensure the compliance of UK and UK Affiliates with any Law including, but not limited to, the Freedom of Information Act 2000 (c.36) ("**FOIA**"), Codes of Practice on Access to Government Information, on the Discharge of Public Authorities' Functions or on the Management of Records ("**Codes of Practice**") or the Environmental Information Regulations 2004 (SI 2004/3391) ("**Environmental Regulations**"), provided, however, that UK and UK Affiliates have provided advance notice of the impending disclosure to Roche and have provided further that they shall only disclose the information to the extent necessary to comply with such Laws and shall redact any Confidential Information which is not required to be disclosed under such Laws.

(d) Notwithstanding section 7(a), but subject to section 7(e), neither Party may disclose the existence and subject matter of this Agreement, including in any press release or public announcement, without the prior written consent of the other Party provided that, upon the request of a Party, the other Party will cooperate in good faith with such requesting Party in making a press release relating to this Agreement, the subject matter hereof and the transactions contemplated hereby.

(e) Notwithstanding section 7(a) or 7(d), Roche hereby gives consent for UK and UK Affiliates to publish this Agreement in its entirety (but with any information which is exempt from disclosure in accordance with the provisions of the FOIA or the Environmental Regulations being redacted), including from time to time agreed changes to this Agreement, to the general public provided that within 90 days following the Effective Date and prior to such publication UK and Roche shall consult, in good faith, as to the form of a redacted version of this Agreement.

(f) Notwithstanding section 7(a), UK will be permitted to disclose Confidential Information of Roche that is reasonably necessary to disclose under applicable Law, and under compliance with the privacy, confidentiality and proactive disclosure policy regimes of the Government of UK for the purposes of government administration and operations provided that it informs Roche of the intended disclosure and the extent and nature of the disclosure. For greater clarity, this includes :

(i) where the need for such disclosure arises out of or in connection with any legal challenge or potential legal challenge against UK arising out of or in connection with this Agreement;

(ii) where the need for such disclosure arises out of or in connection with the examination and certification of UK's accounts (provided that the disclosure is made on a confidential basis) or for any examination pursuant to section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which UK is making use of any services provided under this Agreement;

(iii) where the need for such disclosure arises out of or in connection with the conduct of a Central Government Body review in respect of this Agreement;

(iv) UK has reasonable grounds to believe that Roche is involved in activity that may constitute a criminal offence under the Bribery Act 2010 and the disclosure is being made to the Serious Fraud Office;

(v) on a confidential basis to any Central Government Body for any proper purpose of UK or of the relevant Central Government Body;

(vi) to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirement;

(vii) to the extent that UK (acting reasonably) deems disclosure necessary or appropriate in the course of carrying out its public functions.

(g) Where UK or a UK Affiliate is managing a request under FOIA, Codes of Practice or Environmental Regulations, Roche shall co-operate with UK or UK Affiliate and shall respond within [REDACTED] of any request for assistance in determining how to respond to such request for disclosure. Roche shall provide all necessary assistance as reasonably requested by UK or UK Affiliate to enable UK or UK Affiliate to respond to such request for information within the relevant statutory time limit for compliance, including providing a copy of all information in its possession or power in the form UK or UK Affiliate requires within [REDACTED].

(h) UK and UK Affiliates shall consult with Roche regarding their decisions as to any exemptions and/or redactions which may be applicable to Confidential Information, however the decision on whether any exemption/redaction applies is a decision solely for UK and UK Affiliates. UK and UK Affiliates will follow their own internal policies together with any applicable guidelines, including any published by the Treasury, the Cabinet Office or the Information Commissioner.

(i) Where Roche receives any request for information, as defined under section 8 of the FOIA or the Environmental Regulations, Roche shall transfer such request to UK as soon as practicable after receipt and in any event within [REDACTED] of receipt. Roche shall not respond directly to a request for information addressed to UK unless authorised in writing to do so by UK.

