THIS AGREEMENT is made on 11 August 2021 ("**Effective Date**")

BETWEEN:-

(1) **THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE**, contracting for and on behalf of the Crown, and whose principal office is at 39 Victoria Street, London SW1H 0EU United Kingdom (the "**Authority**") and

(2) **GLAXOSMITHKLINE UK LIMITED**, a company registered in England and Wales under number 04310159 whose registered offices it at 980 Great West Road, Brentford, Middlesex, TW8 9GS ("**Supplier**").

WHEREAS:-

(A) The Authority has informed Supplier that it is taking preparatory measures to counter the COVID-19 pandemic. The Authority wishes to purchase a quantity of Units (as defined in Appendix 1) of the pharmaceutical product, being the monoclonal antibody sotrovimab (previously known as VIR 7831) administered by intravenous infusion ("**Product**") as part of its preparatory measures in respect of the COVID-19 pandemic. As such, the Authority has agreed to purchase a number of Units of the Product from Supplier, and Supplier has agreed to deliver that quantity of Units of Product, subject to Supplier, or any of its approved UK registered affiliates as set out in Appendix 8 (being "**Approved Affiliates**"), securing 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 Authority, in accordance with the with the terms and conditions of this Agreement.

Now, therefore, Supplier and the Authority (each a "**Party**", collectively the "**Parties**") have agreed as follows.

1. PRODUCT REQUIREMENTS, PRICING AND QUANTITIES

1.1 Subject to the terms of this Agreement, Supplier will supply, and the Authority will purchase, the quantity of Units of Product identified as the Firm Quantity in accordance with the "**Product Requirements**" at Appendix 1. The Parties acknowledge that this Agreement constitutes a commitment by the Authority to purchase the Firm Quantity, provided that Supplier or any Approved Affiliate obtains Marketing Approval for the Product, and in accordance with this Agreement.

1.2 Product will be sold by Supplier and purchased by the Authority in accordance with the pricing, payment and other commercial terms set forth in this Agreement, including the provisions of Appendix 2. Subject to section 3.17, Product supplied will be accompanied with all relevant information and notices required pursuant to the Marketing Approval and all applicable Laws and applicable regulations in the Territory, together with those documents and such information as specified in Appendix 6 ("**Documentation**").

2. MANUFACTURE

2.1 Supplier shall manufacture or have manufactured Product in bulk form at Supplier's designated manufacturing facilities in China or South Korea. Supplier shall manufacture and

package finished form of the Product at Supplier's facility in Italy (or an alternative facility in the European Economic Area ("**EEA**") or the United Kingdom). Except where permitted in accordance with section 16, Supplier will ensure that any finished form Product that is supplied pursuant to this Agreement is supplied from its facilities in the EEA or the United Kingdom.

3. **DELIVERY**

3.1 In this Agreement "**Delivered**" shall mean Units of the Product that have been delivered to the applicable Delivery Address (defined below) and QP-released, in each case in accordance with the Marketing Approval (subject to, if applicable, section 3.17). "**Delivery Address**" means either: (a) Supplier's warehouse at [redacted] or other facility within the Territory that is controlled by the Supplier or an Approved Sub-contractor (details of which Approved Sub-contractor and storage facility to be notified by the Supplier to Authority through the Working Committee as soon as practicable after the Effective Date); or (b) in respect of Product for Northern Ireland (unless such Product for Northern Ireland is to be supplied pursuant to a 174A Approval (as defined below), in which case (a) above shall apply), the NHS central warehouse in Belfast, Northern Ireland, or such other location as otherwise agreed by the Parties from time to time. References to "**Delivery**" shall be construed accordingly. The Parties acknowledge and agree that, where (b) applies, the specific requirements set out in Schedule 1Appendix 9 shall apply to such Delivery to Northern Ireland, which shall be in addition to, or, where contrary to any provisions otherwise in this Agreement, apply instead of, those provisions set out herein in respect of such Delivery. For the avoidance of doubt, Schedule 1Appendix 9 shall only apply to such Delivery to Northern Ireland and not to any other Delivery.

3.2 Subject to Supplier obtaining a Marketing Approval and as applicable, any MHRA Alternative Labelling Of Packaging Approval (as defined in section 3.17), Supplier shall Deliver the Firm Quantity of Products (or such lower total amounts of Units of Product to be Delivered pursuant to the terms of this Agreement, including to take account of any rejection or cancellation of any Units of Product thereof in accordance with section 3.10 and/or Appendix 2 (the "**Adjusted Firm Quantity**")) in accordance with Appendix 1 in the applicable amounts and by the dates set forth in Appendix 4 as amended in accordance with this Agreement (the "**Delivery Schedule**"). At least 30 days prior to each Delivery, Supplier shall confirm the actual date on which the applicable Units of Products shall be Delivered within the calendar month ending on the date specified in the Delivery Schedule (the "**Delivery Schedule Window**"). Prior to commencement of any Delivery, and in any event no later than 20 Business Days prior to the commencement of the applicable Delivery Schedule Window, the Authority shall notify Supplier of the allocations of Units of Product to be Delivered in such Delivery Schedule Window between (a) Great Britain and (b) in Northern Ireland. If Authority subsequently wishes to adjust such allocation, such requests shall be discussed by the Working Committee.

3.3 Supplier further agrees, following Delivery and subject to sections 3.4 and 16.2, to use CRE (as defined in section 3.6) to procure, via its approved sub-contractors, being any of those set out in Appendix 8 ("**Approved Sub-contractors**"), the storage and distribution of Units of the Delivered stock of Product on behalf of the Authority to those NHS hospitals and other specific locations in each case as specified in Appendix 3 such storage and distribution to be in accordance with and subject to Supplier's storage and distribution terms and practices with its applicable third party logistics providers, and as further detailed in Appendix 3, or as otherwise agreed by the Parties ("**Distribution**"). For the avoidance of doubt, Distribution in respect of

Product for Northern Ireland shall only apply where such Product for Northern Ireland is to be supplied pursuant to a 174A Approval. Where Product for Northern Ireland is to be supplied other than pursuant to a 174A Approval, such Product shall be Delivered to the Authority in Northern Ireland in accordance with (b) in section 3.1.

3.4 Supplier shall be liable to the Authority for any damage or loss to Units of Product during Distribution (or Non Standard Distribution, as applicable), provided that (a) Supplier shall not be obliged to replace any Units of Product that may be lost or damaged during Distribution (or Non Standard Distribution, as applicable); (b) Supplier shall not have any liability for such loss or damage except in circumstances where Supplier's relevant third party logistics provider is liable to Supplier with respect to the Units of Product that are lost or damaged during Distribution (or Non Standard Distribution, as applicable); and (c) Supplier's liability to the Authority for any damage or loss to Units of Product during Distribution (or Non Standard Distribution, as applicable) (if any) shall be limited to, at Supplier's sole discretion, either (i) Delivery, at no additional costs to the Authority, of replacement Units of Product equivalent to such damaged or lost Units of Product at the earliest commercially possible opportunity or (ii) to the extent already invoiced by Supplier, credit to the Authority of an amount equal to the price per Unit of such damaged or lost Units of Product, such credit note to be raised within ten (10) Business Days of notice of such damage or loss being provided by or on behalf of the Authority to Supplier, with if applicable where the invoice has been paid by Authority, payment of such credit note being processed within thirty (30) Business Days of such credit note being raised. In the event of any product liability claim against the Authority arising as a result of or in connection with an act or omission during Distribution (or Non Standard Distribution, as applicable) of a third party logistics provider appointed by Supplier, Supplier's total liability to the Authority in respect of such claim shall be limited to and shall not in any event exceed the amount that Supplier is able to and actually receives from such third party logistics provider in respect of such claim under Supplier's agreement with such third party logistics provider. The provisions of this section 3.4 shall be the Authority's sole and exclusive remedy, and in full satisfaction of any and all liabilities owed by Supplier to the Authority in respect of Distribution (or Non Standard Distribution, as applicable). For the avoidance of doubt, nothing in this section 3.4 shall limit Supplier's liability to the Authority in respect of any product liability claim against the Authority to the extent arising as a result of an act or omission prior to Delivery of such Product.

3.5 If the Authority notifies Supplier that it requires Units of Product to be distributed to other locations or on materially different terms (such as same day delivery) to those set forth in Appendix 3 ("**Non Standard Distribution**"), the Parties shall discuss in good faith such Non-Standard Distribution and Supplier shall use Commercially Reasonable Efforts (as defined below) to procure such Units of Product are distributed to meet the agreed Non-Standard Distribution requirements (if any). Supplier shall have the right to invoice the Authority for any reasonable additional costs incurred by Supplier in excess of the costs involved in a standard Distribution. For the avoidance of doubt, nothing in this Agreement shall require Supplier to agree to any Non-Standard Distribution requirements.

