Document no.3

TERMS AND CONDITIONS FOR THE SUPPLY, STORAGE, AND MANAGEMENT OF INTRAVENOUS FLUIDS

LICENSED MEDICINES

Contract Reference: CM/EMI/22/C103602

The Authority	The Secretary of State for Health and Social Care acting as part of the Crown through the Department of Health and Social Care whose principal office is at: 39 Victoria Street, London, SW1H 0EU
The Supplier	Baxter Healthcare Ltd, Company Number: 461345 whose registered office is at Caxton Way, Thetford, Norfolk, IP24 3SE. United Kingdom

Date	29th September 2023
Description of Medicine (the Goods)	(Lot 1) Sodium Lactate – Compound Sodium lactate 1 litre iv infusion – 1,392,347 units (Lot 2) Sodium Lactate - Compound Sodium lactate 500ml iv infusion – 254,477 units (Lot 3) Glucose – Glucose/Sodium chloride 4%/0.18% 1 litre iv infusion – 59,773 units (Lot 4) Glucose - Glucose/Sodium chloride 5%/0.45% 500ml iv infusion – 19,709 units (Lot 5) Glucose – Glucose 5%/Sodium chloride 0.9% 500ml iv infusion – 39,740 units (Lot 8) Glucose – Glucose 5% - 1 litre iv infusion – 103,094 units (Lot 9) Glucose - Glucose 5% - 500ml iv infusion – 92,294 units (Lot 10) Glucose - Glucose 5% - 100ml iv infusion - 268,013 units

	(Lot 11) Sodium Chloride – Sodium Chloride 0.9% - 1 litre iv infusion – 1,471,742 units

1. This Contract is made on the date set out above subject to the terms set out in the schedules listed below ("Schedules"). The Authority and the Supplier undertake to comply with the provisions of the Schedules in the performance of this Contract.
2. The Supplier shall supply to the Authority, and the Authority shall receive and pay for, the Goods on the terms of this Contract.
3. Save where the context does not permit, the definitions in Schedule 5 apply to the use of all capitalised terms in this Contract.

Schedules

Schedule 1	Key Provisions
Schedule 2	General Terms and Conditions
Schedule 3	Storage Facilities and Storage Provider
Schedule 4	Information Provisions
Schedule 5	Definitions and Interpretations
Schedule 6	Specification
Schedule 7	Commercial Schedule
Schedule 8	Proforma Change Control Note
Schedule 9	Tender Response Document
Schedule 10	Business Continuity Plan
Schedule 11	[Not Used]
Schedule 12	Stock Report
Schedule 13	Release Plan
Schedule 14	Exit Plan
Schedule 15	Quality Technical Agreement
Schedule 16	Buyback Price

Signed by the authorised representative of THE AUTHORITY

Signed by the authorised representative of THE SUPPLIER

Schedule 1

Key Provisions

1. **Application of the Key Provisions**

1.1 The Key Provisions at Clauses 1 to 10 of this Schedule 1 shall apply to this Contract.

2. **Term**

2.1 This Contract shall commence on the 1st of October 2023 ("**Commencement Date**") and shall expire on 30th September 2025 (**"Term"**).

3. **Contract Managers**

3.1 The Contract Managers at the commencement of this Contract are:

3.1.1 for the Authority:

[redacted]

Commercial Manager

3.1.2 for the Supplier:

[redacted] –

Commercial Business Manager

4. **Notices**

4.1 Subject to Clause 28.5 of Schedule 2, any notice required to be given by either Party under this Contract shall be in writing and shall be delivered by:

4.1.1 hand or sent by prepaid first class recorded delivery to the address listed in Clause 4.3 of this Schedule 1 or such other address as a Party may inform the other Party in writing from time to time; or

4.1.2 email to the person referred to in Clause 4.3 of this Schedule 1 or such other person as a Party may inform the other Party in writing from time to time; or

4.1.3 submitting a notice on the Authority's e-Tendering Portal to the other Party's registered account(s).

4.2 A notice shall be treated as having been received:

4.2.1 if delivered by hand within normal business hours on a Business Day when so delivered, or, if delivered by hand outside normal business hours and/or Business Days, at the next start of normal business hours on a Business Day; or

4.2.2 if sent by first class recorded delivery mail on a Business Day, at 9.00 am on the second Business Day subsequent to the day of posting, or, if the notice was not posted on a Business Day, at 9.00 am on the third Business Day subsequent to the day of posting; or

4.2.3 if sent by email, if sent within normal business hours on a Business Day, when so sent, or, if sent outside normal business hours and/or Business Days, at the next start of normal business hours on a Business Day, provided that the sender must have either received an electronic confirmation of delivery or telephoned and spoken directly with the recipient to inform the recipient that the email has been sent.

4.2.4 if sent via the Authority's e-Tendering Portal, if submitted within normal business hours on a Business Day, when so submitted, or, if submitted outside normal business hours and/or Business Days, at the next start of normal business hours on a Business Day, provided that the sender must have either received an electronic confirmation of delivery or telephoned (and spoken directly with) the recipient to inform the recipient that the notice has been submitted.

4.3 Notices served under this Contract are to be delivered to:

4.3.1 for the Authority:

[redacted], Senior Commercial Manager

[redacted]

39 Victoria Street

London

SE1H 0EU

4.3.2 for the Supplier: [redacted]- Commercial Business Manager– [redacted]

5. Management levels for escalation and dispute resolution

5.1 The management levels at which a Dispute may be dealt with as referred to as part of the Dispute Resolution Procedure are as follows:

Level	**Authority representative**	**Supplier representative**
1	Contract Manager	[redacted] Comms Bus. Mgr
2	Category Lead	[redacted] – Nat Sales Mgr
3	Deputy Director	[redacted] – Country Lead

6. **Order of precedence**

6.1 Subject always to Clause 7.17.1 and 6.9.2 of Schedule 2 and Clause 1.11 of Schedule 5, should there be and only to the extent that there is, a conflict between any of the provisions of this Contract the descending order of priority for construction purposes shall be:

6.1.1 the provisions on page 1 of this Contract;

6.1.2 Schedule 1: Key Provisions;

6.1.3 Schedule 2: General Terms and Conditions;

6.1.4 Schedule 7: Commercial Schedule;

6.1.5 Schedule 6: Specification;

6.1.6 Schedule 5: Definitions and Interpretations;

6.1.7 Schedule 16: Buyback Price

6.1.8 Schedule 15: Quality Technical Agreement

6.1.9 Schedule 9: Tender Response Document;

6.1.10 Schedule 3 Storage Facilities and Storage Provider

6.1.11 Schedule 4: Information Provisions;

6.1.12 Schedule 10: Business Continuity Plan;

6.1.13 Schedule 11: Parent Company Guarantee [Not Used];

6.1.14 Schedule 8: Proforma Change Control Note.

6.1.15 Schedule 12: Stock Report

6.1.16 Schedule 13: Release Plan

6.1.17 Schedule 14: Exit Plan

7. **Purchase Orders**

7.1 The Authority shall issue a Purchase Order to the Supplier in respect of the Goods to be supplied to the Authority under this Contract. The Supplier shall comply with the terms of such Purchase Order as though it were a term of this Contract. For the avoidance of doubt, any actions or work undertaken by the Supplier under this Contract prior to the receipt of a Purchase Order covering the relevant Goods shall be undertaken at the Supplier's risk and expense and the Supplier shall only be entitled to invoice for Goods covered by a valid Purchase Order.