8. Force Majeure

Roche shall not be liable hereunder for any failure or delay to perform any of its obligations arising out of any cause beyond its reasonable control including but not limited to the following (each hereinafter referred to as an “**Excusable Delay**”): acts of God, strikes, lockouts or other industrial disputes, acts of the public enemy, acts of terrorism, riots, fire, storm, flood, explosion, or disruptions or failures in supply of major utilities. For the avoidance of doubt, the pandemic declared in respect of SARs-CoV-2 is a foreseeable risk and shall not be deemed an Excusable Delay. In the event of an Excusable Delay, Roche shall (i) use all Commercially Reasonable Efforts to overcome the cause contributing to the delay and to minimize the delay; and (ii) advise UK of the occurrence of the delay or of the likelihood of a delay occurring as soon as Roche has become aware of it. Any Delivery date or other date that is directly affected shall be postponed for a reasonable time not to exceed the duration of the Excusable Delay. The Parties shall amend this Agreement, as appropriate, to reflect any such change in dates. [REDACTED]

9. Governance and Oversight

(a) The Parties shall establish a working committee (the “**Working Committee**”) to oversee the implementation of the Agreement. The Working Committee shall consist of the Party representatives set out in Annex E. Each Party may replace its representatives upon written notice to the other Party. From time to time, the Working Committee may invite additional, non-voting representatives to its meetings as dictated by the respective meeting agenda. [REDACTED]

(b) The Parties shall co-operate fully, candidly and transparently through the Working Committee in connection with the matters requiring consultation in Annex E, and other matters relating to the Agreement. The Working Committee shall in particular:

(i) agree a plan for supply of Product and [REDACTED]

(ii) report on, discuss, consult on and raise any concerns regarding the Parties’ performance under the Agreement including Roche’s progress towards and achievement of those matters identified in Part C of Annex E ;

(iii) agree a plan for Distribution of the Product including in relation to the procedures in place or to be put in place with NHS hospitals and bona fide distribution hubs relating to supply chain management and a plan for how Non Standard Distribution and associated costs for Non Standard Distribution shall be managed;

- (iv) report on, discuss, consult on and raise any concerns regarding disclosure of Roche Confidential Information as contemplated by Section 7;
 - (v) review, measure performance against and discuss possibilities to update the Delivery Schedule; and
 - (vi) discuss and devise any alternative mechanism for supply of the Product in accordance with Section 2(b)(i).
- (c) The Parties acknowledge and agree that the Working Committee is a forum for discussion to facilitate the operation of this Agreement. For the avoidance of doubt, the Working Committee shall not have the authority to amend any of the terms and conditions of this Agreement or waive any rights of a Party under this Agreement.
- (d) The first meeting of the Working Committee shall occur [REDACTED]
[REDACTED]
Thereafter, the Working Committee shall [REDACTED] or such other intervals and at such additional times as the Parties agree or as required to fulfil functions allocated to the Working Committee pursuant to this Agreement. The Parties shall hold Working Committee meetings by video or telephone conference or as otherwise agreed between the Parties and may agree from time to time to take decisions in writing.
- (e) The Parties acknowledge that the Working Committee will operate by consensus. Each Party shall bear all expenses of their respective Working Committee representatives related to their participation in the Working Committee.
- (f) Roche shall keep UK regularly informed through the Working Committee of the status and its progress in securing all regulatory approvals (including the Marketing Approval) required for Product in the Territory as well as the maintenance and renewal of the same, and the progress towards achieving Delivery of the Units volume of Product in compliance with the Delivery Schedule.
- (g) UK and Roche shall cooperate and share relevant information through the Working Committee to facilitate the Delivery of Product in accordance with the Delivery Schedule and to facilitate and fulfil the objectives of this Agreement.
- (h) If a Regulatory License applicable to the Product to be supplied hereunder, or any regulatory approval (including the Marketing Approval) for the Product is suspended, withdrawn or discontinued in, or withdrawn from, any market (including in the Territory) for safety, quality or regulatory reasons, then Roche shall promptly give UK notice of such discontinuation, suspension or withdrawal through the Working Committee. If a UK License is suspended, withdrawn or discontinued then UK shall promptly give Roche notice of such discontinuation, suspension or withdrawal through the Working Committee.
- (i) Notwithstanding its reporting obligations through the Working Committee, Roche shall keep UK [REDACTED], informed of all material events relating to the development, manufacture and supply of the Product including with respect to those items in Annex E.

