CONTRACT

BETWEEN

The Secretary of State for Health and Social Care

and

Baxter Healthcare Ltd

FOR THE SUPPLY, STORAGE AND MANAGEMENT OF A BUFFER STOCK OF MEDICINES FOR INTRAVENOUS FLUIDS AND PERITONEAL DIALYSIS FLUIDS

CONTENTS

Conditions of Contract

Contract for the supply and storage of Intravenous Fluids and Peritoneal Dialysis Fluids

THIS AGREEMENT is made on ……

BETWEEN:

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

(2) **Baxter Healthcare Ltd**, company number 461365 whose registered office is at Caxton Way, Thetford, Norfolk, IP24 3SE ("**Supplier**").

BACKGROUND:

A The Authority previously contracted with the Supplier for the storage and maintenance of the Products following tenders published in the Official Journal of the European Union on 10th March 2018 and 26th June 2018 respectively. This contract expired on 31st March 2022, following a number of extensions.

B The Authority wishes to continue the arrangements previously contracted for and intends to make a direct award under an exemption from the need to tender on the basis of Regulation 32 (2) b of the Public Contracts Regulations.

C The Supplier will be responsible for rotating the stock of the Products so that it has a minimum agreed shelf life throughout the Term. It is intended for the Products to be distributed for patients solely in the UK during an influenza pandemic or other emergency in the UK and for this purpose the Stockpiled Products must be stored in the UK. In the event of an influenza pandemic or other emergency in the UK, the Authority can direct suppliers to buy back all or some of the stock they hold and release it through the normal UK supply chain. If a release occurs, the Authority may wish to build the Stockpile back to its initial levels, and the Agreement makes provision for that.

D In the period leading up to expiry of this Agreement, or any earlier reduction in Required Volume or partial termination, the Supplier will be required, through an agreed exit plan, to buy back the stock. Title to the stock (prior to any buy back) will remain with the Authority, but the Supplier must store the stock at their own risk and manage it, to include regular reporting and review meetings with the Authority. The stock should also be subject to the Supplier's own internal audits and will be audited by NHS Business Services Authority on behalf of the Authority at least once a year.

E This Agreement is for 12 months from 1 April 2022 expiring on 31 March 2023.

IT IS AGREED as follows:

1 INTERPRETATION

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

Words and Expressions	Meaning
Agreement	these Conditions, the attached Schedules and so far, as expressly incorporated the Invitation to Tender and the Supplier's Offer, which in the event of any inconsistency, shall take priority in that order
Authorised Release	an event commencing when the Authority gives notice to the Supplier under Clause 5 or Clause 18 to allow a release of the Stockpiled Products in accordance with an agreed Release Plan or Exit Plan
Average UK Price	for each week, the mean price of the relevant Product over the week which shall be calculated as follows: (A / B) where: A = the total value of sales (in British pound Sterling (£)) of the Product made by the Supplier within the UK in that week. Such sales to: (a) include sales to wholesalers and retailers; (b) include sales in a primary care setting and secondary care setting; and (c) exclude any distribution fee or delivery charge; and B = the total number of packs / unit sales of the Product made by the Supplier within the UK in that week. Such sales to: (a) include sales to wholesalers and retailers; (b) include sales in a primary care setting and secondary care setting; and (c) exclude any distribution fee or delivery charge
Business Continuity Event	any event or issue that could impact on the operations of the Supplier and its ability to supply the Products 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 sake of clarity, the BCP shall include but is not restricted to the manufacturing process of the Products, 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	as set out in Clause 19.2
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	such information notified by the Supplier to the Authority within 2 weeks of the date of this agreement comprising the information of a commercially sensitive nature relating to the Supplier, its IPRs or its business or which the Supplier has indicated to the Authority 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: (i) was public knowledge at the time of disclosure (subject to Clause 23); (ii) was in the possession of the receiving Party, without restriction as to its disclosure, before receiving it from the disclosing Party; (iii) is received from a third party (who lawfully acquired it) without restriction as to its disclosure; or (iv) is independently developed without access to the Confidential

Information

Defective Product	any Unit of the Products supplied under this Agreement which: (i) 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; or (ii) does not conform to or is not produced in accordance with Good Distribution Practice, Good Manufacturing Practice, Good Industry Practice or the Specification or the Marketing Authorisation; or (iii) has not been dealt with in accordance with Good Industry Practice; or (iv) otherwise fails to conform to the requirements of this Agreement
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
Data Protection Legislation	the DPA and all applicable Law about processing of personal data and privacy
DPA	the Data Protection Act 2018 and any other subordinate legislation made under such Act from time to time together with any Guidance and/ or codes of practice issued by the Information Commissioner or relevant government department in relation to such legislation
Effective Date	the effective date of this Agreement being 1st April 2022
EMEA	the European Medicines Agency
Emergency	a Pandemic or other serious and unexpected situation, where the Authority decides that the normal supply chain of a Stockpiled Product cannot meet the demand
Emergency Authorised Release	as defined in Clause 5.1
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
Force Majeure	means any of the following insofar as the relevant event is beyond the control of the Party in question: (i) 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 Agreement; (ii) acts of terrorism (unconnected with the Emergency); (iii) acts of God; (iv) flood, storm or other like natural disasters; (v) fire; (vi) prolonged unavailability of public utilities to the extent no diligent supplier could reasonably have planned for such unavailability as part of its business continuity planning; (vii) 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; (viii) compliance with any local law or governmental order, rule, regulation or direction that could not have been reasonably foreseen where the compliance is necessary for reasons other than the Emergency, and for the avoidance of doubt a pandemic shall not be a Force Majeure
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
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 (MA) or product specification
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 and the QTA
Guidance	means any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to the Products, 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, NHS England/Improvement, the MHRA, the European Medicine Agency 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)
Intellectual Property Rights	means all patents, copyright, design rights, registered designs, trade marks, know-how, database rights, confidential formula e and any other intellectual property rights and the rights to apply for patents and trade marks and registered designs
Invitation to Tender	the invitation to tender issued by the Authority for the storage and maintenance of the Products
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
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 Products to be supplied and stockpiled under this Agreement
MHRA	Medicines and Healthcare products Regulatory Agency
Pandemic	the pandemic phase as defined in the 'Pandemic Influenza Risk Management World Health Organisation Interim Guidance' or such other categorisation the World Health Organisation may give to a pandemic from time to time
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 together
Personal Data	shall have the meaning given in the DPA
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 under DPA and, for the purposes of this Agreement, it shall include both manual and automatic processing. Processing and Processed shall be construed accordingly;
Products	the products stored and maintained by the Supplier as set out in Schedule 1
Registered Shelf Life	the shelf life that the Products are registered as having as part of the Marketing Authorisation process
Quality Technical	the Quality Technical Agreement entered into between the Authority and the Supplier related to the Products as