7.2 A reference in the Purchase Order to 'current terms and conditions' or any similar reference is a reference to the terms and conditions of this Contract.

8. **Time of the essence**

8.1 Time is of the essence as to any delivery dates under this Contract and if the Supplier fails to meet any delivery date this shall be addressed in accordance with Clause 7.4 of Schedule 2.

9. **Regulatory and information requirements**

9.1 The Supplier shall maintain, and no later than any date on which it would otherwise expire, obtain a renewal of the Marketing Authorisation in accordance with applicable Law from time to time (including the provisions of the Human Medicines Regulations 2012, where applicable Directive 2001/83 and/or Regulation 726/2004 and any amended and/or successor legislation applicable to the UK or any part of it). This obligation shall apply throughout the duration and after the expiry or termination of this Contract until such time as the Authority notifies the Supplier in writing that it has used or disposed of all Goods supplied under this Contract.

9.2 Without prejudice to the provisions of Clause 9.10 of this Schedule 1, where the holder of the Marketing Authorisation is a third party, any obligation on the Supplier under this Contract shall be taken as a requirement on the Supplier to procure the compliance of the holder of the Marketing Authorisation with such obligation to the extent necessary to ensure the relevant obligation is fully met.

9.3 Without prejudice to the Supplier's obligations under Clause 9.10 of this Schedule 1, where the Supplier knows or believes there to be any delay or other problem with the Marketing Authorisation or its renewal it shall promptly and in any event within seven (7) days of such knowledge or belief inform the Authority in writing.

9.4 If the Marketing Authorisation is:

9.4.1 withdrawn by the Licensing Authority;

9.4.2 suspended by the Licensing Authority for a period in excess of one (1) month; or

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

9.4.4 in each case (as set out in Clauses 9.4.1 to 9.4.3 of this Schedule 1) for reasons relating to the safety or efficacy of the Goods or deficiencies in any application made by the Supplier to the Licensing Authority, then the Authority shall be entitled either to:

(a) terminate this Contract by issuing a Termination Notice to the Supplier; or

(b) exercise its rights under Clause 9.5 of this Schedule 1.

9.5 If the Marketing Authorisation is amended or varied by the Licensing Authority and such amendment or variation results in the Authority reducing the scope of its requirement for the Goods, the Authority shall be entitled to proportionately reduce the quantity of the Goods to be delivered during the Term upon written notice to the Supplier provided that it shall take due account of all relevant guidance received from the Licensing Authority.

9.6 The Supplier shall:

9.6.1 reply promptly to all reasonable enquiries and complaints by the Authority relating to the use, effective administration, quality, performance and durability of the Goods;

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

9.6.3 promptly and in any event within five (5) Business Days of becoming aware of the same inform the Authority and provide full details of any claim brought by any third party in relation to the Goods; and

9.6.4 without prejudice to Clause 9.6.2 of this Schedule 1, should the Supplier become aware of an actual or suspected adverse reaction to the Goods which is not described in the Summary of Product Characteristics, promptly inform the Authority in writing and in any event within seven (7) days of becoming aware of the same.

9.7 The Supplier shall notify the Authority promptly and in any event within two (2) Business Days of any engagement or consultation with the Licensing Authority arising out of, or in connection with, any concerns relating to the safety or efficacy of the Goods.

9.8 Following any engagement or consultation with the Licensing Authority the Supplier shall provide the Authority with a copy of any report or other communication published or provided by the Licensing Authority in relation to the Goods.

9.9 Upon receipt of notice pursuant to Clause 9.7 of this Schedule 1 or any report or communication pursuant to Clause 9.8 of this Schedule 1 the Authority shall be entitled to request further information from the Supplier and/or a meeting with the Supplier, and the Supplier shall comply with any such request.

9.10 Without prejudice to the Supplier's obligation to comply with all applicable Law and Guidance, where the sale, manufacture, assembly, importation, storage, distribution, supply, Delivery, or installation of the Goods under this Contract relates to medicinal products (as defined under any relevant Law and Guidance), the Supplier warrants and undertakes that it will comply with any such Law and Guidance relating to such activities in relation to such medicinal products. In particular, but without limitation, the Supplier warrants that:

9.10.1 at the point such Goods are supplied to the Authority, all such Goods which are medicinal products shall have a valid Marketing Authorisation as required by Law and Guidance in order to supply the Goods to the Authority and that all relevant authorisation, labelling, registration, approval and documentation requirements as required under Law and Guidance relating to the sale, manufacture, assembly, importation, storage, distribution, supply or Delivery of such Goods shall have been complied with. Without limitation to the foregoing provisions of this Clause 9.10 of this Schedule 1, the Supplier shall, upon written request from the Authority, make available to the Authority evidence of the grant of any required valid Marketing Authorisation, and evidence of any other authorisations, labelling, registrations, approvals or documentation required; and

9.10.2 it shall maintain, and no later than any due date when it would otherwise expire, obtain a renewal of, any authorisation, registration or approval (including without limitation CE or UKCA marking (as applicable) and/or Marketing Authorisation) required in relation to the Goods in accordance with Law and Guidance until such time as the Goods expire or the Authority notifies the Supplier in writing that it has used or disposed of all units of the Goods supplied under this Contract.

10. **Right to terminate following a specified number of material breaches**

10.1 Either Party may terminate this Contract by issuing a Termination Notice to the other Party if such other Party commits a material breach of this Contract in circumstances where it is served with a valid Breach Notice having already been served with at least two (2) previous valid Breach Notices within a period of twelve (12) consecutive calendar months prior to that as a result of any previous material breaches of this Contract which are capable of remedy (whether or not the Party in breach has remedied the breach in accordance with a Remedial Proposal).

Schedule 2

General Terms and Conditions

Contents

1. Supply of Goods

1.1 The Supplier shall supply the Goods ordered by the Authority under this Contract:

1.1.1 promptly and in any event within any time limits as may be set out in this Contract;

1.1.2 in accordance with the provisions of this Contract;

1.1.3 using reasonable skill and care in their Delivery;

1.1.4 using reasonable skill and care in their installation, associated works and/or training to the extent that such installation, works and/or training is a requirement of this Contract;

1.1.5 in accordance with any quality assurance standards as set out in the Key Provisions, the Specification and/or the Tender Response Document;

1.1.6 in accordance with Law and Guidance;

1.1.7 in accordance with Good Industry Practice;

1.1.8 in accordance with the Policies; and

1.1.9 in a professional and courteous manner.