(j) UK shall have a right of consultation in respect of the matters set out in Part B of Annex E or any other matters which will negatively impact or Delay supply under this Agreement. Before Roche takes or implements any decisions under, or which will negatively impact or Delay supply under, this Agreement, or are decisions in respect of those matters set out in Part B of Annex E, Roche shall provide UK with a reasonable opportunity to consult on and provide comments on Roche's proposed decision. Roche shall take on board and use Commercially Reasonable Efforts to take into account and implement any reasonable requests and comments of UK in respect of such matters.

(k) [REDACTED]

10. Anti-Bribery

Roche represents and warrants, on behalf of itself and its affiliates, and, to the best of its knowledge, its and their respective personnel, if any, directly and effectively involved, in the obtaining or performance of this Agreement (together with Roche, the "**Roche Representatives**") that:

(a) it and the Roche Representatives have not committed any offence under the Bribery Act 2010 in connection with the award, negotiation or performance of this Agreement or done any of the following ("**Prohibited Acts**"):

(i) offered, given or agreed to give any officer or employee of UK, the Crown or UK Affiliate any gift or consideration of any kind as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining or performance of this Agreement or for showing or not showing favor or disfavor to any person in relation to this Agreement; or

(ii) in connection with this Agreement paid or agreed to pay any commission other than a payment, particulars of which (including the terms and conditions of the Agreement for its payment) have been disclosed in writing to UK; and

(b) Roche and its affiliates have in place and shall maintain adequate procedures designed and intended to prevent bribery and corruption, as contemplated by section 7 of the Bribery Act 2010; and

(c) Roche and its affiliates have not knowingly taken and shall not take any action that will, or would reasonably be expected to, cause UK or UK Affiliates to be in violation of any such Laws under (a) and (b).

11. Data Protection

(a) Each Party shall comply with UK GDPR and the Data Protection Act 2018 as amended or superseded from time to time (together, the "**Data Protection Legislation**").

(b) In particular, each Party shall comply with the Data Protection Legislation in force from time to time in the Territory in respect of any personal data provided to it by the other Party under, or in connection with the performance of its obligations under, this Agreement or in the case of UK, related to the use of Product or by UK or any person to whom it is supplied pursuant to this Agreement. In particular, in respect of such personal data, each Party agrees to comply with the obligations placed on it by the Principle (f) (the "**Integrity Principle**") set out in the Data Protection Act 2018.

(c) Both Parties agree to use all reasonable efforts to assist each other to comply with Data Protection Legislation, including in relation to subject access requests.

12. Right of Audit

(a) Each Party shall keep secure and maintain for the Term of this Agreement and [REDACTED] thereafter, or such longer period as may be agreed between the Parties, full and accurate records of all matters relating to this Agreement. In the case of Roche, Roche shall procure that all records relating to the manufacture, testing, packaging, transport and release of the Product shall be retained for no less than [REDACTED] following Delivery of the Product or such longer period as may be required by applicable Laws.

(b) Roche shall grant to UK or its authorised agents such access to those records as they may reasonably require: (i) in order to check Roche's compliance with this Agreement, and (ii) for the purposes of any examination pursuant to section 6(1) of the National Audit Act 1983 of the economic efficiency and effectiveness with which UK has used its resources.

(c) The Comptroller and Auditor General may examine such documents as they may reasonably require which are owned, held or otherwise within the control of Roche and Roche affiliates and may require Roche to provide such oral and/or written explanations as may reasonably be necessary. This section does not constitute a requirement or agreement for the examination, certification or inspection of the accounts of Roche under section 6(3)(d) and 6(5) of the National Audit Act 1983.

(d) In entering into this Agreement and in its performance under this Agreement Roche shall ensure that it, its affiliates, and its staff, act in good faith towards UK and in connection with the subject matter of this Agreement.