Agreement (QTA)	amended and updated from time to time by the Parties (to the QTA)
Regulations	the Public Contracts Regulations 2015 (SI 2015/102) as amended
Rejected Product	any Units of the Products rejected by the Authority under Clause 7.3 or 7.4
Release Plan	a plan for the Emergency Authorised Release of the Stockpiled Products prepared under this Agreement in the form set out in Schedule 4 and sent to Mohammed Sohail (mohammed.sohail@dh.gsi.gov.uk) or such other person notified to the Supplier by the Authority
Released Products	Stockpiled Products that are 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 4
Replacement Products	Products used to replace: (a) Stockpiled Products removed from the Stockpile in accordance with Clause 2; and (b) Rejected Products
Required Volume	has the meaning set out in Schedule 1 in respect of each of the Products, as varied in accordance with Clause 5
Request for Information	a request for information under the FOIA or the EIRs;
Services	the storage of the Products, the supply and delivery to the stockpile of the Products in accordance with Clause 4, stock rotation and any Authorised Release in accordance with this Agreement, and any other services provided by the Supplier under this Agreement
Shelf Life	the shelf life of each of the Products set out in Schedule 1
Specification(s)	the specification(s) of the Products set out in Schedule 1
SmPC	means the Summary of Product Characteristics
Stock Report	to be provided as set out in Schedule 6
Stockpile	where the Stockpiled Products are held within the Storage Facilities
Stockpiled Products	Products held in and stored within the Stockpile, including any Replacement Products supplied under this

Storage Charge	the weekly charge for Storage Services and other services in respect of each pallet of Product as set out in Schedule 1
Storage Facilities	the location(s) in the United Kingdom where the Stockpiled Products are to be stored, as set out in Schedule 3
Storage Provider	any third-party provider of Storage Services appointed by the Supplier in accordance with Clause 30 as set out in Schedule 3
Storage Services	storage of the Products in accordance with Clause 4
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
Supplier's Offer	the offer submitted by the Supplier in response to the Invitation to Tender
Term	a period of 12 months from the Effective Date to 31 March 2023
Unit	a unit of the Products
Wholesale Distribution Authorisation	has the meaning set out in the Human Medicines Regulations 2012/2016 or any replacement regulation.

1.2 In this Agreement unless a provision otherwise expressly provides:

1.2.1 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);

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

1.2.3 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;

1.2.4 Schedules shall mean the schedules to this Agreement;

1.2.5 Clauses shall mean the clauses of this Agreement;

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

1.2.7 any notice or communications to be given under this Agreement by either Party to the other shall be in writing and may be sent by post or by e-mail. All notices or confirmations sent by post shall be sent by first class recorded or registered post addressed to the other Party at its registered office or principal place of business, 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.

1.2.8 each and every obligation of a Party under this Agreement is to be performed at that Party's cost.

1.3 Where a term of this 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 this 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.

1.4 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.

1.5 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.

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

2 STOCK ROTATION

2.1 The Supplier shall ensure that:

2.1.1 the Required Volume of Stockpiled Products is maintained in the Stockpile throughout the Term, subject only to Authorised Releases under a Release Plan or Exit Plan in accordance with this Agreement;

5.1.2 all Stockpiled Products in the Stockpile with a Registered Shelf Life of more than 12 months shall at all times throughout the Term have an unexpired shelf life of at least 12 months; and

5.1.3 all Stockpiled Products in the Stockpile with a Registered Shelf Life of twelve months or less shall at all times throughout the Term have an unexpired shelf life of at least 10 months.

2.2 The Supplier may remove (sell or otherwise dispose of) Stockpiled Products from the Stockpile for the purpose of complying with Clause 2.1, provided that no later than such removal the Supplier has placed in the Stockpile in accordance with this Agreement at least sufficient Units of Replacement Product to replace the removed Stockpiled Products as are necessary to comply with its obligation under Clause 2.1, and that on removal of any Stockpiled Products under this Clause it shall make a written record relating to the Stockpiled Products removal.

Such Units of Replacement Product shall be supplied into the Stockpile without charge.

2.3 Save as set out in Clause 2.2, the Supplier shall not remove any Stockpiled Products from the Stockpile, without the Authority's prior written notice.

2.4 The Supplier shall not at any time use the Stockpiled Products to further its position in the market for the relevant Products.

2.5 If changes are required to a Product as a result of a licensing change (such as a new pack insert or change to the packaging), the Supplier at no additional charge to the Authority, shall rotate the Stockpile to ensure it is compliant with those changes.

3 MANUFACTURE AND CHAIN OF SUPPLY

3.1 The Supplier shall ensure that:

3.1.1 it has or it has access to manufacturing capacity for each Product sufficient to comply with its obligations under this Agreement;

3.1.2 the production facilities used in the manufacture of the Products are in a state and condition necessary to comply with any legal requirements in relation to the Products, and their production and to enable the Supplier to comply with its obligations to supply the Products to the Authority in accordance with this Agreement;

3.1.3 all Products when manufactured are done so with all due care and skill and are 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 product specification, and the relevant SmPC.

4 STORAGE SERVICES

4.1 The Supplier shall store the Stockpiled Products in the Stockpile at the Storage Facilities in accordance with this Agreement and shall invoice the Authority for these Storage Services as set out in Schedule 1.