1.2 The Supplier shall comply fully with its obligations set out in the Specification and the Tender Response Document (to include, without limitation, the KPIs and all obligations in relation to the quality, performance characteristics, supply, Delivery and installation and training in relation to use of the Goods).

1.3 Unless otherwise agreed by the Parties in writing, the Goods shall:

1.3.1 not previously have left the control of the Supplier nor have deviated from their defined distribution path;

1.3.2 be consistent with any sample;

1.3.3 have not been rejected by any other entity prior to their supply to the Authority under this Contract; and

1.3.4 comply with any applicable specification set out in this Contract (to include, without limitation, the provisions of the Authority's requirements set out in the Specification and the Supplier's proposals for meeting such requirements set out in the Tender Response Document) and any applicable manufacturers' specifications.

1.4 The Supplier shall ensure that all relevant consents, authorisations, licences and accreditations required to supply the Goods are in place prior to the Delivery of any Goods to the Authority.

1.5 If there are any incidents that in any way relate to or involve the use of the Goods by the Authority, the Supplier shall cooperate fully with the Authority in relation to the Authority's application of the Policies on reporting and responding to all incidents, including serious incidents requiring investigation, and shall respond promptly to any reasonable and proportionate queries, questions and/or requests for information that the Authority may have in this context in relation to the Goods.

1.6 If there are any quality, performance and/or safety related reports, notices, alerts or other communications issued by the Supplier or any regulatory or other body in relation to the Goods, the Supplier shall promptly provide the Authority with a copy of any such reports, notices, alerts or other communications.

1.7 Upon receipt of any such reports, notices, alerts or other communications pursuant to Clause 1.6 of this Schedule 2, the Authority shall be entitled to request further information from the Supplier and/or a meeting with the Supplier, and the Supplier shall cooperate fully with any such request.

2. **Performance review and delay**

2.1 Should the Authority agree a revised timeline for the Delivery of the Goods or Replacement Goods for any reason in accordance with this Contract, the Supplier shall attend further contract review meetings at such times as may be agreed between the Parties acting reasonably. The Supplier's performance under this Contract, production plans and Business Continuity Plan shall be reviewed at such meetings.

2.2 In the event that the Supplier becomes aware that it is or it may become unable to supply the Goods in accordance with the timelines agreed with the Authority under this Contract the Supplier shall immediately notify the Authority of such fact.

2.3 Where the Supplier has breached any of the KPIs, the Authority shall be permitted to:

2.3.1 publish or disclose such fact to any third party and/or the public; and/or

2.3.2 publish details of any such breaches in such format as the Authority may determine in its absolute discretion from time to time (which may include, without limit, rating the Supplier's performance against other suppliers' performance and publishing the results in a ranking format).

3. **Quality assurance**

3.1 The Supplier shall comply with its quality control monitoring system details of which are included in the Marketing Authorisation and the Manufacturing Licence. The Supplier shall manufacture the Goods in accordance with Good Manufacturing Practice and the Supplier shall at all times comply with those standards set out in the QTA.

3.2 The Supplier shall maintain the Manufacturing Licence(s) and all other licences necessary for the manufacture of the Goods during the Term of this Contract and shall not make any significant changes (including without limitation any changes which shall or may have an impact on the quality or use of the Goods) to the same or to the Specification or the Supplier's quality control monitoring system in relation to the Goods without:

3.2.1 notifying the Authority in writing in advance of its 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 by the Supplier to include details of the consequences which will follow such change being implemented; and

3.2.2 the relevant Licensing Authority formally approving such change.

4. **Storage Services**

4.1 The Supplier shall store the Stockpiled Goods in the Stockpile at the Storage Facilities in accordance with this Contract and shall invoice the Authority for these services as set out in Clause 13 of Schedule 2.

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

4.2.1 the Marketing Authorisation for the relevant Stockpiled Goods;

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 Goods at the Storage Facilities. If the Supplier wishes to relocate the Stockpiled Goods for storage at any location other than the Storage Facilities or to move the Stockpiled Goods 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 Goods will be at the full risk of the Supplier.

4.4 The Supplier shall:

4.4.1 store the Stockpiled Goods in accordance with strict temperature controls as specified in the relevant SmPC and as required to ensure that the Stockpiled Goods 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 Goods are clearly identifiable as Stockpiled Goods belonging to the Authority;

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

4.4.5 allocate sufficient space at the Storage Facilities to store the Quantity Required of the Stockpiled Goods;

4.4.6 ensure that the Stockpiled Goods 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 Goods, and each Stockpiled Goods 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 Goods in accordance with Good Industry Practice and the Wholesale Distribution Authorisation in relation to the Stockpiled Goods;

4.4.8 enter into a QTA with the Authority in the form set out at Schedule 15, in order to ensure compliance with the Authority's Wholesale Distribution Authorisation;

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

4.4.10 implement a comprehensive stock management system in respect of the Stockpiled Goods in accordance with the Law, regulations, directions, and Guidance, and provide any information in relation to stock control of the Stockpiled Goods 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 Ifat all times and in all respects in compliance with this Contract and to ensure that a sufficient reserve of staff is available to provide the Storage Services during holidays or absences;

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

4.4.14 provide to the Authority a Stock Report quarterly, within two weeks of the end of the previous quarter.

4.5 The Supplier shall advise the Authority forthwith in writing of any damage to or loss of the Stockpiled Goods 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 elect to undertake a stock audit in relation to the Stockpiled Goods, 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;

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

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 Contract 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. **Stockpile Build**

5.1 The Supplier shall ensure that the Stockpiled Goods reach the Quantity Required as soon as possible following the Commencement Date of this Contract and in any event no later than the earlier of: (a) 12 weeks following the Commencement Date; or (b) such date as set out in the Tender Response Document, unless otherwise agreed between the Parties.

6. **Authorised Release in an Emergency**

6.1 A Party shall promptly notify the other Party in writing if it anticipates that there may be a shortage of supply in the UK of any medicines that are identical or similar to the Goods due to an Emergency. In the event of such an Emergency any Authorised Release shall be known as an Emergency Authorised Release.

6.2 The Authority and the Supplier shall jointly review any such anticipated shortages and the means for minimising such shortages and their associated impact. Following this, the Supplier, in consultation with the Authority, shall draw up a draft Release Plan containing the information relating to the anticipated shortages, the means for minimising such shortages and their associated impact. This draft Release Plan shall be in the form set out at and shall be submitted to the Authority for approval.

6.3 If the Authority in its absolute discretion considers that: (i) there is an Emergency; and (ii) there is a shortage of supply in the UK of any medicines that are identical or similar to the Goods due to the Emergency, it shall review the draft Release Plan and, where it is satisfied with the draft Release Plan, will provide written notice of approval of the draft Release Plan to the Supplier noting that following the provision of the written notice of approval by the Authority, the draft Release Plan shall no longer be a draft and shall be a Release Plan.