(e) Roche shall take all reasonable steps to prevent any offence under applicable Law creating offences in respect of fraudulent acts (including any fraudulent acts in relation to this Agreement, or defrauding or attempting to defraud or conspiring to defraud the Crown) by staff and Roche in connection with the receipt of monies from UK. Roche shall notify UK immediately if it has reason to suspect that any such fraudulent acts have occurred or is occurring or is likely to occur.

13. Tax Non-Compliance

(a) If, at any point during the Term of this Agreement, any of the following occurs:

(i) any tax return of Roche submitted to HM Revenue & Customs on or after 1 October 2012 is found, on or after 1 April 2013, to be incorrect as a result of:

(A) HM Revenue & Customs successfully challenging Roche under the legislation in Part 5 of the Finance Act 2013; or any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid national insurance contributions (together, the "**General Anti-Abuse Rule**"), or the Halifax Abuse Principle explained in the CJEU Case C-255/02 Halifax and others (the "**Halifax Abuse Principle**"), or under any tax rules or legislation that have an effect equivalent or similar to the General Anti-Abuse Rule or the Halifax Abuse Principle; or

(B) the failure of an avoidance scheme which Roche was involved in, and which was, or should have been, notified to HM Revenue & Customs under the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue and Customs of any specified notifiable arrangements or proposals and to provide prescribed information on those arrangements or proposals within set time limits as contained in Part 7 of the Finance Act 2004 and in secondary legislation made under vires contained in Part 7 of the Finance Act 2004 and as extended to National Insurance Contributions by the National Insurance Contributions (Application of Part 7 of the Finance Act 2004) Regulations 2012, SI 2012/1868 made under s.132A Social Security Administration Act 1992 or any equivalent or similar regime; or

(ii) any tax return of Roche submitted to HM Revenue & Customs on or after 1 October 2012 gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Effective Date or to a civil penalty for fraud or evasion;

(each an "**Occasion of Tax Non-Compliance**"), then Roche shall notify UK in writing of such fact within twenty (20) Business Days of its occurrence.

14. Compliance with Law

(a) During the Term, Roche shall comply, and shall procure that its personnel, its affiliates and their personnel, and all contractors involved in the development, manufacture, packaging, labelling, storage, transport and supply of the Product comply, at all times and in all material respects with all applicable Law, including equality and non-discrimination legislation, labor and employment legislation and environmental and safety legislation, in each case in relation to the development, manufacture and Delivery of Product.

(b) Roche shall notify UK promptly if it becomes aware of:

(i) any actual material failure to comply with section 14(a); or

(ii) any investigation of or proceedings against Roche under human rights legislation, equality and non-discrimination legislation, labor and employment legislation and environmental and safety legislation in relation to the development, manufacture and Delivery of Product and shall cooperate fully and promptly with any reasonable requests of the person or body conducting such investigation or proceedings, including allowing access to any documents or data required, attending any meetings and providing any information requested.

15. Assignment & Subcontracting

(a) Other than with the written consent of UK (such consent to be at UK's discretion), Roche may not assign, transfer, mortgage, charge, or grant any interest in, the whole or any part of the benefit of, or any of its rights or obligations or interests under, this Agreement. Any assignment, transfer, mortgage, charge or grant to a third party shall only be permitted with the written consent of UK.

(b) Without prejudice to Section 15(a) and (c), if a Party performs or has performed any of its obligations under this Agreement through any third party or its affiliates, such Party shall remain bound by its contractual obligations and responsible to the other Party for the implementation of this

Agreement including the acts or omissions of such third party or affiliates as if those acts or omissions were of its own.

(c) Solely to the extent permitted under the terms of this Agreement, either Party may subcontract or delegate certain of its obligations under this Agreement (i) to a contractor (in the case of Roche) or (ii) to an authorized agent or person responsible for administering or having administered Product including all health service bodies (in the case of UK), provided that in each case of (i) and (ii) each applicable Party shall remain responsible for all acts and omissions of its subcontractor or delegee as if they were its own.

16. Supplier Code of Conduct

Roche shall comply with the Supplier Code of Conduct (initially published on behalf of UK by the Government Commercial Function, dated September 2017) as may be amended, restated, updated, re-issued or re-named from time to time, a copy of which is available online at <https://www.gov.uk/government/publications/supplier-code-of-conduct> (the "**Supplier Code of Conduct**"), within a reasonable period from the Effective Date for the remaining duration of the Agreement.