4.2 The Supplier shall maintain the Storage Facilities in accordance with:

4.2.1 the Marketing Authorisation for the relevant Stockpiled Products;

4.2.2 the Wholesale Distribution Authorisation;

4.2.3 any other requirements of the Licensing Authority; and

4.2.4 Good Industry Practice.

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

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

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

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

4.4 The Supplier shall:

4.4.1 store the Stockpiled Products in accordance with strict temperature controls as specified in the relevant SmPC and as required to ensure that the Stockpiled Products remain in good and useable condition;

4.4.2 maintain records showing the temperature controls implemented under Clause 4.4.1 above at all times and make such records available to the Authority on request;

4.4.3 ensure all Stockpiled Products are clearly identifiable as Stockpiled Products belonging to the Authority;

4.4.4 store, handle and carry the Units of the Stockpiled Products separately from any other goods;

4.4.5 allocate sufficient space at the Storage Facilities to store the Stockpiled Products in the Required Volume;

4.4.6 ensure that Products are 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 different Stockpiled Products, and each Stockpiled Product by reference to different characteristics such as formulation, shelf life, pack size or other relevant characteristics;

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

4.4.8 enter into a Quality Technical Agreement (QTA) with the Authority to ensure compliance with the Authority's Wholesale Distribution Authorisation;

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

4.4.10 implement a comprehensive stock management system in respect of the Stockpiled Products in accordance with the Law and Guidance, and provide any information in relation to stock control of the Stockpiled Products that may be requested by the Authority;

4.4.11 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;

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

4.4.13 ensure the number of products used should not change from that detailed in Schedule 1 unless an increase or decrease in the volume of a Stockpiled Product authorised by the Authority has taken place;

4.4.14 obtain written approval from the Authority before changing the size of the container or presentation of the items to be supplied (including pallet configuration);

4.4.15 provide a Stock Report in accordance with Schedule 6.

4.5 The Supplier shall advise the Authority forthwith in writing of any damage to or loss of the Stockpiled Products 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.

4.6 Should the Authority undertake a stock audit in relation to the Stockpiled Products, 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.

4.7 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:

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

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

4.7.3 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 Products)

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;

4.7.4 security at the Storage Facilities.

4.8 Where the Storage Services are provided by a Storage Provider, any obligation on the Supplier under this 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.

5 AUTHORISED RELEASE IN AN EMERGENCY

This Clause shall apply to Authorised Release in an Emergency

5.1 The Authority and the Supplier shall promptly notify the other party in writing if either party anticipates that there may be a shortage in the supply of any of the Stockpiled Products in the UK due to an Emergency. In the event of such an Emergency the Authorised Release shall be known as an Emergency Authorised Release.

5.2 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 4 in relation to releasing Stockpiled Products for addressing such shortages and submit it to the Authority for approval.

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

5.4 The reviewed and 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.

5.5 The Supplier shall then purchase the volume of Stockpiled Product set out in the Release Plan from the Authority at the Buyback Price in accordance with the Release Plan.

5.6 During an Emergency Authorised Release, the Supplier shall:

5.6.1 ensure that the Released Products are supplied immediately into the supply chain upon demand in the UK for such Products in accordance with any applicable Release Plan and any reasonable instructions received from time to time from the Authority;

5.6.2 comply with the Release Plan in respect of the Released Products;

5.6.3 attend any meetings as reasonably requested by the Authority;

5.6.4 provide a Release Report to the Authority following an Emergency Authorised Release at the end of each week as required by the Authority setting out:

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

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

(iii) the buyback price;

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

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

5.7 Following an Emergency Authorised Release, the Required Volume will be reduced by the number of Units of Stockpiled Products removed in accordance with such Emergency Authorised Release. Timelines for any stock replenishment required will be agreed between both Parties.

6 TITLE AND RISK

6.1 Title shall remain with the Authority except where it passes to the Supplier as part of an Authorised Release or on buy back in the event of termination of this Agreement, save that risk in all Units of the Stockpiled Products in the Stockpile shall remain with the Supplier to the extent that the Supplier:

6.1.1 breaches any provision of this Agreement;

6.1.2 is negligent; or

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

6.2 The Supplier acknowledges and agrees that the Authority shall retain full title to the Stockpiled Products and at no time shall the Supplier hold any proprietary or other interest in the Stockpiled Products 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 4.7.3.

6.3 If any Stockpiled Product is removed from the Stockpile by the Supplier in accordance with Clause 2.2, then:

6.3.1 risk in such Units of the Products shall pass to the Supplier upon such removal; and

6.3.2 title to such Units of the Products shall pass to the Supplier upon such removal.

6.4 If the Supplier removes any Stockpiled Products from the Stockpile during a Release Plan then:

6.4.1 risk in such Units of the Products shall pass to the Supplier upon Authorised Release; and

6.4.2 title to such Units of the Products shall pass to the Supplier on the date of the appropriate Authorised Release.

7 INSPECTION OF PRODUCTS AND STORAGE FACILITIES

7.1 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 Products provided that the Authority gives prior written notice to the Supplier of no less than 24 hours. Such inspection may include but is not limited to:

7.1.1 reviewing the Supplier's compliance with this Agreement;

7.1.2 checking any records held by the Supplier under this Agreement;

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

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

7.1.5 checking the quantity of Stockpiled Products.

7.2 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 7.1, including providing or obtaining any necessary permissions.

7.3 The Authority may reject any Units of the Products:

7.3.1 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 this Agreement;

7.3.2 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.

7.4 The Authority may at any time by written notice to the Supplier reject any Defective Products. Where the Authority discovers more than one Defective Product in any given batch of the Products, 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.

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

7.5.1 the Authority may by written notice to the Supplier require the Supplier to replace Rejected Products with Replacement Products that are in compliance with this Agreement free of charge; or

7.5.2 the Authority may choose to source some or all of the Products (which for the sake of clarity shall include all services which enable the Authority to supply and store the Product on similar terms as this 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 the Authority's, damages and costs incurred in having to source the Product from a third party.

7.6 Where the Authority requires the Supplier to replace the Rejected Products, the Supplier shall use its best endeavours to minimise the time taken to provide such Replacement Products and in any event, shall do so at its own cost and within one 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 Products elsewhere, the Supplier shall refund to the Authority any sums paid for the Rejected Products within 30 days of the date of such notification.

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

7.8 Rejected Products 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.

7.9 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 Products in accordance with this 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 30 days of the date of the Authority's invoice for the same.

8 REGULATORY REQUIREMENTS

8.1 The Supplier shall ensure that it, or the Manufacturer or the holder of the Marketing Authorisation, maintains a valid Marketing Authorisation in respect of each Product 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).