6.4 The approved Release Plan shall include the information set out in Schedule 13 and shall set out the volume of Stockpiled Goods that will be subject to an Emergency Authorised Release under the Release Plan.

6.5 The Supplier shall then immediately on receipt of the written notice of approval from the Authority, withdraw from the Stockpile, the volume of Stockpiled Goods set out in the Release Plan.

6.6 During the period of an Emergency Authorised Release, the Supplier shall:

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

6.6.2 comply with the Release Plan;

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

6.6.4 where required by the Authority, provide a Release Report to the Authority at the end of each week and such Release Report shall set out:

(a) the number of Units of Stockpiled Goods removed from the Stockpile during the previous week;

(b) the number of Units of Stockpiled Goods remaining in the Stockpile at the end of the previous week;

(c) the identities of the customers to whom the Supplier has supplied the Released Goods during the previous week; and

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

6.7 Following an Emergency Authorised Release, the Authority accepts that the volume of Stockpiled Goods will be reduced by the number of Units of Stockpiled Goods removed in accordance with such Emergency Authorised Release. At no cost to the Authority, the Supplier shall replenish the stock to return the Stockpiled Goods to the Quantity Required as soon as possible and in any event no later than 12 weeks following the relevant Emergency Authorised Release unless otherwise agreed between the Parties.

6.8 During such period of replenishment as described in Clause 6.7 of this Schedule 2, the Supplier shall provide the following information to the Authority on a weekly basis, or such other frequency as agreed between the Parties from time to time, until such time the Stockpile is returned to the Quantity Required;

6.8.1 the number of Units of the Goods Delivered in the previous week or since the last update if a different frequency of updates is agreed in accordance with Clause 6.8;

6.8.2 the current volume of Units of Stockpiled Goods;

6.8.3 the time within which the Supplier anticipates returning the Stockpile to the Quantity Required; and

6.8.4 any other information reasonably requested by the Authority in relation to the replenishment of the Stockpile to the Quantity Required.

6.8.5 Stock Rotation

6.9 The Supplier shall ensure that:

6.9.1 the Quantity Required of Stockpiled Goods is maintained in the Stockpile throughout the Term, subject only to Authorised Releases under a Release Plan, provided that this will be limited to the period of time required to supply Replacement Goods in accordance with Clause 6.7 of this Schedule 2, or Exit Plan in accordance with this Contract; and

6.9.2 all Stockpiled Goods have an unexpired shelf life of at least 18 months.

6.10 The Supplier may remove (sell or otherwise dispose of) Stockpiled Goods from the Stockpile for the purpose of complying with Clause 6.9.2 of this Schedule 2, provided that immediately upon such removal, the Supplier shall place in the Stockpile sufficient Units of Replacement Goods to meet the Quantity Required, and that on removal of any Stockpiled Goods in accordance with this Clause 6.10, it shall make a written record relating to the removal of the Stockpiled Goods.

6.11 Such Units of Replacement Goods shall be supplied by the Supplier into the Stockpile without charge.

6.12 Save as set out in Clause 6 and Clause 6.10 of this Schedule 2, the Supplier shall not remove any Stockpiled Goods from the Stockpile, without the Authority's prior written consent.

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

7. **Delivery**

7.1 The Supplier shall deliver the Goods to the Stockpile.

7.2 Delivery shall be completed when the Goods have been unloaded at the Stockpile by the Supplier ("**Delivery**").

7.3 Following Delivery, the Supplier shall store the Stockpiled Goods at the Storage Facility in accordance with Law.

7.4 The Supplier acknowledges the critical importance that the Authority places on ensuring that all Goods are delivered in accordance with this Contract. Without prejudice to any other provisions of this Contract, where the Supplier does not deliver the Goods in accordance with this Contract and other than where such failure to deliver is due to the default of the Authority or its agents, without prejudice to its other rights or remedies under this Contract or under Law, the Authority shall:

7.4.1 be entitled to refuse or cancel Delivery of any such Goods not delivered in accordance with the timelines specified in this Contract;

7.4.2 cease to have any liability to pay for any such Goods not Delivered in accordance with the Contract where such Goods have been refused delivery or had their delivery cancelled in accordance with Clause 7.4.1 of this Schedule 2;

7.4.3 be entitled to charge the Supplier for any costs incurred by the Authority as a result of such failure, such costs to include, without limitation:

(a) any additional operational and/or administrative costs and expenses incurred by the Authority including costs spent by or on behalf of the Authority in dealing with the consequences of the breach;

(b) any wasted expenditure or charges; and

(c) any compensation or interest paid to a third party by the Authority,

provided that the Authority shall use its reasonable endeavours to mitigate the same. The Supplier shall pay such costs to the Authority within thirty (30) days of the date of the Authority's invoice for the same; and/or

7.4.4 be entitled to treat this a breach not capable of remedy and terminate this Contract in accordance with Clause 20.4 of this Schedule 2.

7.5 The Supplier's obligations under Clauses 7.5 and 7.6 of this Schedule 2 are without prejudice to its obligations under Clause 24 of this Schedule 2. The Supplier shall deliver all Goods securely packaged with the following details being shown clearly on the shipping carton or other such outer packaging:

7.5.1 a description of the Goods using the Supplier's brand name and/or generic drug name;

7.5.2 the quantity in the package;

7.5.3 special directions for storage (if any);

7.5.4 expiry date for the Goods in the package;

7.5.5 batch number;

7.5.6 name of Supplier; and

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

7.6 The labelling and marking of all packages of the Goods and all relevant information accompanying them shall be in English. The Supplier shall discuss and, other than to the extent required by the Licensing Authority, agree with the Authority any changes to be made to labelling, instructions and patient information relating to the Goods.

7.7 The Supplier shall ensure that a delivery note shall accompany each delivery of the Goods. Such delivery note shall contain the information specified in the Specification or as otherwise agreed with the Authority in writing. Where such information requirements as to the content of delivery notes are not specified or separately agreed, such delivery notes shall, as a minimum, contain the Authority's order number, the name and address of the Authority, a description, weight, measure, batch number and expiry date and quantity of the Goods, and shall show separately any extra agreed charges for containers and/or any other item not included in the Contract Price or, where no charge is made, whether the containers are required to be returned. All ancillary paperwork and literature (including invoices) shall include the same information.

7.8 Unless otherwise agreed with the Authority in writing (including where stated in the Specification and/or the Tender Response Document), the Supplier shall be responsible for carriage, insurance, transport, all relevant licences, all related costs, and all other costs associated with the Delivery of the Goods to the delivery location and unloading of the Goods at that location. Without limitation to the foregoing provision of this Clause 7.8 of this Schedule 2, unless otherwise agreed with the Authority in writing (including where stated in the Specification and/or the Tender Response Document), the Supplier shall be responsible for obtaining all export and import licences for the Goods and shall be responsible for any delays to the Delivery time due to such licences not being available when required. In the case of any Goods supplied from outside the United Kingdom, the Supplier shall ensure that accurate information is provided to the Authority as to the country of origin of the Goods and shall be liable to the Authority for any extra duties or taxes for which the Authority may be accountable should the country of origin prove to be different from that set out in the Specification and/or the Tender Response Document.

