BETWEEN

The Secretary of State for Health and Social Care

And

Ethypharm UK Limited

FOR THE STORAGE AND MANAGEMENT OF PRENOXAD INJECTION (TAKE HOME NALOXONE)

THIS AGREEMENT is made on 27th January.2022 BETWEEN:

(1) **The Secretary of State for Health and Social Care acting as part of the Crown through the Department of Health and Social Care of 39 Victoria Street, London SW1H 0EU ("Authority"); and**

(2) **Ethypharm UK Limited (company number 08565401) whose registered office is at Bampton Road, Harold Hill, Romford, Essex, RM3 BUG ("Supplier").**

BACKGROUND:

A. **The Authority owns 40,000 packs of Naloxone (Prenoxad) 1 mg/ml injection.**

B. **The Authority wishes to purchase storage, stock management and distribution services from the Supplier for the 40,000 packs of Naloxone (Prenoxad) 1 mg/ml injection which the Supplier will store as Stockpiled Product.**

C. **The Supplier will be responsible for rotating the stock into the Business as Usual stock so that it has a minimum agreed shelf life throughout the term of the Agreement. It is intended for the Product to be distributed for patients solely in the UK during an emergency in the UK and for this purpose the Stockpiled Product must be stored in the UK. In the event of an emergency in the UK, title to all the stock that is to be released will pass to the Supplier from the Authority and the Authority shall direct the Supplier to release such stock to cover the emergency demand through the normal process and UK supply chain. If a release occurs, the Authority will require the Supplier to build the Stockpile back to its initial levels within the agreed time at no cost to the Authority.**

D. **In the period leading up to expiry or termination of the Agreement or any earlier reduction in Required Volume the Supplier will be required, through an agreed exit plan, to buy back the stock.**

E. **Title to the stock (prior to any buy back or emergency) will remain with the Authority, but the Supplier must store the stock at its own risk and manage it, to include regular reporting and review meetings with the Authority.**

F. **The initial term of the Agreement is for eighteen (18) months with the Authority having the option (at its sole discretion) to extend the contract for a further period of up to twelve (12) months.**

IT IS AGREED as follows:

1 INTERPRETATION

1.1 In the Agreement unless the context otherwise requires the following words and expressions shall have the following meanings:

Words and Expressions	Meanings
Agreement	these terms and the attached Schedules
Aurum	Aurum Pharmaceuticals Limited (company number 02581060) whose registered office is at Bampton Road, Harold Hill, Romford, Essex, RM3 8UG, being a subsidiary of the Supplier
Authorised Release	An event commencing when the Authority gives notice to the Supplier under Clause 7, Clause 14 or Clause 18 to allow a release of the Stockpiled Product in accordance with an agreed Release Plan or Exit Plan
Business Continuity Event	any event or issue that could impact on the operations of the Supplier and its ability to supply the Product or provide the Services including any Force Majeure event or Emergency
Business Continuity Plan ("BCP")	the Supplier's business contingency plan which provides for continuity of the Services in the event of a Business Continuity Event, in so far as it is relevant to the Services, is attached at Schedule 5. For the avoidance of doubt the BCP shall include but is not restricted to the manufacturing process of the Product, Stock Building Phase, Storage Services and Authorised Release
Business Days	a day (other than a Saturday, Sunday or public holiday) on which banks in the City of London are ordinarily open for the transaction of normal banking business
Buyback Price	means Redacted Under FOIA Section 43(2), Commercial Interests
Central Government Body	a body listed in one of the following sub-categories of the Central Government classification of the Public Sector Classification Guide, as published and amended from time to time by the Office for National Statistics: (a) Government Department; (b) Non-Departmental Public Body or Assembly Sponsored Public Body (advisory, executive, or tribunal); (c) Non-Ministerial Department; or (d) Executive Agency
Commercially Sensitive Information	the information comprising the information of a commercially sensitive nature relating to the Supplier, its Intellectual Property Rights or its business which the Supplier has indicated to the Authority as at the Effective Date that, if disclosed by the Authority, would

	cause the Supplier significant commercial disadvantage or material financial loss
Confidential Information	means any Information which has been designated as confidential by either Party in writing or that ought to be considered as confidential (however it is conveyed or on whatever media it is stored) including information the disclosure of which would, or would be likely to, prejudice the commercial interests of any person, trade secrets, Intellectual Property and know how of either Party and all Personal Data. Confidential Information shall not include information which: (a) was public knowledge at the time of disclosure (subject to Clause 27); (b) was in the possession of the receiving Party, without restriction as to its disclosure, before receiving it from the disclosing Party; (c) is received from a third party (who lawfully acquired it) without restriction as to its disclosure; or (d) is independently developed without access to the Confidential Information
Contract Price	the pallet price per month set out in Schedule 1
Data Protection Legislation	means (i) the Data Protection Act 2018 to the extent that it relates to processing of personal data and privacy; (ii) the GDPR, the Law Enforcement Directive (Directive (EU) 2016/680) and any applicable national implementing Law as amended from time to time; and (iii) all applicable Law about the processing of personal data and privacy
Data Protection Protocol	means any document of that name as provided to the Supplier by the Authority (as amended from time to time in accordance with its terms)
Defective Product	any Unit of the Product supplied under the Agreement which: (a) in the determination of the MHRA, meets the definition of a "Defective Medicinal Product" in accordance with their prevailing Guidance on defective medicinal products and Article 117 of Directive 2001/83; (b) does not conform to or is not produced in accordance with Good Distribution Practice, Good Manufacturing Practice, Good Industry Practice or the Specification of Product or the Marketing Authorisation; (c) has not been dealt with in accordance with Good Industry Practice, or

	(d) otherwise fails to conform to the requirements of the Agreement.
Delivery Notice	notice in writing in the form set out in Schedule 4 confirming delivery to be sent as soon as Stockpiled Product is placed into the Stockpile to Redacted Under FOIA Section 40, Personal Information or such other person notified to the Supplier by the Authority
Delivery Schedule	any delivery schedule agreed in the same form as set out in Schedule 4 for any Replacement Products agreed by the Parties in accordance with Clause 7 and any revised delivery schedule agreed in accordance with Clause 2.4
Directive 2001/83	Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use as amended
Directive 2003/94	Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use as amended
Discounted Buyback Price	Means the discounted buyback price payable by the Supplier at end of contract term and / or where the Authority has given notice to the Supplier pursuant to Clause 14.1 to reduce the Required Volume; Redacted Under FOIA Section 43(2), Commercial Interests
Data Protection Protocol	means any document of that name as provided to the Supplier by the Authority (as amended from time to time in accordance with its terms)
Effective Date	1 October 2021
EMEA	the European Medicines Agency
Emergency	shall have the meaning set out in Clause 7.1
Emergency Authorised Release	shall have the meaning set out in Clause 7.1
EIRs	the Environmental Information Regulations 2004, together with any Guidance and/or codes of practice issues by the Information Commissioner or any Central Government Body in relation to such Regulations
EU References	shall have the meaning set out in in Clause 1.3.10
Exit Day	has the meaning given to it in the European Union (Withdrawal) Act 2018
Exit Phase	a period commencing on one or more of the following events: (a) two (2) months before expiry of the Agreement; or (b) if earlier, from the date of any notice to terminate the Agreement and continuing for a

	period of two (2) months or as agreed by the Parties; or (c) from the date of any agreement to reduce the Required Volume other than by reason of an Emergency Authorised Release and continuing for a period of two (2) months or as agreed by the Parties
Exit Plan	the plan(s), a template of which is set out in Schedule 6, to be filled out in accordance with Clause 14 or Clause 18 and sent to Redacted Under FOIA Section 40, Personal Information or such other person notified to the Supplier by the Authority
Exit Report	the report(s) to be completed during the Exit Phase(s) as set out in Schedule 6
Extension Period	the period of twelve (12) months commencing from the day after the end of the Initial Period, pursuant to Clause 16.2
Force Majeure	means any of the following insofar as the relevant event is beyond the control of the Party in question: (a) war including civil war (whether declared or undeclared), riot, civil commotion or armed conflict materially affecting either Party's ability to perform its obligations under this Contract; (b) acts of terrorism; (c) flood, storm or other natural disasters; (d) fire; (e) unavailability of public utilities and/or access to transport networks to the extent no diligent supplier could reasonably have planned for such unavailability as part of its business continuity planning; (f) government requisition or impoundment to the extent such requisition or impoundment does not result from any failure by the Supplier to comply with any relevant regulations, laws or procedures (including such laws or regulations relating to the payment of any duties or taxes) and subject to the Supplier having used all reasonable legal means to resist such requisition or impoundment; (g) compliance with any local law or governmental order, rule, regulation or direction applicable outside of England and Wales that could not have been reasonably foreseen; (h) industrial action which affects the ability of the Supplier to supply the Goods, but which is not confined to the workforce of the Supplier or the workforce of any Sub-contractor of the Supplier; and (i) a failure in the Supplier's and/or Authority's supply chain to the extent that such failure is

	due to any event suffered by a member of such supply chain, which would also qualify as a Force Majeure Event in accordance with this definition had it been suffered by one of the Parties; but excluding, for the avoidance of doubt, (j) pandemic or epidemic; (k) the withdrawal of the United Kingdom from the European Union; or (l) the COVID-19 pandemic, except for circumstances caused by or related to the COVID-19 pandemic which are changes in applicable law and/or governmental guidance which mean that the Goods cannot be provided as set out in this Contract (in all material respects) without such Laws and/or government guidance being breached, or if the Supplier can reasonably demonstrate that despite all reasonable endeavours, it is unable to secure non-COVID-19 infected personnel to provide the Goods due to the levels of COVID-19 infections in the population of the United Kingdom.
FOIA	the Freedom of Information Act 2000 and any subordinate legislation made under that Act from time to time, together with any Guidance and/or codes of practice issued by the Information Commissioner or any relevant Central Government Body in relation to such Act;
GDPR	means the General Data Protection Regulation (Regulation (EU) 2016/679) as incorporated into, amended and applied under UK law (UK GDPR) and the Data Protection Act 2018 (DPA 2018)
Good Distribution Practice	shall mean the quality assurance which ensures that products are consistently stored, transported, and handled under suitable conditions as required by the Marketing Authorisation or Specification of Product
Good Industry Practice	the exercise of that degree of skill, care, prudence, efficiency, foresight and timeliness as would be expected from a leading company within the relevant industry or business sector
Good Manufacturing Practice	shall have the meaning set out in Directive 2003/94
Guidance	means any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to the Product, to the extent that the same are published and publicly available or the existence or contents of them have been notified to the Supplier by the Authority and/or have been published

	and/or notified to the Supplier by the Department of Health and Social Care, Monitor, NHS England, the MHRA, the EMEA, the European Commission, the Care Quality Commission and/or any other regulator or competent body
Insurable Interest	the Supplier's right, benefit, or advantage arising out of the Supplier's policy of insurance which are required by law
Information	all information of whatever nature, however conveyed and in whatever form, including in writing, orally, by demonstration, electronically and in a tangible, visual or machine-readable medium (including CD-ROM, magnetic and digital form)
Initial Period	the period of eighteen (18) months commencing on the Effective Date
Intellectual Property Rights	means all patents, copyright, design rights, registered designs, trademarks, know-how, database rights, confidential formulae and any other intellectual property rights and the rights to apply for patents and trademarks and registered designs
Law	means any applicable legal requirements including without limitation: (a) any applicable statute or proclamation or any delegated or subordinate legislation or regulation as applicable in England and Wales; (b) any applicable European Union directive, regulation, decision or law; (c) any enforceable community right within the meaning of section 2(1) European Communities Act 1972; (d) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales; (e) requirements set by any regulatory body as applicable in England and Wales; (f) any applicable code of practice as applicable in England and Wales; and (g) any relevant collective agreement and/or international law provisions (to include without limitation as referred to in (a} to {f) above).
Licensing Authority	MHRA or EMEA as the case may be
Manufacturer	means the holder of the manufacturing licence for the Product, being Aurum Pharmaceuticals Limited
Marketing Authorisation	has the meaning set out in the Human Medicines