8.2 The Supplier shall promptly, and in any event within 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.

8.3 If, for any reason a Marketing Authorisation in respect of a Product is:

8.3.1 withdrawn by the Licensing Authority; or

8.3.2 suspended by the Licensing Authority; or

8.3.3 not renewed by the Licensing Authority,

then the Authority shall be entitled to immediately terminate this Agreement in respect of the relevant Product upon written notice to the Supplier.

8.4 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 Products.

8.5 Upon any termination under clause 8.3, the Supplier shall at the discretion of the Authority immediately purchase the Stockpiled Products from the Authority at the Buyback Price.

8.6 The Supplier shall comply with the requirements as set out in the QTA.

8.7 Where the Supplier shall change 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.

9 QUALITY ASSURANCE

9.1 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 Products in accordance with Good Distribution Practice, Good Manufacturing Practice, Good Industry Practice, any other requirement of the Licensing Authority the terms of this Agreement and those standards set out in the (QTA).

9.2 To ensure compliance with Clause 9.1, 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 Products 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 Products) to the same or to the Specification or the Supplier's quality control monitoring system in relation to the Products without:

9.2.1 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

9.2.2 the Licensing Authority formally approving such change.

10 WARRANTIES

10.1 The Supplier warrants and undertakes that:

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

10.1.2 all Units of the Stockpiled Products will throughout the Term comply fully with the relevant Specification, the Marketing Authorisation and the QTA;

10.1.3 the Supplier, and any Sub-contractor that may require the same for the activities subcontracted to it under this Agreement, hold and will

hold throughout the Term a Wholesale Distribution Authorisation or equivalent licence to deal in the Products;

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

10.1.5 the Products will be manufactured in accordance with Good Manufacturing Practice;

10.1.6 the Products are suitable for the treatments and purposes as referred to in the Specification, the Marketing Authorisation and the SmPC;

10.1.7 all Units of Stockpiled Products will at all times while in the Stockpile have the Shelf Life referred to at Clause 2.1;

10.1.8 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

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

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

10.2.1 Directive 2001/83;

10.2.2 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 a European Medicines Agency;

10.2.3 all laws, regulations and guidelines within the UK implementing the legislation referred to in Clause 10.1.110.2.1 and Clause 10.2.210.2.2 above;

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

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

10.2.6 the Human Medicines Regulations 2012/1916.

10.3 The Supplier further warrants and undertakes that:

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

10.3.2 all statements and representations in the Supplier's 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;

10.3.3 all statements or representations in the Supplier's 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;

10.3.4 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 this Agreement and the documents referred to herein;

10.3.5 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 this Agreement;

10.3.6 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;

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

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

10.3.9 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

10.3.10 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 10.3.10 and/or as may be requested or otherwise required by the Authority in accordance with its anti-slavery Policy.

10.4 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 10 have been breached or there is a risk that any warranties may be breached.

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

11 PRICE, PAYMENT AND INVOICING

11.1 In consideration of the provision of the Products, storage and rotation of the Stockpiled Products in accordance with this Agreement the Authority shall pay the Supplier in accordance with this Agreement.

Storage charges

11.2 The Supplier shall send the Authority an invoice for storage costs incurred as set out below:

Month invoice to be sent	**Months payment due**
March	January – March
June	April – June
September	July – September
December	October – December

11.3 The invoice will detail the Storage Charge as set out in Schedule 1, and the generic Product name and Volume of Product that has been stored and any adjustment as stated in clause 11.4.

11.4 If one or more pallets are removed by the Supplier, the weekly storage costs will be reduced by the number of pallets removed.

Authorised Release

11.5 The Supplier shall pay the relevant Buyback Price as set out under this Agreement at Clause 19 in respect of an Authorised Release of such Stockpiled Products within 30 calendar days of receipt of each invoice.

11.6 An invoice shall be issued by the Authority within 30 days following each removal of the volume agreed by the Parties from the Stockpile pursuant to an Authorised Release.

General

11.7 Where the Authority purchases any additional Products in accordance with Clauses 7 or it shall issue a purchase order number to the Supplier and the Supplier will issue an invoice within 30 days of delivery of any additional Product into the Stockpile.

11.8 All prices set out in this Agreement are stated exclusive of any applicable VAT.

11.9 All invoices issued under this Agreement by the Supplier shall be addressed to:

Accounts Payable, Department of Health & Social Care, 39 Victoria Street, Westminster, London, SW1H 0EU.

11.10 All invoices issued under this Agreement by the Authority shall be addressed to:

Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE.

11.11 The Supplier shall pay all invoices issued by the Authority within 30 calendar days from the date of the invoice.

11.12 Where the Supplier submits an invoice to the Authority (in accordance with this Clause 11), the Authority will consider and verify that invoice in a timely fashion.

11.13 The Authority shall pay the Supplier any sums due under such an invoice no later than a period of 30 days from the date on which the Authority has determined that the invoice is valid and undisputed.

11.14 Where the Authority fails to comply with clause 11.13 and there is an undue delay in considering and verifying the invoice, the invoice shall be regarded as valid and undisputed for the purposes of Clause 11.13 after a reasonable time has passed.

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

11.15.1 provisions having the same effect as clauses 11.12 to 11.14 of this Agreement; and

11.15.2 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 11.12 to 11.14 of this Agreement.

11.16 In the event of late payment by either Party of any sums due to the other Party under this 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 11.16 is a reasonable and substantial remedy for late payment of any sum payable under this Agreement in accordance with section 8(2) of the Late Payment of Commercial Debts (Interest) Act 1998.

11.17 The Authority reserves the right to deduct from any monies due to the Supplier any monies due to the Authority from the Supplier under this Agreement.

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

12 CHANGES IN THE MARKET

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

12.1.1 any changes or potential changes in market requirements for any of the Products;

12.1.2 anything that the Supplier reasonably considers may have an adverse effect on the market value of any of the Products in the UK;

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

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

12.2 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 a Product will or may expire, lapse, be withdrawn, be revoked or be declared invalid.

12.3 In the event of any circumstances in Clauses 12.1 and 12.2 arising, the Parties shall agree in writing to any changes in accordance with clause 41.