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

8. **Title and Risk**

8.1 Risk in the Goods shall remain with the Supplier throughout the term.

8.2 Title to the Goods shall pass to the Authority on the earlier of:

8.2.1 full payment for such Goods; or

8.2.2 at the point such Goods are Delivered as specified in this Contract. For the avoidance of doubt, where title passes in accordance with this Clause 8.2.2 of this Schedule 2, then the full Contract Price for such Goods shall be recoverable by the Supplier from the Authority as a debt if there is non-payment of a valid undisputed invoice issued by the Supplier to the Authority in relation to such Goods.

8.3 Following transfer of title to the Authority in accordance with Clause 8.2 and subject to Clauses 8.5, 8.6, 9.4, 15.2 and 21.5 of Schedule 2, title shall remain with the Authority for the rest of the Term, save that risk in all Units of the Stockpiled Goods shall remain with the Supplier.

8.4 The Supplier acknowledges and agrees that the Authority shall retain full title to the Stockpiled Goods and at no time shall the Supplier hold any proprietary or other interest in the Stockpiled Goods 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 of Schedule 2.

8.5 If Stockpiled Goods are removed from the Stockpile by the Supplier in accordance with Clause 6.10 of Schedule 2, then:

8.5.1 risk in such Units of the Stockpiled Goods shall remain with the Supplier upon such removal; and

8.5.2 notwithstanding Clause 8.3, title to such Units of the Stockpiled Goods shall pass to the Supplier upon such removal.

8.6 If the Supplier removes any Stockpiled Goods from the Stockpile during an Authorised Release then:

8.6.1 risk in such Units of the Goods shall remain with the Supplier upon Authorised Release; and

8.6.2 notwithstanding Clause 8.3, title to such Units of the Goods shall pass to the Supplier on the date of the relevant Authorised Release.

8.7 All tools, equipment and materials of the Supplier required in the performance of the Supplier's obligations under this Contract shall be and remain at the sole risk of the Supplier, whether or not they are situated at a delivery location.

9. **Authority's right to Inspect Stockpile and Storage Facilities, Rejection and Recall**

9.1 The Supplier shall procure that the Authority shall on no less than 24 hours' notice be allowed access to the Stockpile for any purpose whatsoever. The Supplier shall on receipt of such notice provide to the Authority and any person authorised by the Authority:

9.1.1 unrestricted access to the Stockpile;

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

9.1.3 access to any personnel and information necessary to enable the Authority to review the Supplier's compliance with this Contract (including records to identify the Stockpiled Goods); and

9.1.4 any cooperation and assistance reasonably requested by the Authority in relation to the exercise of the Authority's rights under this Clause 9 of Schedule 2.

9.2 The Supplier shall, subject to any duty of confidentiality to a third party or security requirement of its insurers, give the Authority or the Authority's 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 to allow inspection under Clause 9.1 of Schedule 2, including providing or obtaining any necessary permissions.

9.3 The Authority may reject any Units of the Stockpiled Goods:

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

9.3.2 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;

such Goods to be referred to as "**Rejected Goods**".

9.4 The Supplier shall immediately remove the Rejected Goods from the Stockpile and, notwithstanding Clause 8.3, title in respect of any Rejected Goods shall pass to the Supplier immediately upon rejection of any such Goods in accordance with Clauses 9.3 and/or 9.7 of this Schedule 2. For the avoidance of doubt, risk shall remain with the Supplier.

9.5 Without prejudice to any other provisions of this Contract or any other warranties or guarantees applicable to the Goods supplied and subject to Clause 9.9 of this Schedule 2, if at any time following the Delivery of any Goods, all or any part of such Goods are found to be defective or otherwise not in accordance with the terms of this Contract ("**Defective Goods**"), the Authority may at any time by written notice to the Supplier reject any Defective Goods and the Supplier shall, at the Authority's discretion:

9.5.1 upon written request from the Authority and without charge, promptly (and in any event within twenty (20) Business Days of such written notice by the Authority under Clause 20.5 of this Schedule 2 or such other time agreed by the Parties in writing) remedy the deficiency by replacing such Defective Goods; or

9.5.2 upon written notice of rejection from the Authority, treat such Defective Goods as Rejected Goods in accordance with Clauses 9.3 to of this Schedule 2.

9.6 Where the Authority discovers more than one Defective Good in any given batch of the Goods, the Authority shall be entitled to reject the entire batch provided always that the Authority shall take due account of all relevant guidance received from the Licensing Authority.

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

the Authority may by written notice to the Supplier require the Supplier to replace Rejected Goods free of charge; or

9.7.1 the Authority may choose to source some or all of the Goods (which for the sake of clarity shall include all services associated with the Goods (including for the avoidance of doubt Storage and Maintenance) which enable the Authority to store those stockpiled goods on similar terms as this Contract), 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 medicines that are identical or similar to the Goods from a third party.

9.8 No failure by the Authority to make a complaint at the time of Delivery nor any other act or omission of the Authority including in particular keeping a sample, inspection of or payment for any Goods by the Authority shall constitute acceptance, waiver or approval of the Goods or limit the Authority's right subsequently to reject Goods should such Goods be Defective Goods.

9.9 The Supplier shall be relieved of its liabilities under Clauses 9.5 to 9.7 (inclusive) of this Schedule 2 to the extent only that the Goods are damaged, there are defects in the Goods and/or the Goods fail to comply with the requirements of this Contract due, in each case, to any acts or omissions of the Authority.

9.10 Where the Supplier is required by Law, Guidance, and/or Good Industry Practice to order a product recall ("**Requirement to Recall**") in respect of the Goods, the Supplier shall:

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

9.10.2 from the date of the Requirement to Recall, treat the Goods which are the subject of such recall as Defective Goods in accordance with Clause 9.5 of this Schedule 2;

9.10.3 consult with the Authority as to the most efficient method of executing the recall of the Goods and use its reasonable endeavours to minimise the impact on the Authority of the recall; and

9.10.4 indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings suffered or incurred by the Authority as a result of such Requirement to Recall.

9.11 Where the Authority notifies the Supplier that it will source Replacement Goods elsewhere, the Supplier shall refund to the Authority any sums paid for the Rejected Goods within 30 days of the date of such notification and the Quantity Required shall be reduced by the number of Units of Replacement Goods sourced elsewhere by the Authority.

10. **Supplier Staff**

10.1 The Supplier shall be solely responsible for all activities associated with the performance of its obligations under the Contract including the management of all personnel employed or contracted by the Supplier to supply the Goods and provide Storage Services.

10.2 The Supplier shall employ for the purpose of this Contract 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 activities associated with the performance of this Contract in accordance with all relevant provisions of the Contract.