3.6 "**Commercially Reasonable Efforts**" or "**CRE**" shall mean

3.6.1 in the case of the performance of the Supplier's activities, the carrying out of such activities by Supplier using a degree of effort that Supplier would typically undertake or use in the development, manufacture, approval and supply for a therapeutic

product (including having regard to one for treating patients to combat the current COVID-19 pandemic) at a similar stage of development or commercialization having regard to the urgent need for such products, taking into account all scientific, commercial, and other factors that the Supplier would take into account, including efficacy and safety and applicable Laws. Such efforts being subject to those activities which are within the power or influence of Supplier having regard to its arrangements with the licensor of the Product and such licensor's obligations and rights in relation to Supplier seeking regulatory approval; and

3.6.2 in the case of the Authority, the activities and degree of effort the Authority would typically undertake or use in supporting its contractor in its regulatory pathway for a product and in the supply of drugs, having regard to the urgent need for drugs to treat patients in a pandemic which is resulting in serious public health issues, restrictions on personal freedoms and economic impact, across the world. Such efforts being subject to those activities which are within the power or influence of the Authority having regard to its legal obligations and public accountability.

3.7 Title to the Units of Product shall pass to the Authority on Delivery. Subject to section 3.4, risk in the Units of Product shall pass to the Authority on Delivery. For the avoidance of doubt, title and risk shall not pass to the Authority until the later of (i) delivery to the applicable Delivery Address; and (ii) QP-release of the Product by Supplier.

3.8 As soon as practicable following the Effective Date the Parties shall (and the Authority shall use CRE to procure that appropriate representatives from the NHS and Department of Health and Social Care shall) meet to discuss the logistics for and other operational aspects in respect of the Distribution for the Product. Such discussions shall include, but not be limited to, discussing:

3.8.1 without prejudice to section 3.2 and Schedule 1Appendix 9, the procedure for notifying Supplier of the Units of Product to be Delivered for Great Britain and for Northern Ireland;

3.8.2 the procedure for the Authority or the NHS hospitals in Great Britain to call off orders of Delivered Product for Distribution, including in respect of the ordering system to be used;

3.8.3 the timings of orders for Distribution to NHS hospitals in Great Britain; and

3.8.4 minimum order quantities.

3.9 After the Effective Date, and through consultation via the Working Committee:-

3.9.1 the Parties shall discuss Supplier’s proposed regulatory pathway for Supplier to achieve Marketing Approval as soon as practicable which as of the Effective Date, Supplier anticipates will be granted in September 2021 (the "**Expected Approval Date**"). Supplier will consider any suggestions or proposals made by the Authority with respect to Supplier’s regulatory pathway for the Product, provided that Supplier shall have sole discretion and final decision making authority in respect of any decisions with regard to the regulatory pathway for the Product;

3.9.2 Supplier shall keep the Authority updated with respect to progress towards securing the grant of a Marketing Approval and, if applicable, any MHRA Alternative Labelling Of Packaging Approval, and any requirement to update the Delivery Schedule to reflect delays in obtaining such approvals;

3.9.3 Supplier shall keep the Authority updated with respect to progress towards Delivering the Units of Product in accordance with the Delivery Schedule including the 30 days advance notice of the actual date of Delivery, and

3.9.4 if necessary and in accordance with this section 3, discuss and, to the extent possible as agreed by the Parties taking into account what is within the reasonable control of the Supplier and other commercial and scientific factors applicable to the Supplier, update the Delivery Schedule for the actual date of an applicable Delivery within the Delivery Schedule, in good faith and, to the extent applicable, in compliance with the Principle of Pro Rata Supply (defined below).

3.10 Subject to section 3.12, if Supplier fails to Deliver Units of Product in the amounts or by the agreed actual date of Delivery within the applicable Delivery Schedule Window (as confirmed in accordance with section 3.1 and as may be updated by the Parties through the Working Committee, including as required to take account of changes in the timing for the grant of the Marketing Approval or, if applicable, obtaining MHRA Alternative Labelling Of Packaging Approval) and to the extent such Units of Delayed Product continue to be delayed ten (10) Business Days after the end of the applicable Delivery Schedule Window (a "**Delay**" or "**Delayed Product**"), then the Parties shall meet to discuss in good faith the timings for when such Units of Delayed Product could be Delivered. If the Parties cannot agree on an updated delivery timeline, the Authority shall, by giving written notice to Supplier within thirty (30) days following the Delay, be entitled to reject, or otherwise cancel its purchase obligation in respect of, some or all Units of Delayed Product. In the event of such cancellation or rejection Supplier shall no longer be obliged to supply such rejected or cancelled Units of Delayed Product. The price for any cancelled or rejected Units of Delayed Products shall no longer be payable by Authority, which shall be the Authority's sole and exclusive remedy and in full satisfaction of any and all liabilities owed by Supplier to the Authority in respect of such Delay.

3.11 In the event that the Authority does not reject or cancel some or all Units of Delayed Product in accordance with section 3.10, Supplier shall still be obliged, in accordance with the updated delivery timelines as agreed by the Parties, to Deliver such Units of Delayed Product that are not rejected or cancelled, including where applicable [redacted] Provided such non-cancelled or non-rejected Units of Delayed Product are subsequently Delivered in accordance with the updated delivery timelines as agreed by the Parties, the Authority shall be obliged to pay the price for such Units of Delayed Product and the Supplier will have no further liability in respect of such Delay.

3.12 Notwithstanding the provisions of section 3.10, Units of Product will not be considered Delayed where a volume of less than 10% 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.

[redacted]

[redacted]

3.14 The Parties may discuss via the Working Committee possibilities for the Delivery of Units of Product earlier than the dates set forth in the Delivery Schedule, provided that Marketing Approval and as applicable, any MHRA Alternative Labelling Of Packaging Approval has been secured. On the basis of such discussions, the Parties may, via the Working Committee, discuss the Delivery of those Units of Product, including the proposed Delivery dates. Subject to agreement between the Parties on such early Delivery for the Units of Product, the provisions of sections 3.10 and 3.12 shall apply mutatis mutandis to any revised Delivery dates for Units of Product agreed in accordance with this section 3.14. Notwithstanding the foregoing, in no circumstances shall Supplier be obliged to Deliver Products earlier than the dates set forth in the Delivery Schedule agreed as of the Effective Date.

3.15 The process for acceptance, rejection, returns and recalls of Units of Product shall be in accordance with Appendix 2.

3.16 During the Term, until the Firm Quantity (or the Adjusted Firm Quantity, as applicable) has been Delivered free of Defects and in full to the Authority, Supplier 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.

3.17 The Authority acknowledges and agrees that, given the Delivery Schedule and the urgent need to deliver Product to patients for the Purpose, the packaging, patient information and labelling of the Units of Product Delivered under this Agreement may, instead of being in accordance with the Marketing Approval, be: (a) EU Single Triple Language Pack, provided Supplier is able to obtain any waivers required from the MHRA to permit marketing of Product packed in EU Single Triple Language Pack in the Territory; or (b) in the event that Supplier is unable to obtain any such waivers, any alternative Product presentation (other than that approved in the Marketing Approval or the EU Single Triple Language Pack) compliant with applicable Laws and approved by the MHRA to allow the Units of Product to be provided to patients in the Territory as soon as reasonably practicable (excluding supply on a specials/unlicensed basis unless otherwise agreed by the Parties), (the waiver under (a) or the approval under (b), whichever is applicable, "**MHRA Alternative Labelling Of Packaging Approval**"). Nothing in this section 3.17 shall diminish Supplier's obligation to Deliver the Firm Quantity (or the Adjusted Firm Quantity, as applicable) pursuant to this Agreement, provided that in respect of the obligation to do so in accordance with the Delivery Schedule, the Delivery Schedule as set forth in Appendix 4 has, if necessary to take account of the timing for receiving MHRA Alternative Labelling Of Packaging Approval, been updated in accordance with this

Agreement. “**EU Single Triple Language Pack**” means the packaging, labelling and patient information label in line with the EU marketing authorisation for the Product, which: (i) shall state on the pack the marketing authorisation holder in the EU and the EU license number; (ii) shall contain the product information label (in three languages), which, for the avoidance of doubt, will not reference the UK; and (iii) shall not contain any UK national labelling requirements, for example statements such as “POM”, the UK marketing authorisation holder, or the UK license number (PLGB number).