	Regulations 2012/2016 and means the marketing authorisation granted by the Licensing Authority as amended or varied from time to time regarding the Replacement Product to be supplied and stockpiled under the Agreement
MHRA	Medicines and Healthcare products Regulatory Agency
Offer	the offer submitted by the Supplier in response to the Service Description as set out in Schedule 9
OMCL	Official Medicines Control Laboratory
Pack	a package comprising Units of the Product as referred to in Schedule 1
Party/Parties	the Authority or the Supplier as appropriate and Parties means the Authority and the Supplier
Personal Data	shall have the meaning given in the GDPR
Policy or Policies	means the policies, rules and procedures of the Authority as notified to the Supplier from time to time
Process	has the meaning given to it in the GDPR and, for the purposes of the Agreement, it shall include both manual and automatic processing. Processing and Processed shall be construed accordingly
Product	the product set out in Schedule 1
Registered Shelf Life	the shelf life that the Product is registered as having as part of the Marketing Authorisation process
Regulations	means the Public Contracts Regulations 2015 (SI 2015/102) as amended
Rejected Product	any Units of the Product rejected by the Authority under Clause 9.3 or Clause 9.4
Release Plan	a plan for the Emergency Authorised Release of the Stockpiled Product prepared under the Agreement in the form set out in Schedule 3 and sent to Redacted Under FOIA Section 40, Personal Information or such other person notified to the Supplier by the Authority
Released Product	Stockpiled Product that is the subject of an Authorised Release
Release Report	the report to be completed as part of any Release Plan, the template for which is set out in Schedule 3
Replacement Product	Product used to replace: (a) Stockpiled Product removed from the Stockpile in accordance with Clause 5 and/or Clause 7; and/or (b) Rejected Product
Required Volume	has the meaning set out in Schedule 1 in respect of the Product, as varied in accordance with Clause 14 or any Exit Plan

Request for Information	a request for information under the FOIA or the ElRs Services
Services	the Storage Services, stock rotation, Authorised Release and replacement of the Stockpile in accordance with the Agreement, and any other services provided by the Supplier under the Agreement
Service Description	the service description issued to the Supplier by the Authority as set out in Schedule 8
Shelf Life	the shelf life of the Product set out in Schedule 1
Specification of Product	the specification set out in Schedule 1
SmPC	means the Summary of Product Characteristics
Stock Building	means building the stock back to the level of the Required Volume with the Replacement Products following an Authorised Release
Stock Report	to be provided as set out in Schedule 7
Stockpile	where the Stockpiled Product is held within the Storage Facilities
Stockpiled Product	Product held in and stored within the Stockpile, including any Replacement Product supplied under the Agreement
Storage Facilities	the location(s) in the United Kingdom where the Stockpiled Product is to be stored, as set out in the Delivery Schedule
Storage Provider	any third party provider of Storage Services appointed by the Supplier in accordance with Clause 34 as set out in Schedule 3
Storage Services	storage of the Product in accordance with Clause 6
Sub-contract	any agreement or proposed agreement between the Supplier and a third party whereby that third party agrees to provide to the Supplier the Services or any part thereof or facilities or services necessary for the provision or the Services or any part thereof or necessary for the management, direction or control of the Services or any part thereof; and where used **as a** verb, agreeing or arranging with any third party to provide the same
Sub-contractor	a third party with whom the Supplier enters into a Sub- contract
Technical Agreement	Means the Quality Technical Agreement between the Authority and the Supplier which defines each party's responsibilities with regards to storage and management of Prenoxad Injection. This is a separate document.
Term	a period of eighteen (18) months with the Authority, at its sole discretion, having the option to extend the Agreement for a further period of up to twelve (12) months

Unit	a unit of the Product
Wholesale Distribution Authorisation	has the meaning set out in the Human Medicines Regulations 2012/2016 or any replacement regulation

1.2 Unless otherwise notified by the Secretary of State for Health and Social Care acting through the Department of Health and Social Care, the Department of Health and Social Care shall perform the Authority's obligations under this Agreement and manage the Authority's day-to-day relationship with the Supplier.

1.3 In relation to the Agreement unless a provision otherwise expressly provides:

1.3.1 references to persons shall be deemed to include those of either sex and also firms or any other body (whether corporate or unincorporated), trust, state or agency of state (in each case, whether or not having separate legal personality);

1.3.2 words importing the singular number only shall include the plural number and vice versa;

1.3.3 references to any statute or order shall include any statutory extension, modification or re-enactment thereof and any order, regulation or bye-law made thereunder;

1.3.4 Schedules shall mean the schedules to the Agreement;

1.3.5 Clauses shall mean the clauses of the Agreement;

1.3.6 headings shall be deemed not to form part of the Agreement and accordingly shall not be taken into account in the construction or interpretation thereof;

1.3.7 any notice or communications to be given under the Agreement by either Party to the other shall be in writing and may be sent by post or by e-mail. The addresses and email addresses for service of all notices or confirmations are:

(a) Authority

(i) Address: Department of Health and Social Care, Wellington House, 133- 155 Waterloo Road, London, SE1 8UG

(ii) For the attention of : Redacted Under FOIA Section 40, Personal Information

(iii) Email address: Redacted Under FOIA Section 40, Personal Information

(b) Supplier

(i) Address: Ethypharm UK Limited, Building A2, Glory Park, Wooburn Green, High Wycombe HP10 0DF

(ii) For the attention of: Redacted Under FOIA Section 40, Personal Information

(iii) Email address: Redacted Under FOIA Section 40, Personal Information

1.3.8 All notices or communications sent by post shall be sent by first class recorded or registered post addressed to the other Party at the address specified above, or such other address

which may have been notified in accordance with this Clause by the other Party. A notice shall be deemed to have been served at 9.00am on the first Business Day after the notice is posted or at 9.00am on the next Business Day after the sender sends an e-mail;

1.3.9 each and every obligation of a Party is to be performed at that Party's cost; and

1.3.10 A reference in this Agreement which immediately before Exit Day was a reference to (as it has effect from time to time):

1.3.10.1 any EU regulation, EU decision, EU tertiary legislation or provision of the EEA agreement ("EU References") which is to form part of domestic law by application of section 3 of the European Union (Withdrawal) Act 2018 shall be read as a reference to the EU References as they form part of domestic law by virtue of section 3 of the European Union (Withdrawal) Act 2018 as modified by domestic law from time to time; and

1.3.10.2 any EU institution or EU authority or other such body shall read as a reference to the UK institution, authority or body to which its functions were transferred.

1.4 Where a term of the Agreement provides for a list of one or more items following the word "including" or "includes" then such list is not to be interpreted as being an exhaustive list. Any such list shall not be treated as excluding any item which might have been included in such list having regard to the context of the contractual term in question. The ejusdem generis principle is not to be applied when interpreting the Agreement. General words are not to be given a restrictive meaning where they are followed by examples intended to be included within the general words.

1.5 All monetary amounts are expressed in pounds sterling but in the event that pounds sterling is replaced as legal tender in England by a different currency then all monetary amounts shall be converted into such other currency at the rate prevailing on the date such other currency first became legal tender in the England.

1.6 Any reference to a Party "procuring" another person to act or omit to act In a certain manner shall mean that the Party so procuring shall be liable for any default on the part of the person acting or omitting to act in that manner.

1.7 All references to the Agreement include (subject to all relevant approvals) a reference to the Agreement as amended, supplemented, substituted, novated or assigned from time to time.

2 STOCK BUILDING

2.1 During any period of Stock Building Phase as required under Clause 7, the Supplier shall supply to the Authority the Product Redacted Under FOIA Section 43(2), Commercial Interests in accordance with the Delivery Schedule to ensure there is the Required Volume of the Product.

2.2 The Supplier shall deliver the Product to the UK based Storage Facilities set out in Clause 3. For the avoidance of doubt all the Product in the Stockpile shall be stored in the UK.

2.3 If the Supplier becomes aware that, for any reason, it will or may not be able to supply the Product in accordance with the Delivery Schedule, it shall promptly give notice in writing to the Authority setting out the reasons for the delay and the anticipated time for delivery. Following receipt of notice under this Clause 2.3, the Authority may review with the Supplier the reasons for the delay and steps which may be taken to mitigate any delay or risk of delay and to secure delivery as promptly as possible and agree to a revised Delivery Schedule. Where despite the revised Delivery Schedule, delivery has not taken place the Authority may at any time thereafter make time for delivery of the essence and terminate the Agreement for material breach.

2.4 Without prejudice to any other right or remedy of the Authority in respect of any delay, the Parties shall use reasonable endeavours to agree a revised Delivery Schedule.

2.5 On delivery in good order and condition in full of the Required Volume of the Product as set out in the Delivery Schedule or revised Delivery Schedule (taking into account any Product which has been the subject of an Authorised Release or removal or is to be treated as removed from the Stockpile in accordance with the Agreement), the Supplier shall give to the Authority written confirmation in the form of a Delivery Notice that the Required Volume has been received.

2.6 The Product delivered into the Stockpile should be of neutral packaging and not display a retailer's brand or trademark.

3 DELIVERY AND STOCKPILING

3.1 The Supplier shall:

3.1.1 transport all Units of the Replacement Product to the Storage Facilities, unload the Units, inspect the Units, designate the Units as Stockpiled Product and deliver them into the Stockpile as set out under the Agreement;

3.1.2 transport and deliver the Product in such manner necessary to ensure that they are delivered in good and usable condition and with such duty and care expected to meet Good Distribution Practice and Good Industry Practice standards;

3.1.3 without prejudice to Clause 3.1.2, store the Product during transportation and delivery in accordance with strict temperature controls as specified in the SmPC and as required to ensure that the Product remains in good and useable condition; and

3.1.4 maintain, complete, accurate records showing the temperature controls implemented under Clause 3.1.3 at all times and make such records available to the Authority on request.

3.2 The Supplier shall deliver all Units of the Product securely packaged with the following details being shown clearly on the shipping carton or other such outer packaging and shall record the following details and make such records available to the Authority on request:

3.2.1 a description of the Product including the Manufacturer's brand name and/or the generic drug name and the holder of the Marketing

Authorisation

3.2.2 the quantity of Units in the Packs;

3.2.3 special directions for storage and handling (if any);

3.2.4 expiry date for the Product in the Packs;

3.2.5 batch number;

3.2.6 name of the Supplier;

3.2.7 name of the Manufacturer or holder of the Marketing Authorisation (if different from the Supplier); and

3.2.8 any other information required by the Licensing Authority to be provided.

3.3 The Supplier shall be responsible for all transport and all related costs associated with the delivery of the Product.

3.4 All third party carriers engaged to deliver the Product shall at no time be agents of the Authority and accordingly the Supplier shall be liable to the Authority for the acts and omissions of all third party carriers engaged to deliver the Product.

3.5 The Supplier shall be deemed to have delivered Units of the Product to the Authority when the requirements of Clause 3.8 have been completed to the satisfaction of the Authority.

3.6 The labelling and marking of all Packs of the Product and all relevant information accompanying them shall be in accordance with the Marketing Authorisation and the SmPC. The Supplier shall discuss and, other than to the extent required by the Licensing Authority, agree with the Authority any changes to be made to labelling, instructions and patient information relating to the Product.

3.7 The Supplier shall apply Good Distribution Practice and Good Industry Practice at all times. In addition, the Supplier shall ensure that the Product is processed, checked and handled with all due care and skill and to the highest standard available in the industry.

3.8 Immediately upon each delivery of the Product to the Storage Facilities the Supplier shall:

3.8.1 ensure all the obligations set out in this Clause 3 have been met;

3.8.2 check the temperature records for the period of transport from the Manufacturer's facilities to the Storage Facilities to ensure that they are complete and accurate and record the results of such checks;

3.8.3 check that the quantity, batch numbers, expiry dates and other details of the Product are in accordance with the Delivery Schedule and record the results of such checks;

3.8.4 subject the Product to a visual inspection of the Packs and containers without opening or tampering with any Product packaging to ensure that there is no obvious damage and record the results of such inspection;

3.8.5 designate the Product as Stockpiled Product and place them into the Stockpile;

3.8.6 send an electronic Delivery Notice to the Authority stating that the Product is

deemed to be acceptable (having made the necessary checks set out in this Clause 3) and has been designated as Stockpiled Product and placed in the Stockpile; and

3.8.7 include in the Delivery Notice the details and quantity of any products which should be deemed to be Rejected Product.

3.9 The Supplier shall maintain a record of each delivery of the Product stating the information required under Clause 3.2 that shall at all times be immediately available to the Authority upon request for the duration of the Agreement and a further six (6) years following the expiry or termination of the Agreement.