10.3 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.

10.4 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.

10.5 The Supplier agrees to indemnify and keep indemnified the Authority against all losses, costs, proceedings or damages whatsoever arising out of or in connection with any breach by the Supplier of its obligations under this Clause 10 of this Schedule 2.

11. **Business continuity**

11.1 The Supplier shall use reasonable endeavours to ensure its Business Continuity Plan operates effectively alongside the Authority's business continuity plan where relevant to the supply of the Goods. The Supplier shall also ensure that its Business Continuity Plan complies on an ongoing basis with any specific business continuity requirements, as may be set out in the Specification and the Supplier's proposals for meeting such requirements as set out in the Tender Response Document.

11.2 Throughout the Term, the Supplier will ensure its Business Continuity Plan provides for continuity during a Business Continuity Event. The Supplier confirms and agrees such Business Continuity Plan details and will continue to detail robust arrangements that are reasonable and proportionate to:

11.2.1 the criticality of this Contract to the Authority; and

11.2.2 the size and scope of the Supplier's business operations,

regarding continuity of the supply of Goods during and following a Business Continuity Event.

11.3 The Supplier shall test its Business Continuity Plan at reasonable intervals, and in any event no less than once every twelve (12) months starting from the Commencement Date or such other period as may be agreed between the Parties taking into account the criticality of this Contract to the Authority and the size and scope of the Supplier's business operations. The Supplier shall promptly provide to the Authority, at the Authority's written request, copies of its Business Continuity Plan, reasonable and proportionate documentary evidence that the Supplier tests its Business Continuity Plan in accordance with the requirements of this Clause 11.3 of this Schedule 2 and reasonable and proportionate information regarding the outcome of such tests. The Supplier shall provide to the Authority a copy of any updated or revised Business Continuity Plan within fourteen (14) Business Days of any material update or revision to the Business Continuity Plan.

11.4 The Authority may suggest reasonable and proportionate amendments to the Supplier regarding the Business Continuity Plan at any time. Where the Supplier, acting reasonably, deems such suggestions made by the Authority to be relevant and appropriate, the Supplier will incorporate into the Business Continuity Plan all such suggestions made by the Authority in respect of such Business Continuity Plan. Should the Supplier not incorporate any suggestion made by the Authority into such Business Continuity Plan it will explain the reasons for not doing so to the Authority and propose other ways that it can incorporate into its Business Continuity Plan other provisions that will address the concerns behind the suggestion made by the Authority.

11.5 Should a Business Continuity Event occur at any time, the Supplier shall implement and comply with its Business Continuity Plan and provide regular written reports to the Authority on such implementation.

11.6 During and following a Business Continuity Event, the Supplier shall use reasonable endeavours to continue to supply the Goods in accordance with this Contract.

12. Contract management

12.1 Each Party shall appoint and retain a Contract Manager who shall be its primary point of contact for the other Party in relation to matters arising from this Contract. Should the Contract Manager be replaced, the Party replacing the Contract Manager shall promptly inform the other Party in writing of the name and contact details for the new Contract Manager. Any Contract Manager appointed shall be of sufficient seniority and experience to be able to make decisions on the day to day operation of the Contract. The Supplier confirms and agrees that it will be expected to work closely and cooperate fully with the Authority's Contract Manager.

12.2 Where the Authority reasonably requests a review meeting, and on the giving of 14 (fourteen) Business Days' notice, the Supplier shall ensure that its representatives (to include, without limitation, its Contract Manager) shall attend such review meetings to review the performance of the Supplier under this Contract and to discuss matters arising generally under this Contract. Each Party shall ensure that those attending such meetings have the authority to make decisions regarding the day to day operation of the Contract.

12.3 The Authority may take minutes of each review meeting and, if it does so, shall circulate draft minutes to the Supplier within a reasonable time following such review meeting. The Supplier shall inform the Authority in writing of any suggested amendments to the minutes within five (5) Business Days of receipt of the draft minutes. If the Supplier does not respond to the Authority within such five (5) Business Days the minutes will be deemed to be approved. Where there are any differences in interpretation of the minutes, the Parties will use their reasonable endeavours to reach agreement. If agreement cannot be reached the matter shall be referred to, and resolved in accordance with, the Dispute Resolution Procedure.

12.4 The Supplier shall provide such management information as the Authority may request from time to time within seven (7) Business Days of the date of the request. The Supplier shall supply the management information to the Authority in such form as may be specified by the Authority and, where requested to do so, the Supplier shall also provide such management information to any Contracting Authority, whose role it is to analyse such management information in accordance with UK government policy (to include, without limitation, for the purposes of analysing public sector expenditure and planning future procurement activities) ("**Third Party Body"**). The Supplier confirms and agrees that the Authority may itself provide the Third Party Body with management information relating to the Goods purchased, any payments made under this Contract, and any other information relevant to the operation of this Contract.

12.5 Upon receipt of management information supplied by the Supplier to the Authority and/or the Third Party Body, or by the Authority to the Third Party Body, the Parties hereby consent to the Third Party Body and the Authority:

12.5.1 storing and analysing the management information and producing statistics; and

12.5.2 sharing the management information or any statistics produced using the management information with any other Contracting Authority.

12.6 If the Third Party Body and/or the Authority shares the management information or any other information provided under Clause 12.5 of this Schedule 2, any Contracting Authority receiving the management information shall, where such management information is subject to obligations of confidence under this Contract and such management information is provided direct by the Authority to such Contracting Authority, be informed of the confidential nature of that information by the Authority and shall be requested by the Authority not to disclose it to any body that is not a Contracting Authority (unless required to do so by Law).

12.7 The Authority may make changes to the type of management information which the Supplier is required to supply and shall give the Supplier at least one (1) month's prior written notice of any changes.

13. **Price and payment**

13.1 The Contract Price shall be calculated as set out in the Commercial Schedule.

13.2 Unless otherwise stated in the Commercial Schedule the Contract Price:

13.2.1 shall remain fixed during the Term; and

13.2.2 is the entire price payable by the Authority to the Supplier in respect of the provision of the Goods and includes, without limitation:

(a) packaging, packing materials, addressing, labelling, loading, Delivery to and unloading at the delivery location, the cost of any import or export licences, all appropriate taxes (excluding VAT), duties and tariffs, any expenses arising from import and export administration, any installation costs and associated works, the costs of all associated documentation and information supplied or made accessible to the Authority in any media, and any training in relation to the use, storage, handling or operation of the Goods;

(b) any royalties, licence fees or similar expenses in respect of the making, use or exercise by the Supplier of any Intellectual Property Rights for the purposes of performing this Contract, and any licence rights granted to the Authority in accordance with Clause 16 of this Schedule 2; and

(c) costs and expenses in relation to supplies and materials used by the Supplier or any third party in the manufacture of the Goods, and any other costs incurred by the Supplier in association with the manufacture, supply or installation of the Goods.