17. General

(a) Governing Law and Jurisdiction

This Agreement (including the annexes) and any dispute or claim arising out of or in connection with it shall be governed by and construed in accordance with English law and subject to the exclusive jurisdiction of the English courts to which the parties irrevocably submit.

(b) Interpretation

Except where the context expressly requires otherwise: (i) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa); (ii) the words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation" and will not be interpreted to limit the provision to which it relates; (iii) the word "shall" will be construed to have the same meaning and effect as the word "will"; (iv) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (v) any reference herein to any person, body or legal entity will be construed to include that person's, body's or legal entity's successors and permitted assigns; (vi) the words "herein," "hereof," and "hereunder," and words of similar import, will be construed to refer to this Agreement in its entirety, as the context requires, and not to any particular provision hereof; (vii) all references herein to Sections or Annexes will be construed to refer to sections or Annexes of this Agreement, and references to this Agreement include all the Annexes attached hereto; (viii) the word "notice" means notice in writing (whether or not specifically stated); (ix) provisions that require that a Party or the Parties "agree," "consent," or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but not by instant messaging); (x) references to any specific Law, rule or regulation, or article, section or other division thereof, will be deemed to include the then current amendments thereto or any replacement or successor Law, rule or regulation thereof;

(xi) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or"; (xii) any undertaking by, or obligation on, a Party to (1) do any act or thing includes an undertaking to procure the doing of that act or thing by a Party's affiliates; and (2) not do any act or thing includes an undertaking not to encourage, solicit, cause, or assist the doing of that act or thing by any affiliate or other person; (xiii) any reference to a Party or the Parties shall include legal successors and/or any permitted assignees of a Party; (xiv) any reference to GBP, Pounds Sterling or £ is to the lawful currency from time to time of the United Kingdom of Great Britain and Northern Ireland and to US Dollars or US\$ is to the lawful currency from time to time of the USA; (xv) any reference to a statute or statutory provision includes any successor legislation thereto, regulations promulgated thereunder, any consolidation or re-enactment, modification or replacement thereof, any statute or statutory provision of which it is a consolidation, re-enactment, modification or replacement and any subordinate legislation in force under any of the same from time to time except in each case to the extent that any consolidation, re-enactment, modification or replacement enacted after the date of this Agreement would extend or increase the obligations, in any manner (and whether financial obligations or otherwise), of either Party hereunder; and (xvi) the interpretation of this Agreement, any notice, consent or the like delivered hereunder, and any action, dispute, arbitration or proceeding, will be provided or conducted in English; (xvii) reference to a party's or person's "affiliate" shall, unless defined elsewhere, mean a person, body or legal entity that controls, is controlled by, or is under common control with that party or person, wherein control is deemed to exist where the applicable party, person, body or legal entity owns or controls, directly or indirectly, more than fifty percent (50%) of the equity securities entitled to vote in the election of directors (or, in the case that such person is not a company or corporation, for the election of the corresponding managing authority), or otherwise has the power to direct the management and policies of such person, body or legal entity save in the case of Roche the term "affiliate" shall not include [REDACTED]

[REDACTED] (xviii) reference to "**Laws**" means those statutes, ordinances, regulations, rules, treaties, directives, judgments, decrees or orders of any governmental authority (being any applicable court, council, tribunal, arbitrator, agency, regulatory body, department, bureau, branch, office, legislative body, commission or other instrumentality of government) in the Territory or any country where activities for or pursuant to this Agreement (including those concerning development, manufacturing, testing, packaging and storage of Product) are undertaken (or, but solely where the context requires, any other relevant geographical area).

(c) *Business Day*

In the event that any action to be taken under this Agreement falls on a day which is not a Business Day (namely Saturday, Sunday or a statutory holiday in England), then such action shall be taken on the next succeeding Business Day.

(d) *Independence of Parties*

Each Party is independent of the other. The Parties are not agents or partners of, or joint venturers with, each other. All covenants contained in this Agreement are contractual in nature.