4. **USE; REGULATORY**

4.1 The Authority shall have sole responsibility for the use and administration of the Product Delivered pursuant to this Agreement and such use and administration shall occur in conformity with applicable Law and in accordance with this Agreement. Without limiting the generality of the foregoing, the Product is sold [redacted]o treat COVID-19 patients during and potentially following the COVID-19 pandemic (as declared by the WHO) (the “**Purpose**”). The Authority shall not sell, lend, donate, supply to or otherwise permit the use of the Product by any third party other than treating physicians and/or nurses in charge of administering the Product to patients in the Territory, save that the Authority may donate, re-sell (on a not-for-profit basis) or export Product to the Crown Dependences and UK Overseas Territories, being those territories listed in Appendix 7 for use by such Crown Dependences and UK Overseas Territories solely for the Purpose ("**Re-Sold Product**"). The Authority shall be solely responsible for obtaining and complying with all applicable Regulatory Licences and Marketing Approvals for such re-sales and exports. By way of exception to the foregoing, the Authority may provide Product which would otherwise be wasted or destroyed as being surplus to the Authority's requirements on a not-for-profit basis to any other country or person (any such Product being "**Donated Product**"), solely for the Purpose. The Authority shall be responsible for obtaining and complying with all applicable Regulatory Licences and Marketing Approvals for such re-sales and exports. Any such supply of Donated Product will be subject to (i) prior notification to and approval of the Supplier, not to be unreasonably withheld, and (ii) an appropriate agreement being entered into by the applicable recipient pursuant to which Supplier is not subject to, and has appropriate protections, from any liability arising from or connected to the supply, administration or other use of Donated Product in such other countries or persons.

4.2 As between the Parties:-

4.2.1 Subject to section 4.1 in respect of Re-Sold Product or Donated Product, Supplier 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 (at Supplier’s designated facilities and up to the point of Delivery) of the Product for, after grant of a Marketing Approval, commercial use in the Territory ("**Regulatory Licenses**"); and

4.2.2 the Authority 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 Supplier ("**Authority Licenses**").

4.3 Supplier intends to use CRE to seek an accelerated approval, conditional or full marketing approval from the UK Medicines and Healthcare products Regulatory Agency ("**MHRA**") for an indication covering the treatment by intravenous infusion of SARS-CoV-2 (the "**Therapeutic Indication**") but excluding any pricing or reimbursement approvals (the "**Marketing Approval**"). In respect of Product to be supplied for Northern Ireland (but not for Great Britain) Product may be Delivered pursuant to a temporary approval under Regulation 174A of the Human Medicines Regulations 2012 (provided that any such temporary approval will require and be subject to the applicable Secretary of State's approval) ("**174A Approval**"). Supplier shall update the Authority on its plan for obtaining such a Marketing Approval or 174A Approval for the Product through the Working Committee as set out in Clause 3.9. In the event that Product for Northern Ireland is to be Delivered pursuant to a 174A Approval, references in this Agreement to Delivery being in accordance with the Marketing Approval shall, in respect of such Product being Delivered under a 174A Approval, be deemed to mean in accordance with such 174A Approval.

4.4 If prior to the Expected Approval Date it seems reasonably likely in the objective and reasonable view of either of the Parties that the Marketing Approval will not be granted or issued by the Expected Approval Date, the Parties shall through the Working Committee cooperate in good faith and the parties shall each use Commercially Reasonable Efforts to devise and execute an alternative mechanism compliant with applicable Laws and any requirements of the MHRA to allow Product to be delivered to patients in the Territory as soon as reasonably practicable (excluding supply on a specials/unlicensed basis unless otherwise agreed by the Parties).

4.5 In addition to using CRE to seek a Marketing Approval for the Product, Supplier 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 authorisations required under applicable Law for the development, manufacture, testing, packaging, labelling, storage and transport of the Product through to Delivery.

4.6 If the Marketing Approval is to be amended or varied by Supplier (including for any change to manufacturer or manufacturing of the Product), Supplier shall notify the Authority such amendment or variation as soon as practicable and in any event, and no later than the date Supplier submits such amendment or variations to the MHRA. Supplier shall provide the Authority with such information regarding such amendments and/or variation as the Authority may request, so as to allow the Authority to comply with its own due diligence obligations.

4.7 Where Supplier knows or believes there to be any delay or other problem with the grant of the Marketing Approval, or its renewal, it shall promptly and in any event within seven (7) days of such knowledge or belief inform the Authority in writing.

4.8 If the Marketing Approval is:

4.8.1 revoked by the MHRA;

4.8.2 suspended by the MHRA for a period in excess of one (1) month; or

4.8.3 not renewed by the MHRA following its expiry for a period in excess of one (1) month; and

in each case (as set out in Clauses 4.8.1 to 4.8.3) for reasons of safety or efficacy of the Product or deficiencies in any application made by Supplier to the MHRA, then the Authority shall be entitled to terminate this Agreement by giving fourteen (14) days' written notice to Supplier.

4.9 Supplier shall:

4.9.1 reply promptly to all reasonable enquiries by the Authority relating to (i) the use, effective administration, quality, performance and durability of the Product;

4.9.2 ensure that the Authority is kept aware at all times of all data or information obtained by Supplier whether in clinical trials or otherwise or any other matters in each case relating to the safety and/or efficacy of the Product including the balance of risk and benefits of using the Product. Supplier will cooperate with the Authority and the MHRA in investigating such data, information or other matters and shall keep the Authority up to date as to the outcome of such investigations;

4.9.3 promptly and in any event within seven (7) Business Days of becoming aware of the same inform the Authority and provide full details of any claim brought by any third party in relation to the Product; and

4.9.4 Without prejudice to section 4.9.2, should Supplier become aware of an actual or suspected adverse reaction to the Product which is not described in the Summary of Product Characteristics, promptly inform the Authority in writing and in any event within seven (7) Business Days of becoming aware of the same.

4.10 Supplier shall notify the Authority promptly and in any event within two (2) Business Days of any engagement or consultation with the MHRA arising out of, or in connection with, any concerns relating to the safety or efficacy of the Product in the Therapeutic Indication.

4.11 Following any engagement or consultation with the MHRA, Supplier shall provide the Authority with a copy of any report or other communication published or provided by the MHRA in relation to the Product.

4.12 Upon receipt of notice pursuant to section 4.10 or any report or communication pursuant to section 4.11, the Authority shall be entitled to request further information from Supplier and/or a meeting with Supplier, and Supplier shall comply with any such request.

4.13 Supplier acknowledges and agrees that the Authority may delegate any of its responsibilities under this Agreement to one or more authorised agents to act on its behalf ("**Authorised Agents**"), 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, provided in each case that such delegation is in accordance with and subject to sections 16.3 and 16.4. Supplier shall work and co-operate reasonably with each Authorised Agent notified to it by the Authority in connection with this Agreement.

4.14 Nothing in this Agreement shall amount to an exclusive purchasing obligation on the Authority or preclude or restrict the Authority 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.

4.15 The Parties, via the Working Committee, shall negotiate and agree a quality agreement (the "**Quality Agreement**") to be entered into prior to the Delivery of any Units of Product by Supplier to the Authority.

5. **TERM AND TERMINATION**

5.1 This Agreement shall become effective and binding on the Parties upon the Effective Date and shall remain valid unless and until it expires or is terminated in accordance with this section 5 (the "**Term**").

5.2 This Agreement shall expire upon payment in full of the total price for and Distribution of, the Firm Quantity (or the Adjusted Firm Quantity, as applicable).

5.3 Either Party may terminate this Agreement in the following circumstances:-

5.3.1 if the other Party commits a material breach of its obligations under this Agreement and has not remedied such breach within [redacted] from receipt of written notice from the other Party reasonably describing the breach and requiring remedy of such breach;

5.3.2 if the Marketing Approval is not granted within 2 months after the Expected Approval Date:

5.3.3 the MHRA notifies Supplier that the Product will not secure a Marketing Approval;

5.3.4 in an Event of Force Majeure in accordance with section 9; or

5.3.5 if Delivery of the whole of the Firm Quantity (or the Adjusted Firm Quantity, as applicable) has not been achieved by [redacted] after the date on which the Units of Product of the Firm Quantity (or the Adjusted Firm Quantity, as applicable) 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 for Delivery**").