13.3 The Supplier shall invoice the Authority for Goods at any time following completion of the supply of the Goods in compliance with this Contract. Each invoice shall contain such information and be addressed to such individual as the Authority may inform the Supplier from time to time.

13.4 The Contract Price is exclusive of VAT, which, if properly chargeable, the Authority shall pay at the prevailing rate subject to receipt from the Supplier of a valid and accurate VAT invoice. Such VAT invoices shall show the VAT calculations as a separate line item.

13.5 Where the Contract Price is or may become subject to any pricing requirements of any voluntary and/or statutory pricing regulation schemes, the Parties shall comply with such pricing requirements as required by Law from time to time and specifically as required by the statutory pricing regulation scheme (and any future regulation) or to the extent applicable to the Supplier from time to time as an industry member of a voluntary scheme, including any reductions in price by reason of the application of such schemes.

13.6 The Authority shall verify and pay each valid and undisputed invoice received in accordance with Clause 13.4 of this Schedule 2 within thirty (30) days of receipt of such invoice at the latest. However, the Authority shall use its reasonable endeavours to pay such undisputed invoices sooner in accordance with any applicable government prompt payment targets. If there is undue delay in verifying the invoice in accordance with this Clause 13.7 of this Schedule 2, the invoice shall be regarded as valid and undisputed for the purposes of this Clause 13.6 after a reasonable time has passed.

13.7 Where the Authority raises a query with respect to an invoice the Parties shall liaise with each other and agree a resolution to such query within thirty (30) days of the query being raised. If the Parties are unable to agree a resolution within thirty (30) days the query shall be referred to dispute resolution in accordance with the Dispute Resolution Procedure. For the avoidance of doubt, the Authority shall not be in breach of any of any of its payment obligations under this Contract in relation to any queried or disputed invoice sums unless the process referred to in this Clause 13.8 of this Schedule 2 has been followed and it has been determined that the queried or disputed invoice amount is properly due to the Supplier and the Authority has then failed to pay such sum within a reasonable period following such determination.

13.8 The Supplier shall pay to the Authority any service credits and/or other sums and/or deductions (to include, without limitation, deductions relating to a reduction in the Contract Price) that may become due in accordance with the provisions of the Specification.

13.9 The Authority reserves the right to set-off:

13.9.1 any monies due to the Supplier from the Authority as against any monies due to the Authority from the Supplier under this Contract; and

13.9.2 any monies due to the Authority from the Supplier as against any monies due to the Supplier from the Authority under this Contract.

13.10 Where the Authority is entitled to receive any sums (including, without limitation, any costs, charges or expenses) from the Supplier under this Contract, the Authority may invoice the Supplier for such sums. Such invoices shall be paid by the Supplier within thirty (30) days of the date of such invoice.

13.11 If a Party fails to pay any undisputed sum properly due to the other Party under this Contract, the Party due such sum shall have the right to charge interest on the overdue amount at the applicable rate under the Late Payment of Commercial Debts (Interest) Act 1998, accruing on a daily basis from the due date up to the date of actual payment, whether before or after judgment.

14. **Warranties**

14.1 The Supplier warrants and undertakes that:

14.1.1 the Goods shall be suitable for the purposes referred to in the Specification, be of satisfactory quality, fit for their intended purpose as indicated in the Marketing Authorisation and shall comply with the standards and requirements set out in this Contract;

14.1.2 unless otherwise confirmed by the Authority in writing (to include, without limitation, as part of the Specification), it will ensure that the Goods comply with requirements five (5) to eight (8), as set out in Annex 1 of the Cabinet Office Procurement Policy Note - Implementing Article 6 of the Energy Efficiency Directive (Action Note 07/14 3rd June 2014), to the extent such requirements apply to the relevant Goods;

14.1.3 it shall ensure that prior to actual Delivery to the Authority the Goods are manufactured, stored and/or distributed using reasonable skill and care and in accordance with Good Industry Practice and Good Manufacturing Practice;

14.1.4 without prejudice to the generality of the warranty at Clause 14.1.3 of this Schedule 2, it shall ensure that, the Goods are manufactured, stored and/or distributed in accordance with good manufacturing practice and/or good warehousing practice and/or good distribution practice, as may be defined under any Law, Guidance and/or Good Industry Practice relevant to the Goods, and in accordance with any specific instructions of the manufacturer of the Goods;

14.1.5 it shall ensure that all facilities used in the manufacture, storage and distribution of the Goods are kept in a state and condition necessary to enable the Supplier to comply with its obligations in accordance with this Contract;

14.1.6 it has, or the manufacturer of the Goods has, manufacturing and warehousing capacity sufficient to comply with its obligations under this Contract;

14.1.7 it will ensure sufficient stock levels to comply with its obligations under this Contract;

14.1.8 it shall ensure that the transport and Delivery of the Goods mean that they are delivered in good and useable condition;

14.1.9 where the Goods are required to be stored at a certain temperature, it shall provide, or shall procure the provision of, complete and accurate temperature records for each Delivery of the Goods during the period of transport and/or storage of the Goods from the point of manufacture to the point of Delivery to the Authority;

14.1.10 where there is any instruction information, including without limitation patient information leaflets, that accompany the Goods, it shall provide a sufficient number of copies to the Authority and provide updated copies should the instruction information change at any time during the Term;

14.1.11 all Goods delivered to the Authority shall comply with any shelf life requirements set out in the Specification;

14.1.12 it has and shall maintain a properly documented system of quality controls and processes covering all aspects of its obligations under this Contract and/or under Law and/or Guidance and shall at all times comply with such quality controls and processes;

14.1.13 unless in the case of urgency duly substantiated to the Authority (in which case the Supplier shall give the Authority as much notice as reasonably practicable) it shall not make any significant changes to its system of quality controls and processes in relation to the Goods without notifying the Authority in writing at least twenty one (21) days in advance of such change (such notice to include the details of the consequences which follow such change being implemented);

14.1.14 it shall not make any significant changes to the Goods without the prior written consent of the Authority, such consent not to be unreasonably withheld or delayed;

14.1.15 any equipment it uses in the manufacture, Delivery, or installation of the Goods shall comply with all relevant Law and Guidance, be fit for its intended purpose and maintained fully in accordance with the manufacturer's specification;

14.1.16 where any act of the Supplier requires the notification to and/or approval by any regulatory or other competent body in accordance with any Law and Guidance, the Supplier shall comply fully with such notification and/or approval requirements;

14.1.17 it has and shall as relevant maintain all rights, consents, authorisations, licences and accreditations required to supply the Goods;

14.1.18 receipt of the Goods by or on behalf of the Authority and use of the Goods or of any other item or information supplied, or made available, to the Authority will not infringe any third party rights, to include without limitation any Intellectual Property Rights;

14.1.19 it will comply with all Law, Guidance, Policies and the Supplier Code of Conduct in so far as is relevant to the supply of the Goods (including, as applicable, Directive 2001/83 and/or Regulation 726/2004 where the Goods are being supplied to Northern Ireland);