(e) *Waiver*

No failure on the part of a Party to exercise, and no delay in exercising any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, will impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor will any single or partial

exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege. No waiver by either of the Parties of any breach of any condition, covenant or term of this Agreement shall be effective unless it is in writing and it shall not constitute a waiver of such breach of such condition, covenant or term except in respect of the particular breach giving rise to such waiver.

(f) Severability

If any provision in this Agreement is held to be invalid, unenforceable or in conflict with any applicable Law that provision shall be deemed to no longer form a part of this Agreement. The Parties agree that the remaining provisions shall be deemed to be in full force and effect as if both Parties had executed such remaining provisions after the invalid provision was expunged.

(g) Entire Agreement

This Agreement constitutes the entire agreement between UK and Roche pertaining to its subject matter and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions, whether oral or written, of the Parties and there are no warranties, representations or other agreements between the Parties in connection with its subject matter except as specifically set forth in this Agreement. No supplement, modification, amendment or waiver of this Agreement shall be binding unless executed in writing by all of the Parties. Any term or condition of any purchase order issued by UK which conflicts with, modifies or imposes obligations on Roche in addition to those contained in, this Agreement shall be null and void.

(h) Surviving Provisions

Any provisions of this Agreement that are expressed to, or by implication are intended to, survive its termination or expiry shall do so, including those provisions of Section 2(b) (*Distribution*), Section 2(c) (*Non Standard Distribution*), Section 3(e) and (f) (*Marketing Approvals*) until Product Delivered has been used or its shelf life expired, Section 5(b), 5(c) and 5(d) (*Indemnities*), Section 7 (*Confidentiality*), Section 11 (*Date Privacy*), Section 12(a) to (c) (*Audits*), Section 15 (*Assignment*), this Section 17 (*General*), and Annex B Sections 5 and 6 (*Defects*). The termination or expiry of this Agreement shall be without prejudice to any accrued rights of the respective Parties which shall survive such termination or expiry.

(i) Further Assurances

Each Party shall do such things, to attend or cause their respective representatives to attend such meetings, and execute such further documents, agreements and assurances as may be deemed necessary, reasonably required or advisable from time to time in order to carry out and give full force and effect to the terms and conditions of this Agreement in accordance with its true intent.

(j) Binding upon Successors

This Agreement shall enure to the benefit of and be binding upon each Party and its heirs, executors, administrators and permitted successors and assigns.

(k) Currency

Except where otherwise expressly provided, all amounts in this Agreement are stated and shall be paid in Pounds Sterling.

(l) No Third Party Beneficiaries

Save as set forth in this Agreement, including pursuant to the indemnities, no person other than the Parties are intended to be beneficiaries of the rights of either Party hereto including pursuant to the Contracts (Right of Third Parties) Act 1999. Notwithstanding any third party beneficiary rights hereunder, the Parties may agree to terminate, amend or vary the terms of this Agreement without the consent or waiver of such rights by any third party beneficiary.

(m) Notices

Any notice required to be given hereunder shall be considered properly given if sent by pre-paid mail, courier, by hand or email (return receipt requested) to the respective address of each Party as set forth in Annex B. Any notice delivered after 5pm GMT shall be deemed not to be received until 9am on the next Business Day.

(n) Language

The parties hereto have requested that this Agreement be written in the English language.

(o) Annexes

The annexes to this Agreement are an integral part thereof.

(p) Counterparts and e-Signature

This Agreement may be executed by the Parties hereto in separate counterparts, each of which when so executed and delivered shall be deemed an original, but all such counterparts shall together constitute one and the same Agreement. The Parties agree that execution of this Agreement by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures.