4 MANUFACTURE AND CHAIN OF SUPPLY

4.1 The Supplier shall:

4.1.1 ensure it has or it has access to manufacturing capacity for the Product sufficient to comply with its obligations under the Agreement;

4.1.2 ensure that the production facilities used in the manufacture of the Product are in a state and condition necessary to comply with any legal requirements in relation to the Product, and its production and to enable the Supplier to comply with its obligations to supply the Product to the Authority in accordance with the Agreement; and

4.1.3 ensure that all Product when manufactured is done so with all due care and skill and is stored in an environment suitable for such goods with the necessary protection and conditions according to Good Manufacturing Practice, Good Industry Practice, the Marketing Authorisation, the Specification of Product, and the SmPC.

5 STOCK ROTATION

5.1 The Supplier shall ensure that:

5.1.1 the Required Volume of Stockpiled Product (and during any Stock Building Phase such volume as is required in accordance with the Delivery Schedule) is maintained in the Stockpile throughout the Term, subject only to Authorised Releases under a Release Plan or Exit Plan in accordance with the Agreement; and

5.1.2 all Stockpiled Product in the Stockpile with a Registered Shelf Life of more than twenty four (24) months shall at all times throughout the Term have an unexpired shelf life of at least twenty four (24) months.

5.2 Redacted Under FOIA Section 43(2), Commercial Interests.

5.3 Save as set out in Clause 5.2 the Supplier shall not remove any Stockpiled Product from the Stockpile without the Authority's prior written consent.

5.4 The Supplier shall not at any time use the Stockpiled Product to further its position in the market for the Product.

5.5 For the avoidance of doubt the requirements of this Clause 5 shall continue during any Exit Phase.

5.6 Redacted Under FOIA Section 43(2), Commercial Interests

6 STORAGE SERVICES

6.1 The Supplier shall store the Stockpiled Product in the Stockpile at the Storage Facilities in accordance with the Agreement.

6.2 The Supplier shall maintain the Storage Facilities in accordance with;

6.2.1 the Marketing Authorisation for the Stockpiled Product;

6.2.2 the Wholesale Distribution Authorisation;

6.2.3 any other requirements of the Licensing Authority; and

6.2.4 Good Industry Practice

6.3 The Supplier shall only store the Stockpiled Product at the Storage Facilities. If the Supplier wishes to relocate the Stockpiled Product for storage at any location other than the Storage Facilities or to move the Stockpiled Product within the Storage Facilities:

6.3.1 the Supplier shall keep the Authority informed of any such movement;

6.3.2 the Supplier shall only be entitled to do so with the prior written consent of the Authority; and

6.3.3 irrespective of approval being provided by the Authority, any such movement of the Stockpiled Product will be at the full risk of the Supplier.

6.4 The Supplier shall;

6.4.1 store the Stockpiled Product in accordance with strict temperature controls as specified in the SmPC and as required to ensure that the Stockpiled Product remains in good and useable condition;

6.4.2 maintain records showing the temperature controls implemented under Clause 6.4.1 at all times and make such records available to the Authority on request;

6.4.3 ensure all Stockpiled Product is clearly identifiable as Stockpiled Product belonging to the Authority;

6.4.4 store, handle and carry the Units of the Stockpiled Product separately from any other goods;

6.4.5 allocate sufficient space at the Storage Facilities to store the Stockpiled Product in the Required Volume in accordance with the Delivery Schedule;

6.4.6 ensure that the Product is stored in an orderly and well organised manner, and adequate records are maintained such that it is readily possible to identify stock location, have access to and inspect the Stockpiled Product, and identify Stockpiled Product by reference to different characteristics such as formulation, shelf life, pack size or other relevant characteristics;

6.4.7 operate and manage the Storage Facilities and storage of the Stockpiled Product in accordance with Good Industry Practice and the Wholesale Distribution Authorisation in relation to the Product;

6.4.8 enter into a Technical Agreement with the Authority to ensure compliance with

the Authority's Wholesale Distribution Authorisation;

6.4.9 not remove or tamper with any markings on the Product or the packaging of the Product, other than as expressly stated in writing by the Authority;

6.4.10 implement a comprehensive stock management system in respect of the Stockpiled Product in accordance with the law, regulations, directions, and guidance, and provide any information in relation to stock control of the Stockpiled Product that may be requested by the Authority;

6.4.11 provide the Storage Services in accordance with its standard operating procedures and not make any material changes to its standard operating procedures, if such proposed changes do or could impact on the provision of the Storage Services, without the prior written consent of the Authority, such consent not to be unreasonably withheld or delayed;

6.4.12 employ sufficient staff to ensure that the Storage Services are provided at all times and in all respects in compliance with the Agreement and to ensure that a sufficient reserve of staff is available to provide the Storage Services during holidays or absences;

6.4.13 obtain written approval from the Authority before changing the size of the container or presentation of the items to be supplied; and

6.4.14 provide a Stock Report.

6.5 The Supplier shall advise the Authority immediately in writing of any damage to or loss of the Stockpiled Product that occurs in the performance of the Storage Services and shall provide evidence in writing of such damage to the Authority where requested by the Authority.

6.6 Should the Authority undertake a stock audit in relation to the Stockpiled Product, the Supplier shall comply with all reasonable requests to facilitate such audit and shall put into effect changes as may reasonably be required by the Authority as a result of the audit.

6.7 The Supplier shall be solely responsible for the direction, management, reporting and organisation of all that is necessary in order to carry out the Storage Services including;

6.7.1 the provision and supervision of use of all the premises, plant, machinery, equipment and delivery vehicles necessary to carry out the Storage Services;

6.7.2 maintenance of all premises, plant, machinery, equipment and delivery vehicles necessary to carry out the Storage Services;

6.7.3 any and all relevant insurance policies required by law, arising out of the Supplier's performance of the Agreement, including death or personal injury, loss of or damage to property (including the Product) or any other loss. Such policies shall include cover in respect of any financial loss arising from any advice given or omitted to be given by the Supplier; and

6.7.4 security at the Storage Facilities.

6.8 Where the Storage Services are provided by a Storage Provider, any obligation on the Supplier under the Agreement shall be taken as a requirement on the Supplier to procure the compliance of the Storage Provider with such obligations to the extent necessary to ensure the relevant obligations are fully met.

6.9 The Supplier shall undertake a physical stock audit in relation to the Stockpiled Product every six (6) months for the purposes of ensuring compliance with this Agreement including but not limited to compliance with clause 6.4, and checking the quantity, quality and labelling of Stockpiled Product. The Supplier shall report the outcome of its physical stock audit within fourteen (14) days of the audit taking place.

7 AUTHORISED RELEASE IN AN EMERGENCY

This Clause shall apply to Authorised Release in an Emergency

7.1 The Authority and the Supplier shall promptly notify the other Party in writing if either Party anticipates that the normal supply chain in the UK for the Product cannot meet demand due to a localised or geographically-dispersed incidence of higher-than- usual opioid overdoses caused by potent opioids in the illicit drug supply (an **'Emergency'**). In the event of such an Emergency the Authorised Release shall be known as an **'Emergency Authorised Release'**

7.2 The Authority and the Supplier shall review together any such anticipated shortages and the means for minimising such shortages or their impact, and the Supplier, in consultation with the Authority, shall draw up a draft Release Plan containing the information described and in the form set out at Schedule 3 in relation to releasing Stockpiled Product for addressing such shortages and submit it to the Authority for approval.

7.3 If the Authority at its sole discretion considers that there is an Emergency it shall review the draft Release Plan and, if satisfied, provide written notice of approval of the Release Plan to the Supplier.

7.4 The approved Release Plan shall include and advise the Supplier of the volume of Stockpiled Product that will be subject to an Emergency Authorised Release under the Release Plan.

7.5 In respect of any volume of Stockpiled Product subject to an Emergency Authorised Release under the Release Plan:

7.5.1 risk in such Units of the Product shall pass to the Supplier upon the date that the Authority approves the draft Release Plan; and

7.5.2 title to such Units of the Product shall pass to the Supplier on the date that the Authority approves the draft Release Plan.

7.6 During an Emergency Authorised Release, the Supplier shall;

7.6.1 ensure that the Released Product is supplied immediately into the supply chain upon demand in the UK for the Product in accordance with any applicable Release Plan and any instructions received from time to time from the Authority (including without limit any instructions as to which customers the Supplier should supply the Released Product to, and in what quantity);

7.6.2 use all reasonable endeavours to ensure that the supply of the Released Product into the supply chain does not materially disrupt or otherwise impact the market for the Product in the UK, including the market price for the Product;

7.6.3 comply with the Release Plan in respect of the Released Product;

7.6.4 attend any meetings as reasonably requested by the Authority; and

7.6.5 provide a Release Report to the Authority following an Emergency

Authorised Release as required by the Authority setting out:

(i) the number of Units of Stockpiled Product removed from the Stockpile during the previous week;

(ii) the number of Units of Stockpiled Product remaining within the Stockpile;

(iii) the identities of the customers to whom the Supplier has supplied product during the previous week; and

(iv) any other information reasonably requested by the Authority in relation to the distribution of the Released Product.

7.7 Following an Emergency Authorised Release;

7.7.1 unless otherwise notified by the Authority, the Supplier shall be required to replace Released Product with Replacement Product that is in compliance with the Agreement in order to maintain the Required Volume of Stockpiled Product. Redacted Under FOIA Section 43(2), Commercial Interests; and

7.7.2 where the Authority requires the Supplier to replace the Released Product;

(i) the Supplier shall use its best endeavours to minimize the time taken to provide such Replacement Product and in any event provide such Replacement Product within twenty-eight (28) Business Days of a request from the Authority to replace the Released Product;

(ii) within five (5) Business Days of a request from the Authority the Supplier shall provide the Authority with a draft Delivery Schedule in the form set out at Schedule 4;

(iii) once the Parties have agreed the draft Delivery Schedule then, further to the Delivery Schedule, a new Stock Building Phase will be agreed and will begin in accordance with Clause 2.

8 TITLE AND RISK

8.1 Risk in all Units of the Product shall pass to the Authority when the relevant Units are deemed to have been delivered in accordance with Clause 3.5, save that risk in all Units of the Stockpiled Product in the Stockpile shall remain with the Supplier to the extent that the Supplier:

8.1.1 breaches the Agreement;

8.1.2 is negligent; or

8.1.3 fails to take reasonable steps to forestall the effects of any reasonably foreseeable events that could cause loss or damage to such Product, having regard to the value of the Product.

8.2 Title to all Units of the Product shall pass to the Authority when the relevant Units are deemed to have been delivered in accordance with Clause 3.5 and the Delivery Notice has been accepted by written notice from the Authority.

8.3 The Supplier acknowledges and agrees that the Authority shall retain full title to the Stockpiled Product during the Initial Period and at no time shall the Supplier hold any proprietary or other interest in the Stockpiled Product other than as required to provide an Insurable Interest to allow the Supplier to put in place all relevant insurance policies needed to comply with Clause 6.7.3.

8.4 If any Stockpiled Product is removed from the Stockpile by the Supplier in accordance with Clause 5.2, then

8.4.1 risk in such Units of the Product shall pass to the Supplier upon removal; and

8.4.2 title to such Units of the Product shall pass to the Supplier upon removal in accordance with Clause 5.2

8.5 If the Supplier removes any Stockpiled Product from the Stockpile during an Exit Phase then;

8.5.1 risk in such Units of the Product shall pass to the Supplier upon such removal; and

8.5.2 title to such Units of the Product shall pass to the Supplier at the time of payment for such Units of Product by the Supplier in accordance with Clause 13.3

8.6 Title to all Units of the Product shall pass to the Supplier at the end of the Extension Period.

9 INSPECTION OF PRODUCTS AND STORAGE FACILITIES

9.1 The Authority or its authorised representative may, at any time during normal business hours, carry out an inspection of the Storage Facilities and the Stockpiled Product provided that the Authority gives prior written notice to the Supplier of no less than twenty four (24) hours. Such inspection may include but is not limited to

9.1.1 reviewing the Supplier's compliance with the Agreement;

9.1.2 checking any records held by the Supplier under the Agreement;

9.1.3 checking the Stockpiled Product to ensure there is no damage to it;

9.1.4 checking batch numbers and expiry dates in accordance with the delivery documents; and

9.1.5 checking the quantity of Stockpiled Product.

9.2 The Supplier shall subject to any duty of confidentiality to a third party or security requirement of its insurers give the Authority or its authorised representative upon reasonable notice unrestricted access to the Storage Facilities, vehicles and any other premises and facilities where the Storage Services are carried out and as otherwise required to allow inspection under Clause 9.1, including providing or obtaining any necessary permissions.