13 TERM AND TERMINATION

13.1 This 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.

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

13.2.1 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 15 days of written notice thereof;

13.2.2 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;

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

13.2.4 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 Products or the reputation of the Authority;

13.2.5 if the Supplier, or any Sub-contractor that may require the same for the activities subcontracted to it under this Agreement, do not hold a Wholesale Distribution Authorisation or equivalent licence to deal in the Products, 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

13.2.6 pursuant to Clause8.3, Clause17.4, Clause27.4, Clause 31.3 or Clause 32.3.

13.3 The Authority may also terminate this Agreement forthwith by notice in writing to the Supplier where:

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

13.3.2 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;

13.3.3 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

13.3.4 there has been a failure by the Supplier and/or one of its Subcontractors 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 Supplier's 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 this Agreement under this Clause 13.3.

13.4 The Authority may terminate the application of this Agreement to any specific Product or subdivision of a Product (such as formulation or pack size) forthwith by notice in writing to the Supplier:

13.4.1 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 15 days of written notice thereof; or

13.4.2 if the Licensing Authority, the Commission on Human Medicines or other relevant regulatory body advises the Authority not to use the Products.

13.5 The Authority may terminate this Agreement (in whole or part) 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.

13.6 The Supplier shall be entitled to terminate this Agreement forthwith by notice in writing if the Authority fails to pay three consecutive undisputed invoices.

14 CONSEQUENCES OF TERMINATION

14.1 Termination of this 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.

14.2 If this Agreement is terminated by the Authority for material breach as stated in Clauses 13.2.1 and 13.4.1, 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. Where the Agreement shall terminate (in whole or part) for whatever reason, an Exit Plan will be implemented and the Supplier shall purchase the Products at the Buyback Price and shall make payment to the Authority within 30 days of termination.

14.3 On expiry of the Term or where this Agreement is terminated in whole or in part for any reason and the provision of the Exit Plan comes into effect the Supplier shall cooperate fully with the Authority to ensure an orderly migration of the Service to the Authority or, at the Authority's request a replacement supplier except as stated in Clause 14.2.

14.4 Upon termination of this Agreement for any reason, Clauses 1 (Interpretation), 8 (Regulatory Requirements), 10 (Warranties), 14 (Consequences of Termination), 21 (Buyback), 22 (Intellectual Property Rights), 23 (Liability), 21 (Liability), 22 (Limitation of Liability), 23 (Confidentiality), 24 (Freedom of Information), 26 (Data Protection), 28 (Right of Audit), and 30 (Sub Contracting and assignment) shall continue in force and any other provision that which expressly provides that it continue after expiry or termination.

15 SUPPLIER STAFF

15.1 The Supplier shall when attending the Authority's or any other relevant premises, procure that its employees and agents shall in the performance of this 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 this Agreement.

15.2 In providing the Services to the Authority in accordance with this 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.

15.3 The Supplier will employ for the purpose of this 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:

15.3.1 the task that person has to perform; and

15.3.2 all relevant provisions of the Agreement.

15.4 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.

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

15.6 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 15.

16 REPORTING AND CONTRACT MANAGEMENT

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

16.2 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 28.1 and any other documents, records, data and such other information related to the Stockpiled Products 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 Products 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.

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

16.4 The Supplier shall participate in contract review meetings with the Authority at least once every six 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. The Supplier shall report to the Authority during such meetings about the Supplier's compliance with its obligations under this Agreement (including under Clause 2) and shall provide to the Authority all information reasonably requested by the Authority in respect of its provision of the Services.

16.5 Review meetings shall include the Supplier's performance under this Agreement, production plans, Release Plan and Business Continuity Plan.

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

16.7 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 three months 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 this 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.

16.8 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 this Agreement and shall pay the Authority any extra costs occasioned by any discrepancies, errors or omissions in it.

17 BUSINESS CONTINUITY

17.1 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:

17.1.1 arrangements the Supplier has and will retain in place with third parties for the delivery of the Products during a Business Continuity Event;

17.1.2 arrangements the Supplier has and will retain in place to continue to deliver the Products in accordance with this Agreement and provide any other Services during a Business Continuity Event;

17.1.3 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;

17.1.4 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 Products in accordance with this Agreement, provision of the Storage Services and provision of any other Services during a Business Continuity Event;

17.1.5 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

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

17.2 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.

17.3 Throughout a Business Continuity Event, the Supplier shall forthwith:

17.3.1 implement and comply with the Business Continuity Plan;

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

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

17.4 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 13.2.

18 ADDITIONAL PROVISIONS

18.1 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 Products and/or supply of the Stockpiled Products into the supply chain in the UK). The Supplier shall on receipt of a request immediately and no later than 24 hours from the Authority's request, provide to the Authority and any person authorised by the Authority:

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

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

18.1.3 access to any personnel and information necessary to enable the Authority to exercise its rights under this Clause18;

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

18.1.5 any cooperation and assistance reasonably requested by the Authority in relation to the Authority exercising its rights under this Clause18,

provided that, where the Authority removes any Stockpiled Product from the Stockpile it will forthwith 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.

19 BUYBACK

19.1 For each Authorised Release (including an Emergency Authorised Release), the Supplier shall purchase the Stockpiled Products at the Buyback Price.

19.2 The Buyback Price shall be determined by the Authority by, firstly, calculating the Average UK Price for each week of the four week period immediately preceding the date that the Supplier sends the Release Plan or Exit Plan (as the case may be) to the Authority and, thereafter, weighting each such Average UK Price, giving a higher value to the most recent Average UK Price, where the most recent week is worth four times more than the other weeks, in order to calculate the Buyback Price as follows:

Buyback Price = (Average UK Price, week 1 + Average UK Price, week 2 + Average UK Price, week 3 + 4* Average UK Price, week 4) / 7

19.3 Where no sales of the Product have been made by the Supplier within the UK in any week of the relevant four-week period described above (such week being a **No Sales Week**), the Authority shall (with the assistance of the Supplier) identify a week immediately preceding such No Sales Week where the Supplier has made sales of the Product within the UK, and the Authority shall calculate the Average UK Price for such week.

19.4 The parties agree the calculations in Annex 1 represent an example of the operation of this Clause.

20 INTELLECTUAL PROPERTY RIGHTS

20.1 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 Products or it is licensed by the relevant owners to supply the Products in accordance with this Agreement and shall use best endeavours to ensure that it remains the owner or licensee (as applicable) of the Intellectual Property Rights in the Products throughout the Term.