EXECUTION VERSION

CONFIDENTIAL

This Agreement is accepted and executed as of the Effective Date first written above by:

ROCHE P

By:

[Redacted Signature]

Name: [Redacted]
Title: General Manager
Date: March 4 2021

The Secretary of State for the Department for Business, Energy and Industrial Strategy acting on behalf of Her Majesty's Government of the United Kingdom (including the Northern Ireland Executive Committee, the Scottish Executive and the Welsh Government)

By:

Name:
Title:
Date:

This Agreement is accepted and executed as of the Effective Date first written above by:

ROCHE PRODUCTS LIMITED

By: _____
Name:
Title:
Date:

The Secretary of State for the Department for Business, Energy and Industrial Strategy acting on behalf of Her Majesty's Government of the United Kingdom (including the Northern Ireland Executive Committee, the Scottish Executive and the Welsh Government)

By: 
Name: 
Title: Director General Vaccine Taskforce
Date: March 5 2021

ANNEX A - PRODUCT REQUIREMENTS

1. Scope

Roche will supply Product duly authorized for sale in UK under an appropriate Marketing Approval .

2. Format and Shelf Life

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

3. Firm Quantity

Item Description	Firm Quantity	Completion Date (Expected Date for all Firm Quantity to be Delivered)
Single dose combination pack of casirivimab and imdevimab (collectively, a "Unit")	[REDACTED]	The Longstop Date

Commercially Reasonable Efforts to Deliver / Inability to Deliver

UK acknowledges that, as of the Effective Date of this Agreement, Roche has not obtained a Marketing Approval to market the Product in UK. The Delivery Schedule reflects the expected timeline to Deliver the Firm Quantity of Product in tranches, which must be ordered from Roche's head office which is responsible for production and allocation of Product globally outside the United States.

4. Optional Quantities

Roche's supply obligations hereunder are restricted to [REDACTED] of Product.

Where UK requests any quantities of Product in excess of this quantity, the Parties shall through the Working Committee discuss such request in good faith and seek to authorize such additional quantities on the same terms as under this Agreement by formal executed amendment to this Agreement.

5. Maintenance of the Cold Chain During Transportation and Storage

Throughout the shipping process, Roche will maintain the Product in temperature controlled and monitored conditions in accordance with the manufacturer's recommended storage conditions and/or as described within the Product monograph. UK and Roche will maintain the Product in temperature controlled and monitored conditions in accordance with the manufacturer's recommended storage conditions and/or as described within the Product monograph in their respective storage facilities.

SW1H 0ET

Attn: Permanent Secretary, Department for Business, Energy & Industrial Strategy

Email: [REDACTED]

UK may submit notices under this Agreement to Roche at:

[REDACTED] General Counsel
Roche Products Limited
6 Falcon Way, Shire Park
Welwyn Garden City
AL7 1TW

Email: [REDACTED]

4. Payment Terms

On Delivery Roche will issue an invoice to UK for such Units of Product so Delivered. Payment is due by the last Business Day of the month following the month stated in the date of invoice. No payment shall be deemed to have been received by Roche until it has received cleared funds. Roche reserves the right at any time to require UK to make payment by direct debit to such bank account of Roche as nominated by Roche from time to time.

5. Title and Risk

Title to and risk in the Product passes upon Delivery, save that Roche shall be responsible for (A) any damage or loss suffered in Distribution and (B) for any Product that is Delivered and then properly rejected following examination by UK and/or is found to be defective

Upon Delivery, except for during Distribution, UK shall be fully responsible for ensuring that Product issued under a Marketing Approval is stored in accordance with the approved Product monograph.

With regard to defective Product (i) damaged prior to Delivery that is notified to Roche by UK [REDACTED]; or (ii) [REDACTED] Roche will at UK's election (i) use CRE to promptly replace or (ii) refund (if any monies have been paid) and account for any out-of-pocket expenses incurred by UK in relation to such defective Product. Defective or damaged Product will be collected and destroyed by Roche at its own cost.

Notwithstanding the above, if a defect in the Product was not reasonably ascertainable from a visual inspection of the Product and review of the accompanying Documentation, [REDACTED] shall not apply, provided that UK notifies Roche in writing of its subsequent detection or receipt of notice of the defect prior to expiration of the shelf life [REDACTED] in the applicable Product. Any acknowledgement of receipt of Product by UK does not constitute an acceptance of Product as defect-free.