9.3 The Authority may reject any Units of the Product:

9.3.1 where inspection reveals such Units or their packaging to be damaged and/or to have batch numbers and/or expiry dates which do not correspond to the relevant delivery documents and/or the provisions of the Agreement;

9.3.2 where the Authority is notified in accordance with Clause 3.8.7 that Product should be rejected; or

9.3.3 in respect of which the Supplier fails to provide complete and accurate temperature records which show that the relevant temperatures have been maintained within the correct range.

9.4 The Authority may at any time by written notice to the Supplier reject any Defective Product. Where the Authority discovers more than one Defective Product in any given batch of the Product, the Authority shall be entitled to reject the entire batch provided always that the Authority shall take due account of all relevant guidance received from the Licensing Authority.

9.5 Without prejudice to any other right or remedy of the Authority:

9.5.1 the Authority may by written notice to the Supplier require the Supplier to replace Rejected Product with Replacement Product that is in compliance with the Agreement free of charge; or

9.5.2 the Authority may choose to source some or all of the Product (which for the avoidance of doubt shall include all services which enable the Authority to supply and store the Product on similar terms as the Agreement) or a substitute product from a third party, and without prejudice to the Authority's other rights or remedies the Supplier shall pay all of the direct losses, damages and direct costs incurred by the Authority in having to source the Product from a third party.

9.6 Where the Authority requires the Supplier to replace the Rejected Product, the Supplier shall use its best endeavours to minimise the time taken to provide such Replacement Product and in any event shall do so at its own cost and within one (1) week of the date of the rejection or such longer period as the Authority may agree in writing at the Supplier's own cost. Where the Authority notifies the Supplier that it will source Replacement Product elsewhere, the Supplier shall refund to the Authority any sums paid for the Rejected Product within thirty (30) days of the date of such notification.

9.7 No act or omission of the Authority including in particular taking delivery, keeping a sample, inspection of or payment for any Units of the Product by the Authority shall constitute acceptance, waiver or approval of the Product or limit the Authority's right subsequently to reject Units of the Product should such Units be Defective Product.

9.8 Any Rejected Product shall be physically removed by the Supplier from the Stockpile immediately and at the Supplier's expense which shall include all associated costs including but not limited to any cost of storage.

9.9 The Authority shall be entitled to charge the Supplier for any losses, costs or damages incurred by the Authority as a result of any Rejected Product in accordance with the Agreement provided that the Authority shall use its reasonable endeavours to mitigate the same. The Supplier shall pay such losses, costs or damages to the Authority within thirty (30) days of the date of the Authority's invoice for the same.

10 REGULATORY REQUIREMENTS

10.1 The Supplier shall ensure that it or the Manufacturer or the holder of the Marketing Authorisation maintain a valid Marketing Authorisation in accordance with the provisions of Directive 2001/83 and where applicable the Human Medicines Regulations 2012/1916 (or any directive or regulation replacing the same).

10.2 The Supplier shall promptly and in any event within seven (7) days inform the Authority in writing if it knows or believes there to be any delay or other problem with the Marketing Authorisation or its renewal.

10.3 If, for any reason, the Marketing Authorisation is:

10.3.1 withdrawn by the Licensing Authority;

10.3.2 suspended by the Licensing Authority; or

10.3.3 not renewed by the Licensing Authority,

then the Authority shall be entitled to immediately terminate the Agreement upon written notice to the Supplier.

10.4 The Supplier shall reply promptly to all reasonable enquiries and complaints by the Authority relating to the use, effective administration, quality, performance and durability of the Product.

10.5 Upon any termination under Clause 10.3 the Supplier shall at the discretion of the Authority immediately purchase the Stockpiled Product from the Authority at the Buyback Price.

10.6 The Supplier shall comply with the requirements as set out in the Technical Agreement.

10.7 Where the Supplier changes the location of the Storage Facilities at any time or from time to time, the Authority shall not be liable to pay any additional costs (including costs charged by the MHRA to the Authority) attributable to the change in the location and the Supplier shall indemnify the Authority in respect of such additional costs.

11 QUALITY ASSURANCE

11.1 The Supplier shall comply with its quality control monitoring system, details of which are included in the Marketing Authorisation. The Supplier shall manufacture or procure the manufacture of the Product in accordance with Good Distribution Practice, Good Manufacturing Practice, Good Industry Practice, any other requirements of the Licensing Authority and the terms of the Agreement.

11.2 To ensure compliance with Clause 11.1 the Supplier shall ensure that the Manufacturer or holder of the Marketing Authorisation shall maintain the Marketing Authorisation and all other licences necessary for the manufacture of the Product during the Term and not make any changes (including any changes which shall or may have an impact on the quality or use of the Product) to the same or to the Specification of Product or the Supplier's quality control monitoring system in relation to the Product without:

11.2.1 notifying the Authority in writing in advance of the intention to implement such change and giving the Authority the opportunity to make representations to the Supplier within twenty one (21) days of receipt by the Authority of notice that the Supplier intends making such change, such notice to include details of the consequences which will follow such change being implemented; and

11.2.2 the Licensing Authority formally approving such change.

12 WARRANTIES

12.1 The Supplier warrants and undertakes that:

12.1.1 it shall supply the Services during the Term in accordance with the Agreement.

12.1.2 all Units of the Stockpiled Product will throughout the Term comply fully with the Specification of Product, the Marketing Authorisation and the Technical Agreement;

12.1.3 the Supplier, and any Sub-contractor that may require the same for the activities subcontracted to it under the Agreement, hold and will hold throughout the Term a Wholesale Distribution Authorisation or equivalent licence to deal in the Product;

12.1.4 all Units of the Product are new and have not been rejected by any other entity prior to their supply of the Stockpiled Product;

12.1.5 the Product will be manufactured in accordance with Good Manufacturing Practice;

12.1.6 the Product is suitable for the treatments and purposes as referred to in the Specification of Product, the Marketing Authorisation and the SmPC;

12.1.7 all Units of Stockpiled Product will at all times while in the Stockpile have the Shelf Life referred to in Clause 5.1;

12.1.8 the Storage Facilities, other premises, vehicles, facilities and all equipment necessary for the provision of the Services are and will be maintained by the Supplier and any other procured third party so that they are suitable and fit for the purpose of providing the Services; and

12.1.9 its Business Continuity Plan set out in Schedule 5 is sufficient to ensure continuity of supply of the Product in accordance with the Agreement and at times of Emergency.

12.2 The Supplier warrants and undertakes that it will comply with all Law and Guidance applicable to the Product, including but not limited to relevant provisions of:

12.2.1 Directive 2001/83;

12.2.2 Title II of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community

procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing an EMEA;

12.2.3 all laws, regulations and guidelines within the UK implementing the legislation referred to in Clause 12.2.1 and Clause 12.2.2;

12.2.4 any guidelines or directions or like documents that may be published during the Term by the MHRA or EMEA and are applicable to the Product at the time of manufacture;

12.2.5 the Medicines Acts 1968 and 1971 and the regulations made thereunder in the respect of the sale, supply, importation, manufacture or assembly of the Product; and

12.2.6 the Human Medicines Regulations 2012/1916.

12.3 The Supplier further warrants and undertakes that:

12.3.1 it has the right and authority to enter into the Agreement and that it has the capability and capacity to fulfil its obligations under the Agreement;

12.3.2 all statements and representations in the Offer and all accompanying materials are to the best of its knowledge, information and belief true and accurate and it will promptly advise the Authority of any fact, matter or circumstance of which it may become aware that would make any such statement false or misleading;

12.3.3 all statements or representations in the Offer as to actions or steps the Supplier will do or take during the Term are made honestly and in good faith, and, unless determined otherwise by the Authority in writing, the Supplier will be bound to, and shall do or take such actions or steps;

12.3.4 it is properly constituted and it is fully empowered by the terms of its constitutional documents to enter into and to carry out its obligations under the Agreement and the documents referred to herein;

12.3.5 to the best of the Supplier's knowledge there are no pending or threatened actions or proceedings before any court or administrative agency which would materially adversely affect the financial condition, business or operations of the Supplier including any proposed operations under the Agreement;

12.3.6 where a court (or other competent authority) makes a finding or determination that any of the Intellectual Property Rights required for the purposes of supplying the Goods is invalid or unenforceable for whatever reason, it will promptly notify the Authority of the same;

12.3.7 there are no material agreements existing to which the Supplier is a party which prevent the Supplier from entering into the Agreement or performing any of its obligations under the Agreement;

12.3.8 all necessary actions to authorise the execution of and performance of its obligations under the Agreement have been taken before such execution;

12.3.9 it shall:

(i) comply with all relevant Law and Guidance and shall use Good Industry Practice to ensure that there is no slavery or human trafficking in its supply chains: and

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

12.3.10 it shall at all times conduct its business in a manner that is consistent with any anti-slavery Policy of the Authority and shall provide to the Authority any reports or other information that the Authority may request as evidence of the Supplier's compliance with this Clause 12.3.10 and/or as may be requested or otherwise required by the Authority in accordance with its anti-slavery Policy.

12.4 The Supplier further warrants and undertakes to the Authority that it will inform the Authority in writing immediately upon becoming aware that any of the warranties set out in this Clause 12 have been breached or there is a risk that any warranties may be breached.

12.5 Any warranties provided under the Agreement are both independent and cumulative and may be enforced independently or collectively at the sole discretion of the enforcing Party.

13 PRICE, PAYMENT AND INVOICING

13.1 In consideration of the provision of the storage, release, and rotation of the Stockpiled Product in accordance with the Agreement, the Supplier will be entitled to buyback the Stockpiled Product in accordance with the terms of the Agreement at the agreed Buyback Price specified in Schedule 2.

13.2 The Contract Price is inclusive of any and all royalties, licence fees, packaging, and storage by the Supplier and the cost of delivery to the Storage Facilities, or similar expenses in connection with the Product. For the avoidance of doubt, no sums in relation to the Contract Price are or will be payable by the Authority to the Supplier.

Release of the Stockpiled Product under Clause 14 or Clause 18

13.3 The Supplier shall pay the Discounted Buyback Price as set out under the Agreement at Clause 23 in respect of any release of the Stockpiled Product in accordance with an agreed Exit Plan within thirty (30) calendar days of receipt of each invoice.

13.4 An invoice shall be issued by the Authority within thirty (30) days following each removal of the Stockpiled Product from the Stockpile pursuant to a release of the Stockpiled Product in accordance with an agreed Exit Plan.

General

13.5 All prices set out in the Agreement are stated exclusive of any applicable VAT.

13.6 All invoices issued under the Agreement by the Authority shall be addressed to: Ethypharm UK Limited, Building A2, Glory Park, Glory Park Avenue, Wooburn Green, High Wycombe, HP10 0PF.

13.7 The Supplier shall pay all invoices issued by the Authority within thirty (30) calendar days.

13.8 The Authority shall not make any payment to the Supplier in respect of the Agreement.

13.9 Where the Supplier enters into a Sub-contract, the Supplier shall include in that Sub-contract:

13.9.1 provisions having the same effect as Clauses 13.7 to 13.11; and

13.9.2 a provision requiring the counterparty to that Sub-contract to include in any Sub-contract which it awards provisions having the same effect as Clauses 13.7 to 13.11.

13.10 In the event of late payment by either Party of any sums due to the other Party under the Agreement, the latter Party shall be entitled to charge interest on such outstanding sums at the rate of 2% above the Bank of England base rate prevailing from time to time per annum calculated on a daily basis from the due date for payment until the date of payment. The Parties agree that this Clause 13.10 is a reasonable and substantial remedy for late payment of any sum payable under the Agreement in accordance with section 8(2) of the Late Payment of Commercial Debts (Interest) Act 1998.

13.11 No payment will be made for containers, crates or packing materials of any description except by special arrangement agreed in writing by the Parties.

14 VARYING THE REQUIRED VOLUME

14.1 Without prejudice to Clause 7, the Authority may at any time during the Term request a decrease of the Required Volume. If the Authority wishes to decrease the Required Volume then it shall give notice in writing to the Supplier setting out the relevant decrease and request an Exit Plan for agreement by the Parties.

14.2 The Supplier shall promptly and in any event within five (5) Business Days of receipt of notice under Clause 14.1 respond to the Authority in writing setting out

14.2.1 the Discounted Buyback Price to be paid by the Supplier to the Authority for any Stockpiled Product to be purchased by the Supplier if the Authority chooses to sell such Stockpiled Product to the Supplier; and

14.2.2 the applicable Discounted Buyback Price as specified in Schedule 2.