5.4 The Authority may terminate this Agreement upon written notice to Supplier in the following circumstances:

5.4.1 pursuant to and in accordance with section 4.8;

5.4.2 if Supplier purports to assign, sub-contract, novate, create a trust in or otherwise transfer or dispose of this Agreement other than as permitted under this Agreement, including as permitted under section 16;

5.4.3 where the Agreement has been substantially amended to the extent that the Public Contracts Regulations 2015 require a new procurement procedure;

5.4.4 where the Authority has become aware that Supplier 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, provided that Supplier has first exhausted its self-cleaning rights with the Authority provided for under Regulations 57(13) and 57(14);

5.4.5 where there has been a failure by Supplier 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 with legal obligations in the fields of environmental, social or labour Law is a failure by a party other than Supplier, as an alternative to the Authority terminating this Agreement under this section 5.4.5 the Authority may request the replacement of such party and Supplier shall use Commercially Reasonable Efforts to comply with such request;

5.4.6 if the Supplier or its staff (or anyone acting on its or their behalf) has breached any of the representations and warranties in section 11; or

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

5.5 If, by the Longstop Date for Distribution there remains any Units of Product at the Delivery Address, Supplier shall arrange for the transfer of such remaining Units of Product to a single location in Great Britain as notified to Supplier by the Authority. The Parties hereby agree that transfer of any remaining Units of Product under this section 5.5 shall be deemed to be a Distribution of such remaining Units of Product and carried out in accordance with section 3.3.

6. WARRANTY; INDEMNITY; LIMITATION OF LIABILITY

6.1 Supplier warrants, represents and undertakes to the Authority that:

6.1.1 at the time of Delivery, Product shall have been manufactured, labelled, handled, stored, and packaged in accordance with:-

(a) the relevant Marketing Approval, subject to section 3.17 in respect of the labelling and packaging of such Product, provided that, where applicable. such labelling and packaging shall be in accordance with the applicable MHRA Alternative Labelling Of Packaging Approval;

(b) applicable Laws, including Good Manufacturing Practice (GMP) in effect at the time of manufacture (including record and sample keeping, deviation reporting, testing and quality requirements) and Good Distribution Practices (GDP) in effect at the time of distribution, to the extent that each standard of GMP or GDP is or can be applicable, and taking into account any waiver, forbearance or exemption granted or allowed by the Authority or any other applicable regulatory authority in the Territory;

(c) all other Regulatory Licenses applicable to the Product in the Territory;

(d) the specifications set forth in the approved Product monograph and Appendix 1; and

(e) 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;

6.1.2 following grant of a Marketing Approval, all Product, prior to Distribution (or, in the case of Product for Northern Ireland which is not under a 174A Approval and therefore will be Delivered in Northern Ireland, Delivery), shall be finally quality released for supply by an entity established in the Territory (or, in the case of Product for Northern Ireland which is not under a 174A Approval and therefore will be Delivered in Northern Ireland, an entity established in the EU);

6.1.3 as at the Effective Date it has the right and authority to enter into this Agreement, to carry out its obligations under this Agreement either directly or by engaging its affiliates or sub-contractors and to grant the rights and benefits granted by it to the Authority under this Agreement and by doing so does not infringe any agreement with any third party;

6.1.4 to Supplier's knowledge, as at the Effective Date there are no pending or threatened actions or proceedings against Supplier and to Supplier's knowledge, its third party licensor of applicable technology relating to the Product, before any court or administrative agency which would materially adversely affect the financial condition, business or operations of Supplier in a way that would prevent Supplier from performing its obligations under this Agreement;

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

6.1.6 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 Supplier before such execution;

6.1.7 it shall:-

(a) comply with all applicable Law and guidance to ensure that there is no slavery or human trafficking in its supply chains; and

(b) notify the Authority immediately if it becomes aware of any actual or suspected incidents of slavery or human trafficking in its supply chains;

6.1.8 it shall at all times conduct its business in a manner that is consistent with any anti-slavery policy of the Authority that is publicly available or notified to Supplier (provided in each case, such policy is generally applicable to other third parties supplying pharmaceutical products to the Authority);

6.1.9 throughout the Term, it shall maintain, review, update and implement a reasonable risk management programme for the manufacture and Delivery of the Product,

including a business continuity plan for the manufacture and Delivery of the Product. The Supplier shall review and update its business continuity plan from time to time as reasonably appropriate and necessary.

6.2 Except as expressly provided in this Agreement, the Supplier does not, nor any of its affiliates, make or will make any representation or warranty of any kind, express or implied, relating to supply of the Product, including any implied warranty of merchantability or fitness for a particular purpose. Any warranties, representations, conditions or other terms that may be implied by statute or law, whether in relation to preparedness to supply, supply, delivery, quality, efficacy or safety of, or any other matter relating to, the Product are, to the fullest extent permitted by law, excluded from this Agreement.

6.3 The Authority warrants and represents that it is legally entitled and has the full power to enter into this Agreement, to carry out its obligations under this Agreement and to grant the rights and benefits granted by it to Supplier under this Agreement and by doing so does not infringe any agreement with any third party.

6.4 Save as expressly provided to the contrary in this Agreement, nothing in this Agreement shall effect or alter the liability of the Authority or the Supplier to third parties for product liability under applicable Laws.

[redacted]

6.6 The Authority shall promptly inform the Supplier of any third party claim brought against an Authority Affiliate that is subject to indemnification pursuant to section 6.5 (an "**Authority Third Party Claim**"), stating the nature and basis of the claim in question. Supplier and/or its affiliates ("**Supplier Indemnifying Party**") shall have the option, but not the obligation, exercisable within 20 days of first notice by the Authority of an Authority Third Party Claim to undertake (at its sole cost) the conduct of defence of such Authority Third Party Claim. If a Supplier Indemnifying Party does not elect to have conduct, the Authority shall, on reasonable notice and at its cost, have the right to assume and control the defence against the Authority Third Party Claims, using legal counsel reasonably chosen by the Authority, provided the Authority shall (i) use commercially reasonable efforts to defend itself and any Authority Affiliate against such Authority Third Party Claim and mitigate the liability incurred; and (ii) keep the Supplier informed of any developments relating to such Authority Third Party Claim. Notwithstanding the foregoing, the Authority may not settle or compromise any claim or make any admission of liability on behalf of the Supplier without its prior written consent, not to be unreasonably withheld.

6.7 The Parties acknowledge that GSK's civil liability in respect of Units of Product that are Delivered under 174A Approval will be determined in accordance with Regulations 174A and 345 of the Human Medicines Regulations 2012.

6.8 Save as in respect of the indemnification obligations under section 6.5, and subject to section 6.9, neither Party shall be liable to the other Party for any indirect or consequential losses or damages.

6.9 Nothing in this Agreement shall exclude or limit a Party's liability to any third party or each other to the extent it would be illegal or invalid in any way for that Party to exclude or attempt to exclude or limit its liability under applicable Laws, including for death or personal injury caused by a Party's negligence.

7. 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 Supplier shall not, during the Term, assert or use any intellectual property rights pertaining to the Product to interfere in the Authority's use or disposal of the Product for the purpose set out in and otherwise in accordance with this Agreement.

8. CONFIDENTIALITY

8.1 "**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:-

8.1.1 is non-public and confidential, privileged or proprietary in nature;

8.1.2 may have actual or potential economic, commercial, scientific, regulatory or other value, in part, from not being publicly known;

8.1.3 is in any form (i.e. fixed, stored, expressed or embodied);

8.1.4 is disclosed in writing, orally, or otherwise;

8.1.5 is treated as confidential, but not required to be marked or identified as confidential at the time of disclosure; and

8.1.6 is owned or controlled by Supplier, the Authority or a third party,

for clarity, "**Confidential Information**" includes this Agreement, the Product price, and any discussions and correspondence relating thereto which shall be deemed Confidential Information of each Party.

8.2 Subject to the remaining provisions of this section 8, or unless otherwise agreed to in writing by the other Party, each Party agrees that with respect to the other Party's Confidential Information it shall not, during and for [redacted] years after the Term of this Agreement, (i) use the other Party's Confidential Information except for the purposes contemplated by or authorised by this Agreement; (ii) disclose or transfer the other Party's Confidential Information to any third parties without the express written permission of the other Party. Notwithstanding the foregoing, a Party is authorised to disclose Confidential Information of the other Party to such disclosing Party's directors, officers, employees, agents or representatives and those of their affiliates (which in the case of the Authority includes the Authority Affiliates as defined

below) 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 shall comply with the confidentiality provisions of this Agreement. Notwithstanding the foregoing, each Party agrees to be responsible for any breach of this section by any of its Advisors. "**Authority Affiliates**" means the Crown (including, but not limited to, government ministers, government departments, government and particular bodies, and government agencies), and all central government bodies (being those listed in one of the following sub-categories of the United Kingdom's Central Government classification of the Public Sector Classification Guide, as published and amended from time to time by the Office for National Statistics: Government Department; Non-Departmental Public Body; Assembly; Sponsored Public Body (advisory, executive, or tribunal); Non-Ministerial Department; or Executive Agency, "**Central Government Bodies**").