20.2 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 Products supplied under this Agreement for the purposes set out in the Supplier's Offer, the Specification and/or this Agreement.

20.3 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 Products under this Agreement or the use of the Products.

21 LIABILITY

21.1 The Supplier shall indemnify and keep indemnified the Authority against all actions, proceedings, costs, claims, demands, liabilities, losses and expenses whatsoever whether arising in tort (including negligence) default or breach of this 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 this Agreement or applicable law by the Authority or its representatives.

21.2 For the avoidance of doubt the Supplier shall indemnify and hold harmless the Authority against all claims, liabilities, losses, damages, costs (including 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 Products or the use of the Products.

21.3 The indemnity in Clause 21.1 shall not apply in respect of any death or personal injury arising from the use of the Products by the Authority to the extent attributable to the Authority accessing or using the Products in a manner contrary to any storage or administration requirements set out in the Marketing Authorisation.

22 LIMITATION OF LIABILITY

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

22.1.1 for death or personal injury resulting from its negligence;

22.1.2 for fraud or fraudulent misrepresentation;

22.1.3 in any other circumstances where liability may not be limited or excluded under any applicable law;

22.2 Nothing in this Agreement shall exclude or restrict the liability of the Supplier under Clause 22.1 (Liability), 23 (Confidentiality), 26 (Data Protection), 31 (Prevention of Corruption), 32 (Prevention of Fraud) and 33 (Modern Slavery).

22.3 Subject to Clauses 22.1 and 22, the total liability of the Supplier under this 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 this Agreement.

22.4 The Authority shall promptly after receipt of any claim or notification of other circumstances to which an indemnity in this 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 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:

22.4.1 shall use appropriately experienced lawyers;

22.4.2 shall defend any relevant claim robustly and expeditiously; and

22.4.3 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.

22.5 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 this 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.

23 CONFIDENTIALITY AND TRANSPARENCY

23.1 For the purposes of this Clause 23, 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.

23.2 Except to the extent set out in this Clause 23 or where disclosure is expressly permitted elsewhere in this Agreement, the Recipient shall:

23.2.1 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);

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

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

23.2.4 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.

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

23.3.1 the Recipient is required to disclose the Confidential Information by Law, provided that Clause 26 (*Freedom of Information*) shall apply to disclosures required under the FOIA or the EIRs;

23.3.2 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 this 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 this Agreement; or

23.3.3 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.

23.4 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.

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

23.5.1 Supplier's 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 this Agreement; and

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

Where the Supplier discloses Confidential Information of the Authority pursuant to this Clause 23.5, it shall remain responsible at all times for compliance with the confidentiality obligations set out in this Agreement by the persons to whom disclosure has been made.

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

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

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

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

23.6.4 on a confidential basis to a professional adviser, consultant, supplier or other person engaged by any of the entities described in Clause 23.6.1 (including any benchmarking organisation) for any purpose relating to or connected with this Agreement;

23.6.5 on a confidential basis for the purpose of the exercise of its rights under this Agreement, including the Audit Rights, its rights pursuant to Clause 27 and Exit Management rights; or

23.6.6 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 this 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 23.

23.7 Nothing in this Clause 23 shall prevent a Recipient from using any techniques, ideas or know-how gained during the performance of this 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.

23.8 The Parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA, the content of this Agreement is not Confidential Information. The Authority shall determine whether any of the content of this 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.

23.9 Notwithstanding any other provision of this Agreement, the Supplier hereby gives its consent for the Authority to publish to the general public this 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 this Agreement agreed from time to time.

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

24 FREEDOM OF INFORMATION

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

24.1.1 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;

24.1.2 transfer to the Authority all Requests for Information relating to this Agreement that it receives as soon as practicable and in any event within 2 working days of receipt;

24.1.3 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 5 working days (or such other period as the Authority may reasonably specify) of the Authority's request for such Information; and

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

24.2 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 this 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.

25 DISPUTES

25.1 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 Products or provision of the Services.

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

25.3 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) Working 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.

25.4 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.

25.5 Of the dispute cannot be resolved by the Authority and the Supplier in accordance with clause 25.4 above, 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.

25.6 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 28 days of the Mediation Notice being served.

25.7 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.

25.8 Neither Party will commence legal proceedings against the other until 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.

25.9 Nothing in this Agreement shall prevent:

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

25.9.2 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.

26 DATA PROTECTION

26.1 The Parties acknowledge their respective duties under Data Protection Legislation and shall give each other all reasonable assistance as appropriate or necessary to enable each other to comply with those duties.

26.2 Where the Supplier is Processing Personal Data under or in connection with this Agreement, the Supplier must, in particular, but without limitation:

26.2.1 only Process such Personal Data as is necessary to perform its obligations under this Agreement, and only in accordance with any instructions given by the Authority under this Agreement;

26.2.2 put in place appropriate technical and organisational measures against any unauthorised or unlawful Processing of that Personal Data, and against the accidental loss or destruction of or damage to such Personal Data having regard to the specific requirements of this Clause 26, the state of technical development and the level of harm that may be suffered by a Data Subject whose Personal Data is affected by unauthorised or unlawful Processing or by its loss, damage or destruction;

26.2.3 take reasonable steps to ensure the reliability of staff who will have access to Personal Data, and ensure that those staff are aware of and trained in the policies and procedures identified in this Clause 26; and

26.2.4 not cause or allow Personal Data to be transferred outside the European Economic Area without the prior consent of the Authority.

26.3 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 purpose for which the transfer is conducted; and (b) that is encrypted in accordance with any international data encryption standards for healthcare, and as otherwise required by those standards applicable to the Authority under any Law and Guidance (this includes, data transferred over wireless or wired networks, held on laptops, CDs, memory sticks and tapes).

26.4 Where any Personal Data is Processed by any Sub-contractor of the Supplier in connection with this Agreement, the Supplier shall procure that such Sub-contractor shall comply with the relevant obligations set out in this Clause 26 as if such Subcontractor were the Supplier.

26.5 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 this Agreement.

27 FORCE MAJEURE

27.1 Subject to Clause27.2, 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.

27.2 The Supplier shall only be entitled to rely on an event of Force Majeure if the Supplier has fulfilled its obligations pursuant to this Clause 27 and the circumstances set out in Clause 66.1.3 do not apply.