15 CHANGES IN THE MARKET

15.1 The Supplier shall promptly give notice in writing to the Authority setting out details of the relevant circumstances if it becomes aware of:

15.1.1 any changes or potential changes in market requirements for the Product;

15.1.2 anything that the Supplier reasonably considers may have an adverse effect on the market value of the Product in the UK;

15.1.3 anything that the Supplier reasonably considers may have an adverse impact on the Supplier's or Authority's ability to sell or supply the Product to the supply chain in the UK in accordance with the Agreement and any Release Plan or Exit Plan; and

15.1.4 if its market share will change in such a way as to impact its ability to rotate the Stockpiled Product in the Stockpile.

15.2 The Supplier shall notify the Authority in writing as soon as reasonably possible if it becomes aware that a patent having effect in the UK in respect of the Product will or may expire, lapse, be withdrawn, be revoked or be declared Invalid.

15.3 In the event of any circumstances in Clauses 15.1 or 15.2 arising the Parties shall agree in writing to any changes.

16 TERM AND TERMINATION

16.1 The Agreement shall commence on the Effective Date and continue for the Term unless terminated earlier in accordance with the provisions of the Agreement, or otherwise lawfully terminated.

16.2 The Authority shall be entitled to extend the Agreement for a further period of up to twelve (12) months (either by way of a single extension or a series of multiple extensions) by giving the Supplier written notice no less than three (3) months prior to the specified expiry date. For the avoidance of doubt, in the event that the Agreement is extended, the Contract Price in Schedule 1 for the Extension Period shall apply and remain fixed for the duration of the Term.

16.3 The Authority may terminate the Agreement immediately by notice in writing to the Supplier:

16.3.1 if the Supplier commits a material breach of any of the terms hereof and in the case of a breach capable of remedy if such breach shall not be remedied or made good within fifteen (15) days of written notice thereof;

16.3.2 if the Supplier ceases or threatens to cease carrying on its business; suspends making payments on any of its debts or announces an intention to do so; is, or is deemed for the purposes of any law to be, unable to pay its debts as they fall due or insolvent; enters into or proposes any composition, assignment or arrangement with its creditors generally; takes any step or suffers any step to be taken in relation to its winding-up, dissolution, administration (whether out of court or otherwise) or reorganisation (by way of voluntary arrangement, scheme of arrangement or otherwise); has a liquidator, trustee in bankruptcy, judicial custodian, compulsory manager, receiver, administrative receiver, administrator or similar officer appointed (in each case, whether out of court or otherwise) in respect of it or any of its assets; has any security over any of its assets enforced; or any analogous procedure or step is taken in any jurisdiction;

16.3.3 if the Licensing Authority, the Commission on Human Medicines or other relevant regulatory body advises the Authority not to use the Product;

16.3.4 if the Supplier undergoes a change of control within the meaning of section 416 of the Income and Corporation Taxes Act 1988 (other than for an intra-group change of control) without the prior written consent of the Authority which, in the reasonable opinion of the Authority, will have a material impact on the supply of the Product or the reputation of the Authority;

16.3.5 if the Supplier, or any Sub-contractor that may require the same for the activities subcontracted to it under the Agreement, do not hold a Wholesale Distribution Authorisation or equivalent licence to deal in the Product, fail to maintain such a licence at any time during the Term or if such a licence is revoked for any reason by the relevant Licensing Authority; or

16.3.6 pursuant to Clause 10.3, Clause 21.5, or Clause 31.4.do

16.4 The Authority may also terminate the Agreement immediately by notice in writing to the Supplier where:

16.4.1 the Agreement has been substantially amended to the extent that the Regulations require a new procurement procedure;

16.4.2 the Authority has become aware that the Supplier should have been excluded under Regulation 57(1) or (2) of the Regulations from the procurement procedure leading to the award of the Agreement;

16.4.3 the Agreement should not have been awarded to the Supplier in view of a serious infringement of obligations under European law declared by the Court of Justice of the European Union under Article 258 of the Treaty on the Functioning of the EU; or

16.4.4 there has been a failure by the Supplier and/or one of its Sub-contractors to comply with legal obligations in the fields of environmental, social or labour Law. Where the failure to comply with legal obligations in the fields of environmental, social or labour Law is a failure by one of the Sub-contractors, the Authority may request the replacement of such Sub-contractor and the Supplier shall comply with such request as an alternative to the Authority terminating the Agreement under this Clause 16.4.

16.5 The Authority may terminate the Agreement at any time by giving three (3) months' written notice to the Supplier. Such notice shall not be served within six (6) months of the Effective Date.

16.7 If before the end of the Exit Phase all the Stockpiled Product is removed from the Stockpile then the Agreement shall immediately expire in respect of such Stockpiled Product.

17 CONSEQUENCES OF TERMINATION

17.1 Termination of the Agreement for whatever reason shall not affect the enforceability of provisions herein expressed to operate following termination and in any event shall be without prejudice to any subsisting right remedy or obligation of either Party.

17.2 If the Agreement is terminated by the Authority for material breach pursuant to Clause 16.3.1, such termination shall be at no loss or costs to the Authority and the Supplier hereby indemnifies the Authority against any such losses or costs which the Authority may suffer as a result of such termination.

17.3 If the Agreement expires or is terminated at the end of the Initial Period and not extended pursuant to Clause 16.2:

17.3.1 an Exit Plan will be implemented and the Supplier shall purchase the Product at the Discounted Buyback Price; and

17.3.2 as requested by the Authority, the Supplier shall co-operate fully with the Authority to ensure an orderly migration of the Services to the Authority or, at the Authority's request, a replacement supplier.

17.4 Upon expiry or termination of the Agreement Clauses 1 (Interpretation), 10 (Regulatory Requirements), 12 (Warranties), 17 (Consequences of Termination), 18 (Exit Plans), 23 (Discounted Buyback), 24 (Intellectual Property Rights), 25 (Liability), 26 (Limitation of Liability), 27 (Confidentiality), 28 (Freedom of Information), 30 (Data Protection), 32 (Right of Audit), and 34 (Sub Contracting and assignment) shall continue in force and any other provision that which expressly provides that it continue after expiry or termination.

18 EXIT PLAN(S) AND EXIT PHASE(S)

18.1 If the Agreement is not extended pursuant to Clause 16.2 then during the Exit Phase the Supplier shall buy back such volume of the Stockpiled Product at the Discounted Buyback Price before the end of the Initial Period as required by the Authority. The Supplier:

18.1.1 shall produce an Exit Plan and provide to the Authority for approval. The Authority and Supplier shall use all reasonable endeavours to agree any updated version of the Exit Plan within fifteen (15) Business Days of receipt by the Authority;

18.1.2 must continue to rotate the Stockpiled Product during the Exit Phase. Any Stockpiled Product that cannot be rotated must be purchased by the Supplier at the Buyback Price. The Parties shall comply with all their obligations under the agreed Exit Plan(s) during the relevant Exit Phase(s) to ensure that the Authorised Release of the Stockpiled Product as set out in the final Exit Plan are supplied into the supply chain in accordance with the Exit Plan; and

18.1.3 shall provide to the Authority an Exit Report(s) as set out in the relevant Exit Plan.

18.2 Once the Exit Phase begins the agreed Authorised Release of the Stockpiled Product should be on the first working day of each month over a two (2) month period unless otherwise notified by the Authority.

18.3 During each Exit Phase, the Supplier shall:

18.3.1 provide to the Authority, at the start of each month (or such other period as the Authority may specify), an updated Exit Plan stating that the Stockpiled Product has been taken from the Stockpile and the actual amount of released stock;

18.3.2 use all reasonable endeavours to ensure that the supply of Stockpiled Product into the supply chain does not materially disrupt or otherwise impact the market for the Product in the UK, including the market price for the Product;

18.3.3 comply with any obligations set out in the Exit Plan to meet with and report to the Authority; and

18.3.4 continue to comply with its obligations under the Agreement in respect of all remaining Stockpiled Product.

18.4 Should the Authority need to action an Emergency Authorised Release of Stockpiled Product whilst an Exit Plan is being implemented any Release Plan shall override the relevant Exit Plan.

19 SUPPLIER STAFF

19.1 The Supplier shall when attending the Authority's or any other relevant premises, procure that its employees and agents shall in the performance of the Agreement comply with all relevant health and safety policies and working practices in force within the Authority's or such other premises from time to time (including smoking and alcohol consumption policies) where the Supplier, its employees and agents have been informed in advance by the Authority or where notices of such policies and working practices are reasonably displayed at the relevant premises and the Supplier shall procure that its employees observe all duties of confidentiality stated in the Agreement.

19.2 In providing the Services to the Authority in accordance with the Agreement, the Supplier shall be solely responsible for all activities associated with the provision of such Services including the management of all personnel employed or contracted by the Supplier to provide such Services.

19.3 The Supplier will employ for the purpose of the Agreement only such persons as are careful, skilled and experienced in the duties required of them, and must ensure that every such person is properly and sufficiently trained and instructed, that records of staff training are kept up-to-date, and that persons have the appropriate licences where required for operating equipment. The Supplier shall ensure that all such persons carry out the Services with regard to:

19.3.1 the task that person has to perform; and

19.3.2 all relevant provisions of the Agreement.

19.4 The Supplier shall not unlawfully discriminate either directly or indirectly on such grounds as race, colour, ethnic or national origin, disability, sex or sexual orientation, religion or belief, or age or any other protected characteristic and without prejudice to the generality of the foregoing the Supplier shall not unlawfully discriminate within the meaning and scope of the Equality Act 2010 and or other relevant or equivalent equalities legislation (or any statutory modification or re-enactment thereof) and shall ensure any Sub-contractor does the same.

19.5 The Supplier shall, and shall use reasonable endeavours to ensure that its employees, Sub-contractors and the employees of any Sub-contractors shall, at an times, act in a way which is compatible with the Convention rights within the meaning of Section 1 of the Human Rights Act 1998.

19.6 The Supplier agrees to indemnify and keep indemnified the Authority against all loss, costs, proceedings or damages whatsoever arising out of or in connection with any breach by the Supplier of its obligations under this Clause 19.

20 REPORTING AND CONTRACT MANAGEMENT

20.1 The Supplier shall keep all records in connection with the provision of the Product and Services as required under the Agreement , any Release Plan, any Exit Plan, details of financial transactions and payment of all sums under the Agreement and as the Authority may otherwise reasonably require for a period of six (6) years after the later of either the expiry or earlier termination of the Agreement

20.2 The Supplier shall provide the Authority and any person authorised in writing by the Authority with access to and copies of all records created under Clause 20.1 and any other documents, records, data and such other information related to the Stockpiled Product and the performance of the Services as may be reasonably required by the Authority, including access to all temperature monitoring records applicable to the Services and all records of all checks and inspections of the Product undertaken upon their receipt or collection, as appropriate, and stock records. The Supplier shall provide information and documents for review meetings in a format and medium specified by the Authority.

20.3 The Supplier shall comply with the reporting requirements set out in the Agreement.

20.4 Not Used

20.5 The Supplier shall participate in contract review meetings with the Authority at least once every four (4) months and at such other times as reasonably requested by the Authority from time to time. Such meetings may be conducted by phone or teleconference unless otherwise required by the Authority. Each Party shall ensure that those attending such meetings have the authority to make decisions regarding the day to day operation of the Agreement. The Supplier shall report to the Authority during such meetings about the Supplier's compliance with its obligations under the Agreement (including under Clause 5) and any agreed key performance indicators, and shall provide to the Authority all information reasonably requested by the Authority.

20.6 Review meetings shall include the Supplier's performance under the Agreement and matters arising generally under the Agreement, updates on production and sales of the Product, forecast information for the buffer stock, production plans and any Release Plan, Business Continuity Plan and/or Exit Plan. Two weeks prior to each review meeting the Supplier shall provide a written contract management report regarding the operation of this Agreement and a separate UK sales report for the preceding four months to the Authority. The contents of the contract management report shall be agreed between the Parties in writing within two (2) months of the date of this Agreement.

20.7 If any issue or problem arises or the Supplier reasonably believes an issue or problem may arise in relation to the Product and/or the performance of the Services, the Supplier shall notify the Authority in writing immediately.

20.8 In the event of an Authorised Release, a review meeting shall be arranged by the Supplier to take place immediately after the Authorised Release has taken place to report on, review and discuss how the Authorised Release process worked, and what improvements (if any) may be required and implemented for any future Authorised Releases. The Supplier shall provide the Authority will all information reasonably requested by the Authority in relation to the Authorised Release.