If the replacement Product is not available in a timeframe acceptable to UK, then UK may, in addition to and without prejudice to any other remedy available, choose to request reimbursement in lieu of replacement Product.

Roche acknowledges that an agent on behalf of UK may examine Product for damage or defects and report the same to Roche, which notification shall be deemed a notification by UK under this Agreement.

6. Returns

All sales are final with no Product return except to the extent that the Product is defective, damaged or otherwise subject to a recall or withdrawal.

In the event of a recall or a withdrawal of Product, Roche must notify UK and the MHRA and must collect and destroy the Delivered, recalled, or withdrawn Product at its own cost. Roche shall also be responsible for all other costs of any recall or market withdrawal of the Product in the Territory, including reasonable, itemized, direct out-of-pocket costs and expenses actually incurred by or on behalf of UK.

Roche must, upon the request of UK, replace as soon as possible any recalled or withdrawn Product at its own cost.

If the replacement Product is not available in a timeframe acceptable to UK, then Roche shall reimburse UK in lieu of replacement Product.

ANNEX C – Distribution

Distribution sites: Pharmacy departments within NHS hospitals within the United Kingdom

Distribution Timeline: Roche will use CRE to deliver Product [REDACTED]

[REDACTED]

[REDACTED]

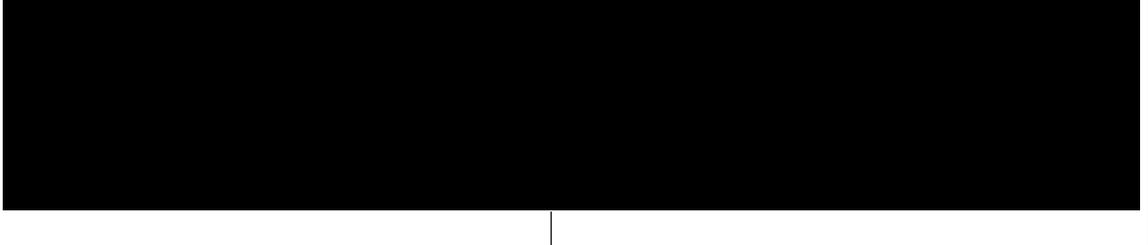
[REDACTED]

ANNEX D – Delivery Schedule



ANNEX E – Governance

Part A: Working Committee Party Representatives

Roche	UK
	

Part B: Matters requiring consultation

- Any proposed changes to the Delivery Schedule, including any actual or anticipated Delays in Delivery against, or updates to, the Delivery Schedule.
- Any application for the Marketing Approval.
- Implications if a Marketing Approval is unlikely to be achieved by the Expected Approval Date .
- Any proposed changes to the Marketing Approval.
- Any proposed reduction to the Minimum Shelf Life.
- Any clinical trial results of findings that impact the efficacy or safety of the Product.
- Any issues or delays in the manufacturing progress or Delivery of Product, including losing capacity at facilities or delays in supply of raw materials and equipment.
- Any proposed changes to Delivery Locations (Annex C)

Part C: Other Reporting or Requirements



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- [REDACTED]
- [REDACTED]

ANNEX F – Documentation

- Pack list and quantity of Units
- Certificate of Analysis (and where relevant, Certificate of Origin)
- Product description
- Batch details
- Expiry date
- Storage and transport temperature control records
- Storage and transport instructions
- Other information and notices required by the Marketing Approval and Applicable Laws
- Quality personnel contact information
- Certificate of Release

ANNEX G – UK Crown Dependencies and Overseas Territories

The Overseas Territories

Anguilla;

Ascension;

Bermuda;

British Antarctic Territory;

British Indian Ocean Territory;

British Virgin Islands;

Cayman Islands;

Falkland Islands;

Gibraltar;

Montserrat;

The Pitcairn Islands;

St Helena;

Tristan da Cunha;

South Georgia and the South Sandwich Islands;

Turks and Caicos Islands; and

UK Sovereign Base Areas of Akrotiri and Dhekelia

The Crown Dependencies

Bailiwick of Jersey;

the Bailiwick of Guernsey (including the jurisdictions of Guernsey, Alderney and Sark); and

the Isle of Man