8.3 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:

8.3.1 the receiving Party can demonstrate by written records was lawfully known to the receiving Party before the date of disclosure hereunder free of any restriction as to its use and disclosure;

8.3.2 is now, or becomes in the future, publicly available other than by breach of this section 8 by the receiving Party or its Advisors;

8.3.3 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 information in confidence;

8.3.4 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 the Authority, includes the Authority Affiliates) without reference to the other Party's Confidential Information (as can be demonstrated by that Party's written records);

8.3.5 receiving Party is required by any Law, by applicable stock exchange regulation, or legal process or government policy, or for the purposes of enforcement of its rights under this Agreement to disclose, in which event receiving Party may so disclose such Confidential Information, provided that the receiving Party shall, where lawful and reasonably possible, (a) 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; (b) exercise commercially reasonable efforts to narrow the scope of any such requirement; and (c) if such protective order or other remedy is not obtained, furnish only that portion of the Confidential Information which the receiving Party (or its Advisors) is compelled to disclose and exercise commercially reasonable efforts to obtain assurance that confidential treatment will be accorded to such Confidential Information. In addition to the foregoing, Supplier agrees that the obligations of confidentiality herein shall not apply to the extent Confidential Information of Supplier 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 the Authority and Authority Affiliates with 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 the Authority and Authority Affiliates have provided advance notice of the impending disclosure to Supplier 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.

8.4 The Parties agree that the Authority (or any other agency or office of the Government of the United Kingdom) and the Supplier (or any affiliate) may issue a press release or public announcement relating to signing of this Agreement, the subject matter hereof and the transactions contemplated hereby. In respect of any press release and/or public announcement contemplated by this section 8.4, the Parties will exchange and agree in good faith draft press releases prior to publication and also agree the date and time of any press releases and/or public announcements.

8.5 Notwithstanding section 8.1 or 8.4, Supplier hereby gives consent for the Authority to publish this Agreement (but with any information which is exempt from disclosure in accordance with the provisions of the FOIA or the Environmental Regulations, and, to the extent possible under applicable Laws, such commercially sensitive information as Supplier may reasonably request, being redacted), including from time to time agreed changes to this Agreement, to the general public. Within 90 days following the Effective Date and prior to such publication, the Authority and Supplier shall consult and agree, in good faith, as to the form of a redacted version of this Agreement.

8.6 Subject to the obligations in respect of disclosure to Advisors set forth in section 8.2, the Authority will be permitted to disclose Confidential Information of Supplier that is necessary to disclose under applicable Law, and under compliance with the privacy, confidentiality and proactive disclosure policy regimes of the Government of the Authority and solely for the purposes of government administration and operations provided that it informs Supplier of the intended disclosure and the extent and nature of the intended disclosure. For greater clarity, this may include:

8.6.1 where the need for such disclosure arises out of or in connection with a legal challenge or potential legal challenge against the Authority arising out of or in connection with this Agreement;

8.6.2 to any relevant party who need to know such information solely for the purposes of the examination and certification of the Authority's accounts or for any examination pursuant to section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Authority is making use of any services provided under this Agreement;

8.6.3 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;

8.6.4 the Authority has reasonable grounds to believe that Supplier 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;

8.6.5 on a confidential basis to any Central Government Body for any Proper Purpose of the Authority or of the relevant Central Government Body. "**Proper Purpose**" means the fulfilment of any function of a Central Government Body acting reasonably and lawfully;

8.6.6 to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirement; and

8.6.7 to a proposed successor body in connection with any proposed or actual, assignment, novation or other disposal of rights, obligations, liabilities or property in connection with this Agreement.

8.7 Where the Authority or an Authority Affiliate is managing a request under FOIA, Codes of Practice or Environmental Regulations in relation to this Agreement, Supplier shall co-operate with the Authority or Authority Affiliate and shall respond within seven Business Days of any request for assistance in determining how to respond to such request for disclosure. Supplier shall provide all necessary assistance as reasonably requested by the Authority or Authority Affiliate to enable the Authority or Authority Affiliate to respond to such request for information within the relevant statutory time limit for compliance.

8.8 The Authority and Authority Affiliates shall consult with Supplier 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 the Authority and Authority Affiliates. The Authority and Authority 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.

8.9 Where Supplier receives any request for information, as defined under section 8 of the FOIA or the Environmental Regulations, relating to this Agreement, Supplier shall transfer such request to the Authority as soon as practicable after receipt and in any event within seven Business Days of receipt. Supplier shall not respond directly to a request for information addressed to the Authority unless authorised in writing to do so by the Authority.

9. FORCE MAJEURE

9.1 Supplier shall not be responsible or liable hereunder for any failure or delay to perform any of its obligations under this Agreement if such failure or delay results from events or circumstances beyond its reasonable control including but not limited to the following (each hereinafter referred to as an "**Event of Force Majeure**"): 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, any constraint order or requisition or embargo on the Products by a jurisdiction, or restrictions by a jurisdiction on the

export of the Product or components thereof. In the event of an Event of Force Majeure, Supplier shall:-

9.1.1 use Commercially Reasonable Efforts to overcome the cause contributing to the delay and to minimize the delay; and

9.1.2 advise the Authority of the occurrence of the delay or of the likelihood of a delay occurring as soon as Supplier 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 Event of Force Majeure. The Parties shall amend this Agreement, as appropriate, to reflect any such change in dates. Either Party may, after an Event of Force Majeure has continued for 90 days or more, terminate the Agreement.

10. GOVERNANCE AND OVERSIGHT

10.1 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 Appendix 5. 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. Each Party shall endeavour to achieve 90% attendance at Working Committee meetings with their respective lead or deputy present, and to ensure that no member shall miss more than two consecutive meetings.

10.2 The Parties shall co-operate fully, candidly and transparently through the Working Committee in connection with the matters requiring consultation in Appendix 5, and other matters relating to the Agreement. The Working Committee shall in particular:-

10.2.1 agree a plan for supply of Product in accordance with the requirements of this Agreement,

10.2.2 discuss Supplier's strategy and regulatory pathway to achieve Marketing Approval by the Expected Approval Date and if Marketing Approval is not achieved by the Expected Approval date agree an alternative strategy for use of the Product earmarked to be made available to patients in the Territory (provided that Supplier shall have sole discretion and final decision making authority in respect of any decisions with regard to the regulatory pathway for the Product);

10.2.3 report on, discuss, consult on and raise any concerns regarding the Parties' performance under the Agreement including Supplier's progress towards and achievement of those matters identified in Part 3 of Appendix 5;

10.2.4 discuss and facilitate implementation of Distribution of the Product in accordance with the terms of this Agreement including in relation to the procedures in place or to be put in place with relevant NHS hospitals and bona fide distribution hubs relating to supply chain management and a plan for how, subject to section 3.5 Non Standard Distribution and associated costs for Non Standard Distribution shall be managed, and discuss the allocation of Units of Products between Great Britain and Northern Ireland (including discussing the possibility of, prior to Delivery, Supplier reallocating Product that has been allocated for Northern Ireland or Great Britain for Delivery for

the other, respectively, provided that Supplier shall not be obliged to agree to any such reallocation);

10.2.5 report on, discuss, consult on and raise any concerns regarding disclosure of Supplier's Confidential Information as contemplated by section 8, provided the Authority shall not disclose Supplier's Confidential Information other than as and to the extent permitted under section 8; and

10.2.6 review, measure performance against and discuss possibilities to update the Delivery Schedule.

10.3 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.

10.4 The first meeting of the Working Committee shall occur as soon as reasonably possible following the Effective Date, but no later than within 15 Business Days after the Effective Date. Thereafter, the Working Committee shall meet at least every two weeks 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.

10.5 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.

10.6 Supplier shall keep the Authority 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.

10.7 The Authority and Supplier 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.

10.8 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 Supplier shall promptly give the Authority notice of such discontinuation, suspension or withdrawal through the Working Committee. If an Authority License is suspended, withdrawn or discontinued then the Authority shall promptly give Supplier notice of such discontinuation, suspension or withdrawal through the Working Committee.

10.9 Notwithstanding its reporting obligations through the Working Committee, Supplier shall keep the Authority promptly, and in any event within five days of becoming aware of the same,

informed of all material events relating to the development, manufacture and supply of the Product with respect to those items in Appendix 5 Part 2.

10.10 The Authority shall have a right of consultation in respect of the matters set out in Part 2 of Appendix 5 . Before Supplier takes or implements any decisions in respect of those matters set out in Part 2 of Appendix 5, Supplier shall provide the Authority with a reasonable opportunity to consult on and provide comments on Supplier's proposed decision. Supplier shall use CRE to consider any reasonable requests and comments of the Authority in respect of such matters.

10.11 In order to facilitate the Parties' respective obligations under this Clause 10 each Party will use reasonable efforts to reply promptly to communications from the other.