20.9 The Authority shall take minutes of each review meeting and shall circulate draft minutes to the Supplier within a reasonable time following such review meeting. The Supplier shall inform the Authority in writing of any suggested amendments to the minutes within five (5) Business Days of receipt of the draft minutes. If the Supplier does not respond to the Authority within such five (5) Business Days the minutes will be deemed to be approved. Where there are any differences in interpretation of the minutes, the Parties will use their reasonable endeavours to reach agreement. If agreement cannot be reached the matter shall be referred to, and resolved in accordance with, the dispute resolution procedure set out in clause 29.

20.10 The Supplier shall notify the Authority of the identity of the manager who is in charge of the provision of the Services to the Authority. The Authority may make representations to the Supplier concerning the performance of the manager from time to time. The Supplier shall have due regard for all such representations. If the Authority so requires, the Supplier will cease to use any given manager in connection with the Services and provide a replacement acceptable to the Authority within one (1) month of the date of request to do so. The manager shall have full authority to act on behalf of the Supplier during the Term. The Authority shall be entitled to treat any act of the manager in connection with the Agreement as being expressly authorised by the Supplier and the Authority shall not be required to determine whether any express authority has in fact been given. Unless given prior approval by the Authority the Supplier shall make the manager available for the entire period needed to fulfil his part in the provision of the Services, whilst he is employed or engaged by the Supplier.

20.11 The Supplier shall be responsible for the accuracy of all documentation and other information supplied to the Authority by the Supplier in connection with the performance of its obligations under the Agreement and shall pay the Authority any extra costs occasioned by any discrepancies, errors or omissions in it.

21 BUSINESS CONTINUITY

21.1 Throughout the Term, the Supplier shall ensure its Business Continuity Plan provides for continuity during a Business Continuity Event. The Supplier shall ensure that the Business Continuity Plan details and will continue to detail:

21.1.1 arrangements the Supplier has and will retain in place with third parties regarding continuity of supply of raw materials and manufacture and delivery of the Product during a Business Continuity Event;

21.1.2 arrangements the Supplier has and will retain in place to continue to deliver the Product in accordance with Clauses 2, 3 and 4 and provide any other Services during a Business Continuity Event;

21.1.3 how the Supplier will provide the Storage Services and associated Services during a Business Continuity Event, assuming that up to 50% of employees providing such Services may be unavailable;

21.1.4 robust arrangements the Supplier has and will retain in place with third parties regarding continuity of utility services at Storage Facilities and any other third party services connected with the delivery of the Product in accordance with Clauses 2, 3 and 4, provision of the Storage Services and provision of any other Services during a Business Continuity Event;

21.1.5 disaster recovery and emergency back-up facilities including back-up power supplies the Supplier has to enable the Services to be provided continuously notwithstanding an emergency, disaster or power failure or similar event arising at the Storage Facilities; and

21.1.6 how the Supplier will protect against and mitigate the effect of pilferage of the Stockpiled Product or security breaches.

21.2 The Supplier shall test its Business Continuity Plan at reasonable intervals and shall provide to the Authority copies of its Business Continuity Plan, any updated or revised Business Continuity Plan, evidence that the Supplier tests its Business Continuity Plan at reasonable intervals and information regarding the outcome of such tests.

21.3 Not Used

21.4 Throughout a Business Continuity Event, the Supplier shall immediately:

21.4.1 implement and comply with the Business Continuity Plan;

21.4.2 report to the Authority on its implementation of the Business Continuity Plan; and

21.4.3 use its best endeavours to continue to fulfil its obligations to supply the Product in accordance with the Delivery Schedule and maintain the Required Volume in accordance with the Agreement.

21.5 The Supplier must notify the Authority of any updates or revisions to its Business Continuity Plan during the Term. If the Authority considers that such updates or revisions increase any risks in relation to the Supplier's ability to satisfactorily perform the Services during a Business Continuity Event, the Authority may terminate the Agreement in accordance with Clause 16.3.

22 ADDITIONAL PROVISIONS

22.1 At any time during the Term the Authority shall be allowed immediate access to the Stockpile for any purpose whatsoever (including the collection, removal and rapid distribution of the Stockpiled Product and/or supply of the Stockpiled Product into the supply chain in the UK). The Supplier shall on receipt of a request immediately and

no later than twenty (24) hours from the Authority's request, provide to the Authority and any person authorised by the Authority:

22.1.1 unrestricted access to the Stockpile to allow the Authority to access and/or remove any Stockpiled Product efficiently from the Stockpile;

22.1.2 access to the Storage Facilities, vehicles and any other premises or facilities where the Stockpiled Product is stored and/or the Storage Services are carried out;

22.1 .3 access to any personnel and information necessary to enable the Authority to exercise its rights under this Clause 22 {including the records held under Clause 3 identifying the Stockpiled Product);

22.1 .4 delivery of the Stockpiled Product to the Storage Facilities loading bay in a deliverable state packaged for transportation and load the Product onto a vehicle provided by a third party for transportation by the Authority; and

22.1.5 any cooperation and assistance reasonably requested by the Authority in relation to the Authority exercising its rights under this Clause 22,

provided that, where the Authority removes any Stockpiled Product from the Stockpile it will immediately provide a report to the Supplier providing relevant details of the Removed Product, and any delivery or removal under this Clause other than as part of an Authorised Release shall not be deemed to be an Authorised Release.

23 DISCOUNTED BUYBACK

23.1 For each release of the Stockpiled Product in accordance with an agreed Exit Plan, the Supplier shall purchase the same Stockpiled Product at the Discounted Buyback Price.

24 INTELLECTUAL PROPERTY RIGHTS

24.1 The Supplier warrants, represents and undertakes to the Authority that either it is the sole proprietor and legal and beneficial owner of all Intellectual Property Rights in the Product or it is licensed by the relevant owners to supply the Product in accordance with the Agreement and shall use best endeavours to ensure that it remains the owner or licensee (as applicable) of the Intellectual Property Rights in the Product throughout the Term.

24.2 The Supplier grants to the Authority a non-exclusive irrevocable licence to use and to authorise third parties to use the Intellectual Property Rights in Units of the Product supplied under the Agreement for the purposes set out in the Service Description, the Specification of Product and/or the Agreement.

24.3 The Supplier shall indemnify and hold harmless the Authority against all claims, liabilities, losses, damages, costs (including legal costs) and expenses incurred in connection with any claim by any party that its Intellectual Property Rights have been infringed as a result of the supply of the Product under the Agreement or the use of the Product.

25 LIABILITY

25.1 The Supplier shall indemnify and keep indemnified the Authority against all actions, proceedings, costs, claims, demands, liabilities, direct losses and expenses whatsoever whether arising in tort (including negligence) default or breach of the Agreement, to the extent that any such loss or claim is due to the breach of contract, negligence, wilful default or fraud of itself or of its employees or of any of its representatives or Sub-contractors save to the extent that the same is directly caused by or directly arises from the negligence, breach of the Agreement or applicable law by the Authority or its representatives.

25.2 For the avoidance of doubt the Supplier shall indemnify and hold harmless the Authority against all claims, liabilities, direct losses, damages, costs (including reasonable legal costs) and expenses in respect of or relating directly or indirectly to any death or personal injury suffered by any person, where such death or personal injury arises or results or allegedly arises or results from the Product or the use of the Product.

25.3 The indemnity in Clause 25.2 shall not apply in respect of any death or personal injury arising from the use of the Product by the Authority to the extent attributable to the Authority accessing or using the Product in a manner contrary to any storage or administration requirements set out in the Marketing Authorisation.

26 LIMITATION OF LIABILITY AND INSURANCE

26.1 Nothing in the Agreement shall exclude or restrict the liability of either Party:

26.1.1 for death or personal injury resulting from its negligence;

26.1.2 for fraud or fraudulent misrepresentation; and/or

26.1.3 in any other circumstances where liability may not be limited or excluded under any applicable law.

26.2 Nothing in the Agreement shall exclude or restrict the liability of the Supplier under Clauses 24.1, 25.1, 35.3 and 36.3.

26.3 Subject to Clauses 26.1 and 26.2, the total liability of the Supplier under the Agreement shall be limited in aggregate to 125% (one hundred and twenty five percent) of the total gross sums paid or payable by the Authority to the Supplier under the Agreement.

26.4 The Authority shall promptly after receipt of any claim or notification of other circumstances to which an indemnity in the Agreement may apply, notify the Supplier of such fact and the Supplier shall assume the defence of any relevant claim or legal proceedings and the Authority shall provide the Supplier with all reasonable cooperation requested by the Supplier subject to the Supplier reimbursing the Authority's reasonable direct costs incurred in providing such cooperation; provided, however, that if the defendants in any such action include both of the Parties and/or both the Supplier and the Authority have reasonably concluded that there may be defences available to it which are different from, additional to or inconsistent with those available to the Supplier and/or the interests of the Authority and Supplier in respect of such action differ materially, the Authority shall have the right to select separate counsel to participate in the defence of such action on behalf of the Authority. In defending any legal proceedings under this Clause the Supplier:

26.4.1 shall use appropriately experienced lawyers;

26.4.2 shall defend any relevant claim robustly and expeditiously; and

26.4.3 shall not make an admission of liability or settle any relevant claim unless the admission or settlement is advised by the lawyer acting in defence of such claim and the Authority has provided its written consent to such admission or settlement, such consent not be unreasonably withheld or delayed.

26.5 In exercising any right to recover any sums in relation to any claims, liabilities, losses, damages, costs and expenses from the Supplier under any indemnity contained in the Agreement, such sums shall be reduced to the extent only that the Authority has not taken reasonable steps within its reasonable control to mitigate such claims, liabilities, losses, damages, costs or expenses and the direct effect of not taking such steps has been the inflation of such sums.

26.6 The Supplier shall not in any circumstances be liable under this Agreement for any indirect, special or consequential loss or damage.

26.7 Without prejudice to the generality of the foregoing, the Supplier shall insure with a reputable commercial insurer against its liability under the Agreement with a minimum limit of indemnity of £10 million per annum or such other sum as may be agreed between the Authority and the Supplier in writing or, to the extent such arrangements have been approved by the Authority in advance, self insure against its liability under the Agreement with a minimum indemnity provision of £10 million per annum or such other sum as may be agreed between the Authority and the Supplier in writing.

27 CONFIDENTIALITY AND TRANSPARENCY

27.1 For the purposes of this Clause 27, the term "Disclosing Party" shall mean a Party which discloses or makes available directly or indirectly its Confidential Information and "Recipient" shall mean the Party which receives or obtains directly or indirectly Confidential Information.

27.2 Except to the extent set out in this Clause 27 or where disclosure is expressly permitted elsewhere in the Agreement, the Recipient shall:

27.2.1 treat the Disclosing Party's Confidential Information as confidential and keep it in secure custody (which is appropriate depending upon the form in which such materials are stored and the nature of the Confidential Information contained in those materials);

27.2.2 not disclose the Disclosing Party's Confidential Information to any other person except as expressly set out in the Agreement or without obtaining the owner's prior written consent;

27.2.3 not use or exploit the Disclosing Party's Confidential Information in any way except for the purposes anticipated under the Agreement; and

27.2.4 immediately notify the Disclosing Party if it suspects or becomes aware of any unauthorised access, copying, use or disclosure in any form of any of the Disclosing Party's Confidential Information.

27.3 The Recipient shall be entitled to disclose the Confidential Information of the Disclosing Party where:

27.3.1 the Recipient is required to disclose the Confidential Information by Law, provided that Clause 28 shall apply to disclosures required under the FOIA or the EIRs;

27.3.2 the need for such disclosure arises out of or in connection with:

(i) any legal challenge or potential legal challenge against the Authority arising out of or in connection with the Agreement;

(ii) the examination and certification of the Authority's accounts (provided that the disclosure is made on a confidential basis) or for any examination pursuant to section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Authority is making use of the Services under the Agreement; or

(iii) the conduct of a Central Government Body review in respect of the Agreement; or

27.3.3 the Recipient has reasonable grounds to believe that the Disclosing Party 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.

27.4 If the Recipient is required by law to make a disclosure of Confidential Information, the Recipient shall as soon as reasonably practicable and to the extent permitted by law notify the Disclosing Party of the full circumstances of the required disclosure including the relevant Law and/or regulatory body requiring such disclosure and the Confidential Information to which such disclosure would apply.