27.3 A Party wishing to rely on an event of Force Majeure shall promptly and in any event within 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.

27.4 If an event of Force Majeure relied on by the Supplier shall subsist for 28 days or more then the Authority shall have the right to terminate this Agreement at once by giving notice to the Supplier.

27.5 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 27.2, the obligations of both parties shall be suspended to the extent that they are affected by such event of Force Majeure unless and until:

27.5.1 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

27.5.2 this Agreement is terminated,

whichever shall be the earlier.

31.6 Where this Agreement shall be terminated for Force Majeure the provisions in clause 14 (Consequences of Termination) shall apply with such amendments as the Parties may, acting reasonably, agree.

28 RIGHT OF AUDIT

28.1 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 this Agreement.

28.2 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 this Agreement for the purposes of:

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

28.2.2 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.

28.3 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.

28.4 The Authority shall have the right to audit the Supplier's compliance with this 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 Business Days, access to any premises and facilities, books and records used in the performance of the Supplier's obligations under this Agreement.

29 ENVIRONMENTAL CONSIDERATIONS

29.1 The Supplier shall comply in all material respects with applicable environmental laws and regulations in force from time to time in relation to the Products 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 Invitation to Tender. Without prejudice to the generality of the foregoing, the Supplier shall:

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

29.1.2 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 Products;

29.1.3 comply with all obligations imposed on it in relation to the Products 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 Directive 94/62/EC);

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

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

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

29.2 The Supplier shall meet all reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of this Clause 29.

30 SUB-CONTRACTING AND ASSIGNMENT

30.1 The Supplier shall not Sub-contract any of its obligations to a Storage Provider or any of its obligations under this Agreement without the Authority's prior written consent, which, subject to Clause 30.2, shall not be unreasonably withheld or delayed.

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

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

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

30.2.3 the proposed Sub-contractor employs unfit persons.

30.3 Subject to Clause 30.2, in making a request pursuant to Clause 30.1the Supplier shall provide the Authority with the following information about the proposed Subcontractor:

30.3.1 its name, registered office and company registration number;

30.3.2 a copy of the proposed Sub-contract;

30.3.3 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

30.3.4 any further information reasonably requested by the Authority.

30.4 If the supply of information required pursuant to Clause 30.3would 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.

30.5 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.

30.6 The Supplier shall not terminate or materially amend the terms of any Sub-contract relating to any obligations referred to in Clause 30.1without the Authority's prior written consent, which shall not be unreasonably withheld or delayed.

30.7 Notwithstanding the Supplier's right to Sub-contract pursuant to this Clause 30, 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.

30.8 Without prejudice to Clause 30.7, 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.

30.9 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 this Agreement.

30.10 The Supplier shall not assign or in any other way dispose of the whole or any part of this Agreement without the previous consent in writing of the Authority.

31 PREVENTION OF CORRUPTION

31.1 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.

31.2 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.

31.3 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:

(i) terminate the Agreement and recover from the Supplier the amount of any 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

(ii) recover in full from the Supplier any other loss sustained by the Authority in consequence of any breach of this clause 31.

32 PREVENTION OF FRAUD

32.1 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.

32.2 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.

32.3 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:

(i) terminate the Agreement and recover from the Supplier the amount of any 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

(ii) recover in full from the Supplier any other loss sustained by the Authority in consequence of any breach of this clause.

33 MODERN SLAVERY

33.1 The Supplier:

(i) shall not use, nor allow its sub-contractors to use forced, bonded or involuntary prison labour;

(ii) shall not require any Supplier Personnel or the personnel of any sub-contractors to lodge deposits or identity papers with their employer and shall be free to leave their employer after reasonable notice;

(iii) warrants and represents that it has not been convicted of any slavery or human trafficking offences anywhere around the world;

(iv) warrants that to the best of its knowledge it is not currently under investigation, inquiry or enforcement proceedings in relation to any allegation of slavery or human trafficking offences anywhere around the world;

(v) shall make reasonable enquires to ensure that its officers, employees and sub-contractors have not been convicted of slavery or human trafficking offences anywhere around the world;

(vi) shall have and maintain throughout the Term its own policies and procedures to ensure its compliance with the Modern Slavery Act 2015 and include in its contracts with its sub-contractors antislavery and human trafficking provisions;

(vii) shall implement due diligence procedures to ensure that there is no slavery or human trafficking in any part of its supply chain performing obligations under the Contract;

(viii) shall prepare and deliver to the Authority, an annual slavery and human trafficking report setting out the steps it has taken to ensure that slavery and human trafficking is not taking place in any of its supply chains or in any part of its business;

(ix) shall not use, nor allow its employees or sub-contractors to use physical abuse or discipline, the threat of physical abuse, sexual or other harassment and verbal abuse or other forms of intimidation of its employees or sub-contractors;

(x) shall not use or allow child or slave labour to be used by its sub-contractors; and

(xi) shall report the discovery or suspicion of any slavery or trafficking by it or its sub-contractors to the Authority and the Modern Slavery Helpline.

34 WAIVER

34.1 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 this Agreement.

35 CUMULATION OF REMEDIES

35.1 Subject to the specific limitations set out in this Agreement, no remedy conferred by any provision of this Agreement is intended to be exclusive of any other remedy except as expressly provided for in this 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.

36 SEVERABILITY

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

37 PARTNERSHIP OR AGENCY

37.1 Nothing in this 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 this agreement.

38 THIRD PARTY RIGHTS

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

39 PUBLICITY

39.1 The Supplier shall not:

(i) make any press announcements or publicise this Agreement or its contents in any way; or

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

without the prior written consent of the Authority.

40 ENTIRE AGREEMENT

40.1 These terms, the schedules and the documents annexed to it or otherwise referred to in it contain the whole 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.

40.2 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 this 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 this Agreement or unless such representation was made fraudulently.

41 VARIATION

41.1 Any variation must be agreed in writing by both parties.

42 COUNTERPARTS

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

43 GOVERNING LAW AND JURISDICTION

43.1 This 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.

43.2 The parties irrevocably agree that, subject to clause 25 (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 this Agreement or its subject matter.

44 MISCELLANEOUS

44.1 The Supplier acknowledges that the Authority has entered into this Agreement in the context of the exercise of performance of the duties of the Secretary of State for Health 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.I.14).