11. ANTI-BRIBERY

Supplier 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 performance of this Agreement (together with Supplier, the "**Supplier Representatives**") that:-

11.1 it and the Supplier 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**"):-

11.1.1 offered, given or agreed to give any officer or employee of the Authority, the Crown or Authority 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 favour or disfavour to any person in relation to this Agreement; or

11.1.2 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 the Authority; and

11.2 Supplier 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

11.3 Supplier and its affiliates have not knowingly taken and shall not take any action that will, or would reasonably be expected to, cause the Authority or Authority Affiliates to be in violation of any such Laws under 11.1 and 11.2.

12. DATA PROTECTION

12.1 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**").

12.2 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 the Authority, related to the use of Product or by the Authority 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.

12.3 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.

13. **RIGHT OF AUDIT**

13.1 Each Party shall keep secure and maintain for the Term of this Agreement and six years thereafter, or such longer period as may be agreed between the Parties or as may be required by applicable Law, full and accurate records of all matters relating to this Agreement. In the case of Supplier, Supplier shall procure that all records relating to the manufacture, testing, packaging, transport and release of the Product supplied under this Agreement ("**Product Records**") shall be retained for no less than five years following Delivery of the Product or such longer period as may be required by applicable Laws.

13.2 Supplier shall grant to the Authority or its Authorised Agents, at reasonable times and upon reasonable notice to Supplier and at Authority's cost:

13.2.1 access [redacted], provided such access shall be granted no more than once a quarter (unless a review during such quarterly period reveals non-compliance with respect to such period), and

13.2.2 such access to those records as they may reasonably require 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 the Authority has used its resources.

13.3 The Comptroller and Auditor General may examine such documents as they may reasonably require which are owned, held or otherwise within the control of Supplier and may require Supplier 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 Supplier under section 6(3)(d) and 6(5) of the National Audit Act 1983.

13.4 The Supplier shall provide reasonable cooperation to the Authority, its representatives and any regulatory body in relation to any audit, review, investigation or enquiry carried out in relation to the subject matter of this Agreement.

13.5 The Supplier shall provide all reasonable information as may be reasonably requested by the Authority to evidence the Supplier's compliance with the requirements of this Agreement.

13.6 Supplier shall take 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 its staff and by the Supplier in connection with the receipt of monies from the Authority. Supplier shall notify the Authority immediately if it has reason to suspect that any such fraudulent acts have occurred or is occurring or is reasonably likely to occur.

14. **TAX NON-COMPLIANCE**

14.1 If, at any point during the Term of this Agreement, any of the following occurs:-

14.1.1 any tax return of Supplier 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 Supplier 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 Supplier 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

14.1.2 any tax return of Supplier 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 Supplier shall notify the Authority in writing of such fact within 20 Business Days of its occurrence.

15. **COMPLIANCE WITH LAW**

15.1 During the Term, Supplier 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, labour

and employment legislation and environmental and safety legislation, in each case in relation to the development, manufacture and Delivery of Product.

15.2 Supplier shall notify the Authority promptly if it becomes aware of:-

15.2.1 any actual material failure to comply with section 15.1; or

15.2.2 any investigation of or proceedings against Supplier under human rights legislation, equality and non-discrimination legislation, labour 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.

16. ASSIGNMENT & SUBCONTRACTING

16.1 The Authority may at any time transfer, assign, novate, sub-contract or otherwise dispose of its rights and obligations under this Agreement or any part of this Agreement (a) to another Contracting Authority and the Supplier warrants that it will, at the Authority's request and cost, carry out such reasonable further acts required to effect such transfer, assignment, novation, sub-contracting or disposal; or (b) to any other body that is not a Contracting Authority with the prior written consent of the Supplier, such consent not to be unreasonably withheld or delayed by the Supplier. For the purpose of this Agreement, "**Contracting Authority**" means any contracting authority as defined in regulation 3 of the Public Contracts Regulations 2015 (SI 2015/102) (as amended), other than the Authority.

16.2 Other than with the written consent of the Authority (such consent to be at the Authority's discretion), Supplier 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. Supplier may, subject to section 5.4.5, sub-contract some or all of its:

(a) pre-Delivery activities, including in respect of transport, logistics and manufacturing; and
(b) Distribution (including transportation and storage after Delivery) requirements under this Agreement to Approved Sub-contractors,

in each case (a) and (b) without the written consent of the Authority.

16.3 Without prejudice to section 16.1, 16.2 and 16.4, but subject to the final sentence of section 16.4, 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.

16.4 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) in accordance with the last sentence of section 16.2 (in the case of Supplier) or (ii) to an Authorised Agent or person responsible for administering or having administered Product including all health service bodies (in the case of the Authority), 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; provided that for the purpose of sections 16.3 and 16.4 only, Distribution

(or Non Standard Distribution, as applicable) is not an obligation of Supplier and, without prejudice to sections 3.4 to 3.7, Supplier shall not be responsible for any act or omission of its third party logistics provider that undertakes such Distribution (or Non Standard Distribution, as applicable) pursuant to sections 16.3 or 16.4.

17. SUPPLIER CODE OF CONDUCT

Supplier shall, in so far as is relevant to the supply of the Product under this Agreement and except where agreed otherwise between the Parties, comply with the Supplier Code of Conduct (initially published on behalf of the Authority 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. In the event of any conflict between the terms of this Agreement and the Supplier Code of Conduct, the terms of this Agreement shall prevail.

18. GENERAL

18.1 Governing Law

This Agreement (including the annexes) shall be governed by and construed in accordance with English law, provided that any treaty, including the UN Convention on Contracts for the International Sale of Goods, shall hereby be expressly excluded.

18.2 Disputes and Arbitration

18.2.1 All contractual or non-contractual disputes, controversies or claims arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination ("**Dispute**") shall first be referred to informal dispute resolution discussions between representatives of the Authority and the Supplier, by the Authority sending to the Supplier, or the Supplier sending to the Authority, a written notice of the Dispute, and, within ten (10) days of such notice, the representatives shall meet and attempt to resolve the Dispute by good faith negotiations. In the event such Dispute cannot be resolved within such ten (10) day period, such Dispute shall be submitted to the International Court of Arbitration of the International Chamber of Commerce and shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce in effect at the time of the arbitration, except as they may be modified herein or by mutual agreement of the Parties by one or more arbitrators appointed in accordance with the said Rules.

18.2.2 The seat of the arbitration shall be London, England. The governing law of the arbitration agreement shall be English law. The language of the arbitration shall be English. The party commencing arbitration (the claimant) shall send to the other party (the respondent) a notice of arbitration demanding that the dispute be referred to arbitration. The arbitral tribunal shall consist of three arbitrators, one appointed by the claimant and named in the notice of arbitration, the second appointed by the respondent within fourteen (14) days of receipt of the notice of arbitration, and the third, who shall act as presiding arbitrator, appointed by the two parties within fourteen (14) days of the appointment of the second arbitrator. If any arbitrators are

not appointed within these periods, the International Chamber of Commerce shall, upon the request of any party, make the appointment in accordance with its Rules. The arbitration award shall be final and binding, and judgment upon the award may be entered by any court having jurisdiction thereof or having jurisdiction over the relevant Party and its assets.

18.2.3 The above is expressly without prejudice to, and shall not be construed as a waiver of, the right of any Party to seek injunctive or similar interim relief in any court of competent jurisdiction.

18.2.4 The Parties agree that the arbitration shall be kept confidential and that the existence of and any aspect of the proceeding shall not be disclosed beyond the tribunal, ICC International Court of Arbitration, the Parties and their affiliates, their counsel, insurers and re-insurers, accountants and auditors, and any person necessary to the conduct of the proceeding. The confidentiality obligations shall not apply if (i) disclosure is required by Law or (ii) to the extent necessary to enforce the rights arising out of the award.

18.3 **Interpretation**

Except where the context expressly requires otherwise:

18.3.1 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);

18.3.2 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;

18.3.3 the word "shall" will be construed to have the same meaning and effect as the word "will";

18.3.4 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);

18.3.5 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;

18.3.6 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;

18.3.7 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;

18.3.8 the word "notice" means notice in writing (whether or not specifically stated);

18.3.9 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);

18.3.10 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;

18.3.11 the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or";

18.3.12 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;

18.3.13 any reference to a Party or the Parties shall include legal successors and/or any permitted assignees of a Party;

18.3.14 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;

18.3.15 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;

18.3.16 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;

18.3.17 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 Supplier the term "affiliate" shall not include Supplier; and

18.3.18 reference to "**Laws**" means (a) 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 to the extent relevant to those activities when conducted for or pursuant to this Agreement (or, but solely where the context requires, any other relevant geographical area) and (b) the common law and laws of equity as applicable from time to time.

18.4 **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.

18.5 **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.

18.6 **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.

18.7 **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.