27.5 The Supplier may disclose the Confidential Information of the Authority on a confidential basis only to:

27.5.1 its employees who are directly involved in the provision of the Services and need to know the Confidential Information to enable performance of the Supplier's obligations under the Agreement; and

27.5.2 its professional advisers for the purposes of obtaining advice in relation to the Agreement.

Where the Supplier discloses Confidential Information of the Authority pursuant to this Clause 27.5, it shall remain responsible at all times for compliance with the confidentiality obligations set out in the Agreement by the persons to whom disclosure has been made.

27.6 The Authority may disclose the Confidential Information of the Supplier:

27.6.1 on a confidential basis to any Central Government Body for any proper purpose of the Authority or of the relevant Central Government Body;

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

27.6.3 to the extent that the Authority (acting reasonably) deems disclosure necessary or appropriate in the course of carrying out its public functions;

27.6.4 on a confidential basis to a professional adviser, consultant, supplier or other person engaged by any of the entities described in Clause 27.6.1 (including any benchmarking organisation) for any purpose relating to or connected with the Agreement;

27.6.5 on a confidential basis for the purpose of the exercise of its rights under the Agreement; or

27.6.6 on a confidential basis to a proposed successor body in connection with any assignment, novation or disposal of any of its rights, obligations or liabilities under the Agreement,

and for the purposes of the foregoing, references to disclosure on a confidential basis shall mean disclosure subject to a confidentiality agreement or arrangement containing terms no less stringent than those placed on the Authority under this Clause 27.

27.7 Nothing in this Clause 27 shall prevent a Recipient from using any techniques, ideas or know-how gained during the performance of the Agreement in the course of its normal business to the extent that this use does not result in a disclosure of the Disclosing Party's Confidential Information or an infringement of Intellectual Property Rights.

27.8 The Parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA, the content of the Agreement is not Confidential Information. The Authority shall determine whether any of the content of the Agreement is exempt from disclosure in accordance with the provisions of the FOIA. The Authority may consult with the Supplier to inform its decision regarding any redactions but shall have the final decision in its absolute discretion.

27.9 Notwithstanding any other provision of the Agreement, the Supplier hereby gives its consent for the Authority to publish to the general public the Agreement in its entirety (but with any information which is exempt from disclosure in accordance with the provisions of the FOIA redacted), including any changes to the Agreement agreed from time to time.

27.10 The Supplier shall assist and co-operate with the Authority to enable the Authority to publish the Agreement.

28 FREEDOM OF INFORMATION

28.1 The Supplier acknowledges that the Authority is subject to the requirements of the FOIA and the ElRs. The Supplier shall:

28.1.1 provide all necessary assistance and cooperation as reasonably requested by the Authority to enable the Authority to comply with its obligations under the FOIA and EIRs;

28.1.2 transfer to the Authority all Requests for Information relating to the Agreement that it receives as soon as practicable and in any event within two (2) Business Days of receipt;

28.1.3 provide the Authority with a copy of all Information belonging to the Authority requested in the Request for Information which is in its possession or control in the form that the Authority requires within five (5) Business Days (or such other period as the Authority may reasonably specify) of the Authority's request for such Information; and

28.1.4 not respond directly to a Request for Information unless authorised in writing to do so by the Authority.

28.2 The Supplier acknowledges that the Authority may be required under the FOIA and EIRs to disclose Information (including Commercially Sensitive Information) without consulting or obtaining consent from the Supplier. The Authority shall take reasonable steps to notify the Supplier of a Request for Information (In accordance with the Secretary of State's section 45 Code of Practice on the Discharge of the Functions of Public Authorities under Part 1 of the FOIA) to the extent that it is permissible and reasonably practical for it to do so but (notwithstanding any other provision in the Agreement) the Authority shall be responsible for determining in its absolute discretion whether any Commercially Sensitive Information and/or any other information is exempt from disclosure In accordance with the FOIA and/or the EIRs.

29 DISPUTES

29.1 The Supplier confirms to the Authority that it is not aware of any dispute or circumstances likely to give rise to a dispute relating to the production, design, supply or use of the Product or provision of the Services.

29.2 During any dispute, including a dispute as to the validity of the Agreement, the Supplier shall continue its performance of the provisions of the Agreement (unless the Authority requests in writing that the Supplier does not do so).

29.3 The Authority and the Supplier shall attempt in good faith to negotiate a settlement to any dispute between them arising out of or in connection with the Agreement within twenty (20) Business Days of either notifying the other Party of the dispute and such efforts shall involve the escalation of the dispute to senior management of each Party.

29.4 Nothing in this dispute resolution procedure shall prevent the Authority or the Supplier from seeking from any court of competent jurisdiction an interim order restraining the other Party from doing any act or compelling the other Party to do any act.

29.5 If the dispute cannot be resolved by the Authority and the Supplier in accordance with Clause 29.4, the Parties will attempt to settle it by mediation in accordance with the latest version of the Centre for Effective Dispute Resolution ("CEDR") Model Mediation Procedure or any other model mediation procedure as agreed by the Parties.

29.6 To initiate mediation a Party shall give notice in writing (a "Mediation Notice") to the other Party requesting mediation of the dispute and shall send a copy thereof to CEDR or an equivalent mediation organisation as agreed by the Parties asking them to nominate a mediator in the event that the Parties shall not be able to agree such

appointment by negotiation. The mediation shall commence within twenty eight (28) days of the Mediation Notice being served.

29.7 Neither Party will terminate such mediation until each Party has made its opening presentation and the mediator has met each Party separately for at least one hour or one Party has failed to participate in the mediation process. Thereafter paragraph 9 of the CEDR Model Mediation Procedure (or the equivalent paragraph of any other model mediation procedure agreed by the Parties) will apply.

29.8 Neither Party will commence legal proceedings against the other until thirty (30) days after such mediation of the dispute in question has failed to resolve the dispute. The Authority and the Supplier will co-operate with any person appointed as mediator providing him with such with such information and other assistance as he shall require and will pay his costs, as he shall determine or in the absence of such determination such costs will be shared equally.

29.9 Nothing in the Agreement shall prevent:

29.9.1 the Authority taking action in any court in relation to any death or personal injury arising or allegedly arising in connection with the Product or Services; or

29.9.2 either Party seeking from any court any interim or provisional relief that may be necessary to protect the rights or property of that Party, pending resolution of the relevant dispute in accordance with the CEDR procedure.

30 DATA PROTECTION

30.1 The Parties acknowledge their respective duties under the Data Protection Legislation and shall give each other all reasonable assistance as appropriate or necessary to enable each other to comply with those duties. For the avoidance of doubt, the Supplier shall take reasonable steps to ensure it is familiar with the Data Protection Legislation and any obligations it may have under such Data Protection Legislation and shall comply with such obligations.

30.2 Where the Supplier is Processing Personal Data under or in connection with the Agreement, the Parties shall comply with the Data Protection Protocol.

30.3 The Supplier and the Authority shall ensure that Personal Data is safeguarded at all times in accordance with the Law, and this obligation will include (if transferred electronically) only transferring Personal Data (a) if essential, having regard to the purposes for which the transfer is conducted; and (b) that is encrypted in accordance with any applicable international data encryption standards for healthcare, and as otherwise required by those standards applicable to the Authority under any Law and guidance (this included data transferred over wireless or wired networks, held on laptops, CDs, memory sticks and tapes).

30.4 Where any Personal Data is Processed by any Sub-contractor in connection with the Agreement, the Supplier shall procure that such Sub-contractor shall comply with the relevant obligations set out in this Clause 30 as if such Sub-contractor were the Supplier.

30.5 The Supplier shall indemnify and keep the Authority indemnified against any loss, damages, costs, expenses (including without limitation legal costs and expenses),

claims or proceedings whatsoever or howsoever arising from the Supplier's unlawful or unauthorised Processing, destruction and/or damage to Personal Data in connection with the Agreement.

31 FORCE MAJEURE

31.1 Subject to Clause 31.2, neither Party shall be considered to be in default or liable for breach of any obligation hereunder nor liable to the other Party for any loss or damage whatsoever arising out of the prevention, hindrance or delay of the performance of any such obligation to the extent that the performance of such obligation is prevented, hindered or delayed by an event of Force Majeure.

31.2 The Supplier shall only be entitled to rely on an event of Force Majeure under Clause 31 if the Supplier has fulfilled its obligations pursuant to Clause 21 and the circumstances set out in Clause 8.1.3 do not apply.

31.3 A Party wishing to rely on an event of Force Majeure shall promptly and in any event within seven (7) days of becoming aware of the same give written notice to the other Party of the nature of the event of Force Majeure and its impact and shall use its best endeavours to mitigate the effects of such event of Force Majeure.

31.4 If an event of Force Majeure relied on by the Supplier shall subsist for twenty eight (28) days or more then the Authority shall have the right to terminate the Agreement immediately by giving notice to the Supplier.

31.5 On the occurrence of an event of Force Majeure the Parties shall meet as soon as reasonably practicable and acting in good faith shall use all reasonable endeavours (but without incurring undue costs) to agree the measures (if any) necessary to mitigate the effects of such event of Force Majeure and or to remedy any effects of the Force Majeure and, subject to Clause 31.2, the obligations of the Parties shall be suspended to the extent that they are affected by such event of Force Majeure unless and until:

31.5.1 the event of Force Majeure shall have ceased and any such measures shall have been agreed and the damage shall have been remedied pursuant to such agreement; or

31.5.2 the Agreement is terminated whichever shall be the earlier.

31.6 Where the Agreement shall be terminated for Force Majeure the provisions in Clause 17 (Consequences of Termination) and Clause 18 (Exit Plan(s) and Exit Phase(s)) shall apply with such amendments as the Parties may, acting reasonably, agree.

32 RIGHT OF AUDIT

32.1 The Supplier shall keep secure and maintain for the Term and six (6) years thereafter, or such longer period as may be agreed between the Parties, full and accurate records of all matters relating to the Agreement.

32.2 The Supplier shall grant to the Authority or its authorised agents, such access to those records as they may reasonably require in order to check the Supplier's compliance with the Agreement for the purposes of:

32.2.1 the examination and certification of the Authority's accounts; or

32.2.2 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.

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

32.4 The Authority shall have the right to audit the Supplier's compliance with the Agreement. The Supplier shall permit or procure permission for the Authority or its authorised representative during normal business hours having given advance notice of no less than five (5) Business Days, access to any premises and facilities, books and records used in the performance of the Supplier's obligations under the Agreement.

33 ENVIRONMENTAL CONSIDERATIONS

33.1 The Supplier shall comply in all material respects with applicable environmental laws and regulations in force from time to time in relation to the Product and the Services. Where the provisions of any such legislation are implemented by the use of voluntary agreements or codes of practice, the Supplier shall comply with such agreements or codes of practice as if they were incorporated into English law subject to those voluntary agreements being cited in the Service Description. Without prejudice to the generality of the foregoing, the Supplier shall:

33.1.1 comply with all reasonable stipulations of the Authority aimed at minimising the packaging in which the Product is supplied;

33.1.2 promptly provide such data as may reasonably be requested by the Authority from time to time regarding the weight and type of packaging according to material types used in relation to the Product;

33.1.3 comply with all obligations imposed on it in relation to the Product by the Producer Responsibility Obligations (Packaging Waste) Regulations 2005 (or any other equivalent legislation giving effect in any part of the European Economic Area to the Packaging and Packaging Waste Directive94/62/EC);

33.1.4 without prejudice to the Supplier's other obligations under the Agreement, label all Units of the Product, and the packaging of those Units, to highlight environmental and safety information as required by applicable UK and EU legislation;

33.1.5 promptly provide all such information regarding the environmental impact of the Product as may reasonably be required by the Authority to permit informed choices by patients and other third parties; and

33.1.6 where the Product is imported into the United Kingdom then for the purposes of the Producer Responsibility Obligations (Packaging Waste) Regulations 2005, assume the rolled-up obligations for all the activities performed outside the United Kingdom in relation to the

Product and the packaging which is used for the containment, protection, handling, delivery and presentation of the Product in addition to any other obligations it may have pursuant to the said Regulations.

33.2 The Supplier shall meet all reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of this Clause 33.

34 SUB-CONTRACTING AND ASSIGNMENT

34.1 The Supplier shall not sub-contract any of its obligations to a Storage Provider or any of its obligations under Clauses 2 to 6 without the Authority's prior written consent, which, subject to Clause 34.2, shall not be unreasonably withheld or delayed.