44.2 The Supplier acknowledges that the Authority has entered into this Agreement on behalf of the UK's Devolved Administrations. Accordingly, any losses suffered by the Devolved Administrations owing to a breach of this Agreement by the Supplier will be deemed to be losses of the Authority and the Authority shall be entitled to recover such losses from the Supplier as if they were losses of the Authority.

IN WITNESS whereof this Agreement has been entered into the day and year first before written

Redacted Under FOIA Section 40, Personal Information

SIGNED BY: ……..
FOR AND ON BEHALF OF THE SECRETARY OF STATE FOR HEALTH & SOCIAL CARE **Redacted Under FOIA Section 40, Personal Information**

(**NAME**) ……..

DATE: 21-Jun-2022 ……

Redacted Under FOIA Section 40, Personal Information

SIGNED BY: ……
FOR AND ON BEHALF OF THE SUPPLIER
Redacted Under FOIA Section 40, Personal Information

(**NAME**) ……..

DATE: 17th June 2022 ……

SCHEDULE 1

Award Schedule Template

Redacted Under FOIA Section 43(2), Commercial Interests

Award Schedule Template

Company name: Baxter Healthcare Ltd

Redacted Under FOIA Section 43(2), Commercial Interests

SCHEDULE 2

EXAMPLE Delivery Schedule

Redacted Under FOIA Section 43(2), Commercial Interests

EXAMPLE Delivery Schedule

SCHEDULE 3

Storage Facilities and Storage Provider

Company Name: Baxter Healthcare Ltd

Storage Details - Template

Details of location where stock is to be stored. Please fill out multiple templates if more than one storage location is being proposed.

Cells coloured yellow are input fields

Question	Supplier Response
Name of storage location	**Redacted Under FOIA Section 43(2), Commercial Interests**
Address of storage location	**Redacted Under FOIA Section 43(2), Commercial Interests**
Wholesale Distribution Authorisation (H) number	Baxter 116 **Redacted Under FOIA Section 43(2), Commercial Interests**
Wholesale Distribution Authorisation (H) date	Baxter 3/4/2018 **Redacted Under FOIA Section 43(2), Commercial Interests**
WDA(H) Licence Number - Site number (This number is of the facility where the product will be stored.)	Baxter 116 **Redacted Under FOIA Section 43(2), Commercial Interests**
Name of Responsible Person within contracted organisation (this should be filled in even if contracting to a third party storage location)	**Redacted Under FOIA Section 40, Personal Information**
Name of Responsible Person within proposed storage location (if different from above i.e. the stock is being held at a third party location)	**Redacted Under FOIA Section 40, Personal Information**
Name of medicine being offered to be stored at this site in ambient storage conditions	All products pertained in the agreement
Name of medicine being offered to be stored at this site in chilled storage conditions	Not applicable - no chilled products

Name of medicine being offered to be stored at this site in controlled storage conditions	Not applicable - no controlled substances

SCHEDULE 4

Release Plan Template

ESSENTIAL MEDICINES BUFFER STOCK IV & PD FLUIDS RELEASE PLAN AND REPORT

Date (of first submission to the Authority):

Date (of return back to Supplier):

Date [Please insert the date of subsequent submissions]

(a) Introduction

This plan is provided in order that both parties have a documented and agreed record of a release of the Essential Medicines Buffer Stock. The plan must be sent in order to gain authorisation to release the stock.

The plan should be sent again, a week after the initial release, or as required, with the reporting information filled in. Subsequent reports may also be required and the same document should be updated and sent again.

The release will be managed by the Authority and [insert name], as detailed in the contract. Once the plan has been agreed by both parties, notice served and accepted, it will be reviewed weekly by both parties or sooner if required. The plan cannot be amended without the permission of the Authority.

(b) Product to be released

[Please insert here]

(c) Confirmation that they have no other stock available and that demand exists

[Yes]

(d) Confirmation that the stock will be released immediately to meet demand ahead of other products held at the location of the EMBS

[Yes]

(e) Buyback price

[Please provide the 'Average UK Price' as described in clause 1.1]

(f) How the supplier will sell the stock

[Please provide details here of how stock will be sold, by organisation and/or geographically]

(g) Any other relevant information regarding the product or release plan

[Please detail here any other relevant information that the Department of Health and Social Care should be aware of]

(h) When will the supplier receive sufficient stock for the EMBS IV & PD Fluid not to be needed

[Please provide a forecast of when non EMBS stock will be available for sale]

FIRST REPORT – TO BE SENT WEEKLY OR AS REQUIRED

(a) The number of Units of Products removed from the Stockpile during the previous week

[Insert number]

(b) The number of Units of Products remaining in the Stockpile.

[Insert number]

(c) Buyback price

[Please provide the 'Average UK Price' as described in clause 1.1]

(d) The identities of the customers to whom the Supplier has supplied product to during the previous week.

[Insert the name of customers who have received the EMBS IV & PD fluid stock]

(e) Any other relevant information regarding the product or release plan

[Please detail here any other relevant information that the Department of Health and Social Care should be aware of]

IF SUBSEQUENT REPORTS ARE REQUIRED THE REPORT SECTION ABOVE SHOULD BE CUT AND PASTED HERE AND NEW INFORMATION ADDED. PLEASE DO NOT DELETE THE FIRST REPORT.

SCHEDULE 5

Supplier's Business Continuity Plans

[To be completed from the Supplier's offer]

SCHEDULE 6

Stock Report

To be provided quarterly, within two weeks of the end of the previous quarter. For these purposes the quarters run from January. This will comprise of two worksheets. These should be sent to **Redacted Under FOIA Section 40, Personal Information** or such other person notified to the Supplier by the Authority

Worksheet 1

- Pallet Location ID
- Storage Location (in the event of multiple sites)
- MPC
- Product Description using the generic Product name.
- Pack Size
- Quantity Fields x 2 (packs/ units)
- Expiry Date
- Batch Reference

Worksheet 2

- Product Level (whole stockpiled product, not brand segregated)
- Volume in Units
- Earliest Expiry
- Latest Expiry
- % product in minimum contractual shelf life
- Details of any Products replaced owing to damage during preceding quarter and reasons for replacement
- Details of any Products replaced through stock rotation/ recycling during preceding quarter

ANNEX 1

Redacted Under FOIA Section 43(2), Commercial Interests