18.8 **Entire Agreement**

This Agreement constitutes the entire agreement between the Authority and Supplier 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; provided that an amendment to Appendix 4 may be made by a representative of each Party on the Working Committee initialling the updated Delivery Schedule. Any term or condition of any purchase order issued by the Authority which conflicts

with, modifies or imposes obligations on Supplier in addition to those contained in, this Agreement shall be null and void.

18.9 **Surviving Provisions**

18.9.1 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 sections 6.2, 6.5-6.9 (Warranty; *Indemnity; Limitation of Liability*), section 8 (*Confidentiality*), section 12 (*Data Privacy*), section 13.1 to 13.3 (*Audits*), section 16 (*Assignment*), this section 18 (*General*), and Appendix 2 sections 5 and 6 (*Defects*).

18.9.2 The termination or expiry of this Agreement for whatever reason shall be without prejudice to any rights or obligations of the respective Parties which accrued prior to such termination or expiry.

18.9.3 Upon expiry or earlier termination of this Agreement, the Authority agrees to pay the Supplier for the Product which has been Delivered in accordance with this Agreement prior to expiry or earlier termination of this Agreement. For clarity, nothing in this Agreement shall require the Supplier to deliver any further Product after termination or expiration of this Agreement.

18.10 **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.

18.11 **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.

18.12 **Currency**

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

18.13 **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.

18.14 **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 Appendix 2. Any notice delivered after 5pm GMT shall be deemed not to be received until 9am on the next Business Day.

18.15 **Language**

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

18.16 **Annexes**

The annexes to this Agreement are an integral part thereof.

18.17 **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. No counterpart shall be effective until each Party has executed and delivered at least one counterpart.

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

Title: [redacted]

Date: 23/07/2021

The Secretary of State for Health and Social Care

By: _____

Name:

Title:

Date:

APPENDIX 1

PRODUCT REQUIREMENTS

1. **SCOPE**

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

2. **FORMAT AND SHELF LIFE**

2.1 Format: vial

2.2 Dosage forms (Label Claims): As per the Marketing Approval

2.3 Packaging configuration: As per the Marketing Approval or any MHRA Alternative Labelling Of Packaging Approval.

2.4 Labelling: As per the Marketing Approval or any MHRA Alternative Labelling Of Packaging Approval.

At the time of Product being Delivered, the minimum remaining shelf life of Product shall be no less than the Minimum Shelf Life. All Products must be labelled with an expiry date.

** Note that final format, volume, vial size and other Product details are yet to be finalized, pending final production decisions and ongoing dose studies.*

3. **FIRM QUANTITY**

Item Description	**Firm Quantity**	**Completion Date (Expected Date for all Firm Quantity to be Delivered)**
Single dose (collectively, a "**Unit**")	100,008 Units	Longstop Date for Delivery: [redacted] Longstop Date for Distribution: [redacted]

3.1 **Commercially Reasonable Efforts to Deliver / Inability to Deliver**

The Authority acknowledges that, as of the Effective Date of this Agreement, Supplier has not obtained a Marketing Approval to market the Product in UK. Supplier's obligation to supply the Firm Quantity, or any portion thereof, shall be contingent upon Supplier (or as applicable, any Approved Affiliate) obtaining Marketing Approval for the Product.

4. **MAINTENANCE OF THE COLD CHAIN DURING TRANSPORTATION AND STORAGE**

Throughout the shipping process, Supplier 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. The Authority and Supplier 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.

APPENDIX 2

BASIS OF PAYMENT AND OTHER TRADE TERMS

1. **ORDERING AND PRICING INFORMATION**

1.1 The Authority must submit to Supplier a purchase order for Product prior to the requested actual date of Delivery, which purchase order shall be subject to the terms and conditions of this Agreement.

1.2 All prices are firm Unit prices, in British Pounds, excluding VAT for [redacted] and are inclusive of Distribution (but not the costs associated with Non Standard Distribution). Each firm Unit price is applicable for all destinations in the Territory other than destinations for Non Standard Distribution. No other payments (other than VAT and agreed Non Standard Distribution costs) beyond the price are payable for the supply, and Delivery of Product or Supplier's performance hereunder.

[redacted]

2. **PRODUCT UNIT PRICE**

Product Name	**Definition of One Unit**	**Firm Quantity**	**Firm price per Unit**
Sotrovimab (VIR-7831)	Single dose vial containing 500 mg of Sotrovimab (VIR-7831) in 8 mL (62.5 mg/mL).	100,008 Units (the "**Firm Quantity**")	GBP [redacted]

3. **INVOICING INSTRUCTIONS AND NOTICES**

3.1 Supplier must submit VAT invoices to the Authority upon Delivery of Product.

3.2 Supplier must submit VAT invoices (in accordance with paragraph 4 below) for certification and payment, and other notices under this Agreement, to the Authority at:

Secretary of State for Health and Social Care,
39 Victoria Street
London
SW1H 0EU
United Kingdom
Attn: Director General of the Therapeutics Task Force

With a copy to:
Secretary of State for Health and Social Care,
39 Victoria Street
London
SW1H 0EU
United Kingdom
Attn: Permanent Secretary, Department for Health and Social Care

Email: [redacted]

The Authority may submit notices under this Agreement to Supplier at:
Email [redacted] and [redacted]

4. **PAYMENT TERMS**

On Delivery Supplier will issue an invoice to the Authority 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 Supplier until it has received cleared funds. Supplier reserves the right at any time to require the Authority to make payment by direct debit to such bank account of Supplier as nominated by Supplier from time to time.

5. **ACCEPTANCE AND NON-CONFORMING PRODUCT**

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

5.2 With regard to Defective Product (i) damaged prior to Delivery that is notified to Supplier by the Authority within [redacted] of Delivery; or (ii) where Product is Distributed, that is notified within [redacted] of the Authority being made aware of the damage, the procedures and remedies in this section 5 shall apply.

5.3 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, then such [redacted] time limit, as the case may be, shall not apply, provided that the Authority notifies Supplier in writing of its subsequent detection or receipt of notice of the defect prior to expiration of the shelf life and within [redacted] of the time the Authority first becomes aware of a defect in the applicable Product. Any acknowledgement of receipt of Product by the Authority does not constitute an acceptance of Product as Defect-free.

5.4 In the event that the Authority considers that Product is Defective within the time periods set out above, the Authority may by written notice notify the Supplier of its intent to reject such shipment of the Product, or any part thereof (such notice, the "**Rejection Notice**"). The Authority shall describe to the Supplier the alleged Defect in the Rejection Notice and, if requested by the Supplier, promptly provide sample(s) of the alleged Defective Product.

5.5 Where it is agreed between the Parties after the conduct of further investigation (such further investigation to be completed within ten (10) Business Days of the Supplier's receipt of the Rejection Notice and sample(s) of the alleged Defective Product, unless otherwise agreed by

the Parties), that the Product is Defective Product, the Authority may reject such Defective Product and the Supplier shall:

5.5.1 at the Authority's written request collect such Defective Product at the Supplier's risk and expense within ten (10) Business Days of the Parties agreeing such Product is Defective Product; and

5.5.2 at Supplier's sole discretion, either (i) without extra charge, Deliver replacement Product for such Defective Product at the earliest commercially possible opportunity; or (ii) if previously paid, credit to the Authority an amount equal to the price per Unit of such Defective Product, such credit note to be raised within ten (10) Business Days of the Parties agreeing such Product is Defective Product, with, if applicable where the invoice has been paid by Authority, payment of such credit note being processed within thirty (30) Business Days of such credit note being raised. For the avoidance of doubt, under no circumstances shall Supplier be required to under this Agreement, to supply additional Units of the Product or replace Product that is Defective, lost or expired.

5.6 In the event that the Parties cannot agree whether or not the Product is Defective Product, the matter shall be determined by an independent laboratory, to be nominated by the Authority, subject to being agreed by the Supplier, within ten (10) Business Days of the Parties completing the further investigation described in paragraph 5.4 of this Appendix 2.

5.7 Notwithstanding paragraph 5.5.1 of this Appendix 2, if the Supplier request and the Authority accepts that the Defective Product should be disposed of by the Authority rather than returned to the Supplier, the Authority reserves the right to charge the Supplier for the reasonable and documented costs associated with the disposal of the Defective Product and the Supplier shall promptly pay any such costs within thirty (30) Business Days of the Supplier's receipt of an invoice for such costs.

5.8 Without prejudice to section 6.4 and paragraph 6, the liabilities under paragraphs 5 and 6 shall be the Authority's sole and exclusive remedy in respect of such Defective Product and any Requirement to Recall Product pursuant to paragraph 6. Without prejudice to the foregoing, Supplier shall be relieved of its liabilities under this paragraph 5 of Appendix 2 and shall have no liability to the Authority to the extent that the Defect was caused by any acts or omissions of the Authority or its directors, officers, employees, agents or representatives, or, subject to section 3.4 of this Agreement, that occurs after Delivery.