34.2 The Authority may withhold or delay its consent where it considers that:

34.2.1 the appointment of a proposed Sub-contractor may prejudice the delivery of the Product or the provision of the Services or be contrary to the interests of the Authority;

34.2.2 the proposed Sub-contractor is considered not to be sufficiently reliable and/or has not provided reasonable services to its other customers; and/or

34.2.3 the proposed Sub-contractor employs unfit persons.

34.3 Subject to Clause 34.4, in making a request pursuant to Clause 34.1 the Supplier shall provide the Authority with the following information about the proposed Sub-contractor:

34.3.1 its name, registered office and company registration number;

34.3.2 a copy of the proposed Sub-contract;

34.3.3 the purposes for which the proposed Sub-contractor will be employed, including the scope of any services to be provided by the proposed Sub-contractor; and

34.3.4 any further information reasonably requested by the Authority.

34.4 If the supply of information required pursuant to Clause 34.3 would amount to a breach of any rules and regulations of any exchange on which the shares of the Supplier are admitted for listing and/or trading, or any other rules or regulations with which the Supplier is obliged to comply as a result of that listing, the Supplier shall provide the Authority with the relevant information to the fullest extent permitted by those rules and regulations.

34.5 The Supplier shall ensure that any Sub-contract with a Storage Provider includes provisions restricting the ability of the Storage Provider to further sub-contract elements of the service provided to the Supplier without first seeking the consent of the Authority.

34.6 The Supplier shall not terminate or materially amend the terms of any Sub-contract relating to any obligations referred to in Clause 34.1 without the Authority's prior written consent, which shall not be unreasonably withheld or delayed.

34.7 Notwithstanding the Supplier's right to sub-contract pursuant to this Clause 34, the Supplier shall remain responsible for all acts and omissions of its Sub-contractors and the acts and omissions of those employed or engaged by the Sub-contractors as if they were its own. An obligation on the Supplier to do, or to refrain from doing, any act or thing shall include an obligation upon the Supplier to procure that its employees, staff, agents and Sub-contractors' employees, staff and agents also do, or refrain from doing, such act or thing.

34.8 Without prejudice to Clause 34.7, the Supplier shall remain responsible for all acts and omissions of any Storage Provider and the acts and omissions of those employed or engaged by the Storage Provider as if they were its own. An obligation on the Supplier to do, or to refrain from doing, any act or thing shall include an obligation upon the Supplier to procure that the Storage Provider and its Sub-contractors' employees, staff and agents also do, or refrain from doing, such act or thing.

34.9 Any authority given by the Authority for the Supplier to sub-contract any of its obligations hereunder shall not impose any duty on the Authority to enquire as to the competency of any authorised Sub-contractor, and the Supplier shall ensure that any authorised Sub-contractor has the appropriate capability and capacity to perform the relevant obligations and that the obligations carried out by such Sub-contractor are fully in accordance with the Agreement.

34.10 The Supplier shall not assign or in any other way dispose of the whole or any part of the Agreement without the prior written consent of the Authority.

35 PREVENTION OF CORRUPTION

35.1 The Supplier shall not offer or give, or agree to give, to the Authority or any other public body or any person employed by or on behalf of the Authority or any other public body any gift or consideration of any kind as an inducement or reward for doing, refraining from doing, or for having done or refrained from doing, any act in relation to the obtaining or execution of the Agreement or any other contract with the Authority or any other public body, or for showing or refraining from showing favour or disfavour to any person in relation to the Agreement or any such contract.

35.2 The Supplier warrants that it has not paid commission or agreed to pay commission to the Authority or any other public body or any person employed by or on behalf of the Authority or any other public body in connection with the Agreement.

35.3 If the Supplier, its staff or anyone acting on the Supplier's behalf, engages in any offence under the Bribery Act 2010, the Authority may:

35.3.1 terminate the Agreement and recover from the Supplier the amount of any direct Joss suffered by the Authority resulting from the termination, including the cost reasonably incurred by the Authority of making other arrangements for the supply of the Services and any additional expenditure incurred by the Authority throughout the remainder of the Term; or

35.3.2 recover in full from the Supplier any other direct loss sustained by the Authority in consequence of any breach of this Clause 35.

36 PREVENTION OF FRAUD

36.1 The Supplier shall take all reasonable steps, in accordance with Good Industry Practice, to prevent fraud by staff and the Supplier (including its shareholders, members, directors) in connection with the receipt of monies from the Authority.

36.2 The Supplier shall notify the Authority immediately if it has reason to suspect that any fraud has occurred or is occurring or is likely to occur.

36.3 If the Supplier or its staff commits fraud in relation to this or any other contract with the Crown (including the Authority) the Authority may:

36.3.1 terminate the Agreement and recover from the Supplier the amount of any direct loss suffered by the Authority resulting from the termination, including the cost reasonably incurred by the Authority of making other arrangements for the supply of the Services and any additional expenditure incurred by the Authority throughout the remainder of the Term; or

36.3.2 recover in full from the Supplier any other direct loss sustained by the Authority in consequence of any breach of this Clause 36.

37 WAIVER

37.1 No forbearance or delay by either Party in enforcing its respective rights will prejudice or restrict the rights of that Party, and no waiver of any such rights or of any breach of any contractual terms will be deemed to be a waiver of any other right or of any later breach. In particular, but without limitation to the generality of the foregoing, any prior acceptance or approval communicated by the Authority to the Supplier in respect of the Services or any omission on the part of the Authority to communicate such prior acceptance or approval shall not relieve the Supplier of its obligations to deliver the Services in accordance with the provisions of the Agreement.

38 CUMULATION OF REMEDIES

38.1 Subject to the specific limitations set out in the Agreement, no remedy conferred by any provision of the Agreement is intended to be exclusive of any other remedy except as expressly provided for in the Agreement and each and every remedy shall be cumulative and shall be in addition to every other remedy given thereunder or existing at law or in equity by statute or otherwise.

39 SEVERABILITY

39.1 If any of the provisions of the Agreement is judged to be illegal or unenforceable, the continuation in full force and effect of the remainder of them will not be prejudiced.

40 PARTNERSHIP OR AGENCY

40.1 Nothing in the Agreement shall be construed as constituting a partnership between the Parties or as constituting either Party as the agent of the other for any purpose whatsoever except as specified by the terms of the Agreement.

41 THIRD PARTY RIGHTS

41.1 No term of the Agreement is intended to confer a benefit on, or to be enforceable by, any person who is not a party to the Agreement.

42 PUBLICITY

42.1 The Supplier shall not:

42.1.1 make any press announcements or publicise the Agreement or its contents in any way; or

42.1.2 use the Authority's name or brand in any promotion or marketing or announcement of orders,

without the prior written consent of the Authority.

43 ENTIRE AGREEMENT

43.1 These terms, the Schedules and the documents annexed to it or otherwise referred to in it contain the entire agreement between the Parties relating to the subject matter hereof and supersede all prior agreements, arrangements and understandings between the Parties relating to that subject matter.

43.2 The Supplier acknowledges and agrees that it has not relied on any representation, warranty or undertaking (whether written or oral) in relation to the subject matter of the Agreement and therefore irrevocably and unconditionally waives any rights it may have to claim damages against the Authority for any misrepresentation (whether made carelessly or not) or for breach of any warranty unless the representation relied upon is set out in the Agreement or unless such representation was made fraudulently.

44 VARIATION

44.1 Any variation must be agreed in writing by the Parties.

45 COUNTERPARTS

45.1 The Agreement may be executed in any number of counterparts, each of which when executed and delivered shall constitute an original of the Agreement, but all the counterparts shall together constitute the same Agreement.

46 GOVERNING LAW AND JURISDICTION

46.1 The Agreement and any dispute or claim arising out of or in connection with it or its subject matter shall be governed by and construed in accordance with the law of England and Wales.

46.2 The Parties irrevocably agree that, subject to Clause 29 (Disputes), the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with the Agreement or its subject matter.

47 MISCELLANEOUS

47.1 The Supplier acknowledges that the Authority has entered into the Agreement in the context of the exercise of performance of the duties of the Secretary of State for Health and Social Care under the National Health Service Act 1977 as replaced by the National Health Service Act 2006, the National Health Service (Scotland) Act 1978 and/or the Health and Personal Social Services (Northern Ireland) Order 1972 S.I 1972/1265 (N.1.1 4).

IN WITNESS whereof the Agreement has been entered into on the 27th Day of January 2022

SIGNED BY: .edacted Under FOIA Section 40, Personal Information

FOR AND ON BEHALF OF THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE

NAME edacted Under FOIA Section 40, Personal Information

POSITION Senior Manager, Vaccines and Medicines Countermeasure Team

DATE: 27th January 2022

FOR AND ON BEHALF OF THE SUPPLIER

(NAME) edacted Under FOIA Section 40, Personal Information

POSITION SVP Commercial Operations

DATE: 27th January 2022

SIGNED BY: edacted Under FOIA Section 40, Personal Information

SCHEDULE 1

Contract Price

Redacted Under FOIA Section 43(2), Commercial Interests

SCHEDULE 2

Buyback Price

Redacted Under FOIA Section 43(2), Commercial Interests

SCHEDULE 3

Release Plan Template

Redacted Under FOIA Section 43(2), Commercial Interests

SCHEDULE 4

Delivery Notice & Delivery Schedule Templates

Redacted Under FOIA Section 43(2), Commercial Interests

SCHEDULE 5

Supplier's Business Continuity Plan

Redacted Under FOIA Section 43(2), Commercial Interests

SCHEDULE 6

Exit Plan template

Redacted Under FOIA Section 43(2), Commercial Interests

SCHEDULE 7

Stock Report

Redacted Under FOIA Section 43(2), Commercial Interests

SCHEDULE 8

Service Description

1 REQUIREMENT:

To store and manage the buffer stock (this stock is classed as ring fenced virtual stock, but should be recycled as part of BAU stock to ensure end of shelf life is not reached) of 40,000 units of the naloxone product (Prenoxad) 1mg/ml Injection for use in a community setting, in a sealed box, with a suitable needle for intramuscular use and with instructions aimed at non-medics in the community.

The supplier is to be responsible for the manufacturing of replacement product, storage and delivery on behalf of DHSC in line with standard licencing and procedures of the reserve buffer stock of 40,000 kits. This is in addition to any normal business as usual (BAU) stock. The supplier is to cycle this reserve through their BAU stock on a first expiry, first out basis to reduce the likelihood of the product expiring whilst in stock. The buffer stock is to be utilised as a reactive supply in the event of an increase of demand against BAU stock, the increase in demand is to cover the whole of the UK, not just England.

2 DELIVERY:

The buffer stock must be delivered to customers in response to exceptional demand, this is only to be used when BAU stock has been exhausted. This is to be executed in the same manner as BAU model. From the commencement of the contract the Supplier must be able to react to local demand and fulfil all orders successfully within agreed timescales, ensuring that wholesalers have sufficient stock to guarantee delivery in a timely manner.

3 STORAGE:

The buffer stock is to be held at suppliers' premises, including third party storage and distribution providers. Arrangements to be in put in place for rapid supply throughout their wholesalers, to ensure successful response to surge in demand. Storage, handling and transportation of products to be in accordance with manufacturers' guidelines and procedures.

4 REPLENISHMENT OF STOCK:

Supplier is to obtain permission from DHSC before utilising the additional buffer stock for BAU orders. Clearance will only be obtained when supplier provides a detailed explanation of reasons why this stock is to be used for BAU supported by a contingency plan to replace the stock.

5 CONTRACT DURATION AND EXTENSION PROVISION:

The contract start date is 1 October 2021 and will run for an initial period of 18 months, up to 31st March 2023. Extension provision for a further period of up to 12 months.

6 DISCOUNTED BUY BACK DETAILS:

Redacted Under FOIA Section 43(2), Commercial Interests

7 DETAILS OF LICENCES THROUGHOUT SUPPLY CHAIN

Supplier must hold UK licence, which should include wholesale dealers and manufacturing authorisations issued by MHRA

8 STORAGE COSTS & PAYMENT

Redacted Under FOIA Section 43(2), Commercial Interests

9 REPORTING

As set out in clause 20 of this Agreement

10 LEVELS OF INSURANCE

Insurance limits to be at a minimum indemnity limit of £10m per annum

11. MINIMUM ORDER TO EACH CUSTOMER

The supplier must endeavour to ensure all additional buffer stock is distributed to customers in genuine need. Rationing mechanisms to be put into place.

SCHEDULE 9

Offer

Redacted Under FOIA Section 43(2), Commercial Interests