5.9 For the purpose of paragraph 5 of Appendix 2, "**Defective Product**" means Product that has not been Delivered in accordance with the specification of the Marketing Approval, GMP (in effect at the time of manufacture) or GDP (in effect at the time of Delivery). "**Defect**" shall have the corresponding meaning.

6. **RETURNS AND RECALLS**

6.1 All sales are final with no Product return.

6.2 Where there is a requirement under applicable Law, GMP or GDP to order a Product recall ("**Requirement to Recall**") in the Territory in respect of the Product, the Supplier shall be responsible for making any Product recall decisions in respect of such recall, and for initiating

and executing any such Product recall in accordance with applicable Law. Without limiting the generality of the foregoing, the Supplier shall:

6.2.1 promptly (taking into consideration the potential impact of the continued use of the Product on patients, service users and the Authority as well as compliance by the Supplier with applicable Law, including any regulatory requirements) notify the Authority in writing of the recall together with the circumstances giving rise to the recall;

6.2.2 from the date of the Requirement to Recall, where it is agreed between the Parties after the conduct of further investigation (to be completed within ten (10) Business Days of notifying the Authority pursuant to paragraph 6.2.1 of this Appendix 2), or determined in accordance with paragraph 5.4 and 5.6 of this Appendix 2 that the Requirement to Recall was caused by Defective Product as at the time of Delivery, treat the Product that is the subject of such recall as Defective Product in accordance with paragraph 5.4 of this Appendix 2, or, where arising in respect of Distribution section 3.4 of this Agreement shall apply;

6.2.3 consult with the Authority as to the most efficient method of executing the recall of the Product and use its Commercially Reasonable Efforts to minimise the impact on the Authority of the recall in accordance with the following:

(a) If the Requirement to Recall is due to noncompliance with GMP or GDP, or in respect of the manufacturing, storage (except to the extent such storage is by the Authority), Delivery or Distribution of the Product, the recall shall be carried out wholly at the cost of the Supplier;

(b) If the Requirement to Recall relates to any other issues other than those set out in (a), the recall shall be wholly at the cost of the Authority.

APPENDIX 3

DISTRIBUTION

Distribution sites: Those pharmacy departments within NHS hospitals within Great Britain, or in the case of Distribution to Northern Ireland, which shall apply only where such Product for Northern Ireland is supplied under a 174A Approval, the NHS central warehouse in Belfast, Northern Ireland. For the avoidance of doubt this shall not include any sites within:(i) the UK Crown Dependencies and Overseas Territories; or (ii) any other countries or territories which the Authority supplies Donated Product.

Distribution Timeline: Following Delivery (including, for the avoidance of doubt, Product release) of the relevant quantity of the Units of Product, Supplier will use CRE to procure delivery of [redacted] of receipt of an order for Distribution for pharmacy departments within NHS hospitals in Great Britain or except for pharmacy departments within NHS hospital in the UK postcode districts identified in the table below (being the "**Special Postcode Districts**"), for which Supplier will use CRE to procure delivery of Product [redacted] of receipt of an order for Distribution. :

Special Postcode Districts
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
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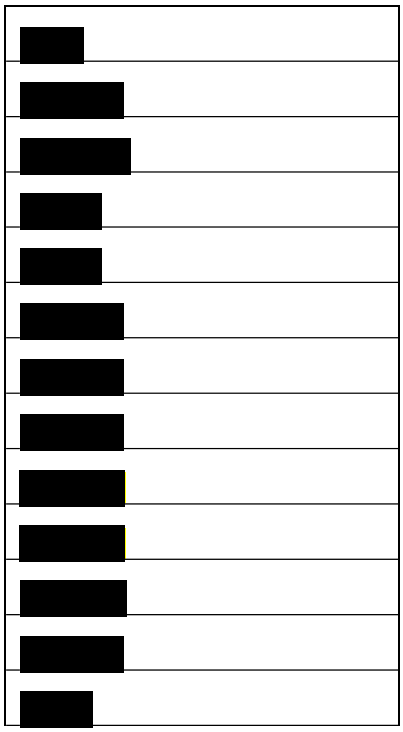

APPENDIX 4

DELIVERY SCHEDULE

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

The Parties acknowledge and agree that the Delivery Schedule as of the Effective Date is based on the Expected Approval Date and until Supplier obtains Marketing Approval for the Product, the Delivery timelines set out in this Delivery Schedule are indicative only. In the event that the Marketing Approval is not granted by the Expected Approval Date, or where MHRA Alternative Labelling Of Packaging Approval is required, the Parties shall, through the Working Committee, amend this Delivery Schedule to reflect changes in the timing of the grant of the Marketing Approval, or the timing for receiving MHRA Alternative Labelling Of Packaging Approval, where applicable.

APPENDIX 5

GOVERNANCE

PART 1

WORKING COMMITTEE PARTY REPRESENTATIVES

Supplier	Authority
[redacted]	[redacted]

PART 2

MATTERS REQUIRING CONSULTATION

1. Any proposed changes to the Delivery Schedule, including any actual or anticipated Delays in Delivery against, or updates to, the Delivery Schedule.

2. Any proposed material change to the application for the Marketing Approval.

3. Implications if it becomes apparent that a Marketing Approval is unlikely to be achieved by the Expected Approval Date.

4. Any proposed material changes to the Marketing Approval.

5. Any proposed reduction to the Minimum Shelf Life.

6. Any clinical trial results or findings that adversely impact the efficacy or safety of the Product.

7. Any issues or delays in the manufacturing progress that are reasonably expected to have an adverse impact on the Delivery of Product, including losing capacity at facilities or delays in supply of raw materials and equipment.

8. Any proposed changes to Distribution sites or Distribution timelines (Appendix 3).

9. The measures taken to ensure that appropriate amounts of Product are Distributed to pharmacy departments within NHS hospitals, and to ensure that appropriate amounts of Product are replenished, especially in pharmacy departments within NHS hospitals in Special Postcode Districts.

10. Any proposed changes to the facilities for the manufacture and packaging of the finished form Product pursuant to section 2.1.

11. The requirements and negotiations for the Quality Agreement.

PART 3

OTHER REPORTING OR REQUIREMENTS

In addition to the above, Supplier will report to the Working Committee on the following or use CRE to meet the following requirements:-

1. Number of Deliveries on time against the Delivery Schedule.

2. Data from temperature loggers, to be available 100% of the time prior to Delivery or whilst the Product is in the care and control of Supplier during Distribution.

3. No temperature deviations outside of specification range are recorded prior to Delivery.

4. Number of rejections less than 10% from total of each Delivery made.

APPENDIX 6

DOCUMENTATION

1. Pack list and quantity of Units;
2. Certificate of Analysis (and where relevant, Certificate of Origin);
3. Product description;
4. Batch details;
5. Expiry date;
6. Storage and transport temperature control records;
7. Storage and transport instructions;
8. Other information and notices required by the Marketing Approval and applicable Laws;
9. Quality personnel contact information; and
10. Certificate of Release.

APPENDIX 7

UK CROWN DEPENDENCIES AND OVERSEAS TERRITORIES

1. **THE OVERSEAS TERRITORIES**

1.1 Anguilla;

1.2 Ascension;

1.3 Bermuda;

1.4 British Antarctic Territory;

1.5 British Indian Ocean Territory;

1.6 British Virgin Islands;

1.7 Cayman Islands;

1.8 Falkland Islands;

1.9 Gibraltar;

1.10 Montserrat;

1.11 The Pitcairn Islands;

1.12 St Helena;

1.13 Tristan da Cunha;

1.14 South Georgia and the South Sandwich Islands;

1.15 Turks and Caicos Islands; and

1.16 UK Sovereign Base Areas of Akrotiri and Dhekelia.

2. **THE CROWN DEPENDENCIES**

2.1 Bailiwick of Jersey;

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

2.3 the Isle of Man.

APPENDIX 8

SUPPLIER APPROVED AFFILIATES AND APPROVED SUB-CONTRACTORS

Name	Service Provided
[redacted]	[redacted]
[redacted]	
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

APPENDIX 9

NORTHERN IRELAND DELIVERY REQUIREMENTS

- Labelling/Packaging: EU Single Triple Language Pack or otherwise in accordance with the 174A Approval.

- Delivery Ordering Requirements: Any orders for Product to be supplied to Northern Ireland must be specified as being for the Northern Ireland market in accordance with section 3.2 of the Agreement.

- Supplier will use CRE to procure delivery of Product within four Business Days of receipt of an order for Distribution for pharmacy departments within NHS hospitals in Northern Ireland.