14.1.20 it will promptly notify the Authority of any health and safety hazard which has arisen, or the Supplier is aware may arise, in connection with the Goods and take such steps as are reasonably necessary to ensure the health and safety of persons likely to be affected by such hazards;

14.1.21 it shall: (i) comply with all relevant Law and Guidance 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;

14.1.22 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 14.1.22 and/or as may be requested or otherwise required by the Authority in accordance with its anti-slavery Policy.it will fully and promptly respond to all requests for information and/or requests for answers to questions regarding this Contract, the Goods, any complaints and any Disputes at the frequency, in the timeframes and in the format as requested by the Authority from time to time (acting reasonably);

14.1.23 all information included within the Supplier's responses to any documents issued by the Authority as part of the procurement relating to the award of this Contract (to include, without limitation, as referred to in the Tender Response Document and Commercial Schedule) and all accompanying materials is accurate;

14.1.24 when supplying the Goods, it shall comply with all timescales set out in or agreed in accordance with this Contract and the KPIs;

14.1.25 its Business Continuity Plan is sufficient to ensure continuity of supply of the Goods to the Authority in accordance with this Contract in the event of any manufacturing site failure including emergency maintenance work;

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

14.1.27 it is a properly constituted entity and it is fully empowered by the terms of its constitutional documents to enter into and to carry out its obligations under this Contract and the documents referred to in this Contract;

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

14.1.29 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;

14.1.30 there are no material agreements existing to which the Supplier is a party which prevent the Supplier from entering into or complying with this Contract; and

14.1.31 it has and will continue to have the capacity, funding and cash flow to meet all its obligations under this Contract; and it has satisfied itself as to the nature and extent of the risks assumed by it under this Contract and has gathered all information necessary to perform its obligations under this Contract and all other obligations assumed by it.

14.2 If the Supplier is in breach of Clause 14.1 of this Schedule 2, then, without prejudice to any other right or remedy of the Authority, the Authority shall be entitled to reject and/or return the Goods and the Supplier shall, subject to Clause 18.2 of this Schedule 2, indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings suffered or incurred by the Authority as a result of such breach.

14.3 The Supplier agrees to use reasonable endeavours to assign to the Authority upon request the benefit of any warranty, guarantee or similar right which it has against any third party manufacturer or supplier of the Goods in full or part.

14.4 The Supplier warrants that all information, data and other records and documents required by the Authority as set out in the Specification and the Tender Response Document shall be submitted to the Authority in the format and in accordance with any timescales set out in the Specification and the Tender Response Document.

14.5 The Supplier warrants and undertakes to the Authority that, as at the Commencement Date, it has notified the Authority in writing of any Occasions of Tax Non-Compliance or any litigation that it is involved in that is in connection with any Occasions of Tax Non-Compliance. If, at any point during the Term, an Occasion of Tax Non-Compliance occurs, the Supplier shall:

14.5.1 notify the Authority in writing of such fact within five (5) Business Days of its occurrence; and

14.5.2 promptly provide to the Authority:

(d) details of the steps which the Supplier is taking to address the Occasion of Tax Non-Compliance and to prevent the same from recurring, together with any mitigating factors that it considers relevant; and

(e) such other information in relation to the Occasion of Tax Non-Compliance as the Authority may reasonably require.

14.6 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 14 have been breached or there is a risk that any warranties may be breached.

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

15. **Exit Phase**

15.1 The Authority and the Supplier agree that during the Exit Phase the Supplier shall buy back all of the Stockpiled Goods at the Buyback Price in accordance with an Exit Plan.

15.2 Notwithstanding Clause 8.3 of this Schedule 2, during the Exit Phase, title of the Goods shall pass to the Supplier on the earlier of:

15.2.1 full payment for such Goods; or

15.2.2 removal of such Goods from the Stockpile by the Supplier. For the avoidance of doubt, where title passes in accordance with this Clause 15.2.2 of this Schedule 2, then the full Buyback Price for such Goods shall be recoverable by the Authority from the Supplier as a debt if there is non-payment of a valid undisputed invoice issued by the Authority to the Supplier in relation to such Goods.

16. **Intellectual property**

16.1 Unless specified otherwise in the Specification, the Supplier hereby grants to the Authority, for the life of the use of Goods by the Authority, an irrevocable, royalty-free, non-exclusive licence of any Intellectual Property Rights required for the purposes of receiving and using, and to the extent necessary to receive and use, the Goods (to include any associated technical or other documentation and information supplied or made accessible to the Authority in any media) in accordance with this Contract.

17. **Indemnity**

17.1 The Supplier shall be liable to the Authority for, and shall indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings in respect of:

17.1.1 any injury or allegation of injury to any person, including injury resulting in death;

17.1.2 any loss of or damage to property (whether real or personal); and/or

17.1.3 any breach of Clause 14.1.18 and/or Clause 16 of this Schedule 2;

that arise or result from the Supplier's negligent acts or omissions or breach of contract in connection with the performance of this Contract including the supply of the Goods, except to the extent that such loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings have been caused by any act or omission by, or on behalf of, or in accordance with the instructions of, the Authority.

17.2 Liability under Clauses 17.1.1 and 17.1.3 of this Schedule 2 shall be unlimited. Liability under Clauses 9.10.4, 14.2, and 17.1.2 of this Schedule 2 shall be subject to the limitation of liability set out in Clause 14 of this Schedule 2.

17.3 In relation to all third party claims against the Authority, which are the subject of any indemnity given by the Supplier under this Contract, the Authority shall use its reasonable endeavours, upon a written request from the Supplier, to transfer the conduct of such claims to the Supplier unless restricted from doing so. Such restrictions may include, without limitation, any restrictions:

17.3.1 relating to any legal, regulatory, governance, information governance, or confidentiality obligations on the Authority; and/or

17.3.2 relating to the Authority's membership of any indemnity and/or risk pooling arrangements.

17.4 Such transfer shall be subject to the Parties agreeing appropriate terms for such conduct of the third party claim by the Supplier (to include, without limitation, the right of the Authority to be informed and consulted on the ongoing conduct of the claim following such transfer and any reasonable cooperation required by the Supplier from the Authority).

18. **Limitation of liability**

18.1 Nothing in this Contract shall exclude or restrict the liability of either Party:

18.1.1 for death or personal injury resulting from its negligence;

18.1.2 for fraud or fraudulent misrepresentation; or

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

18.2 Subject to Clauses 17.2, 18.1, 18.3 and 18.6 of this Schedule 2, the total liability of each Party to the other under or in connection with this Contract whether arising in contract, tort, negligence, breach of statutory duty or otherwise shall be limited in aggregate to the greater of: (a) five million GBP (£5,000,000); or (b) one hundred and twenty five percent (125%) of the total Contract Price paid or payable by the Authority to the Supplier for the Goods.

18.3 There shall be no right to claim losses, damages and/or other costs and expenses under or in connection with this Contract whether arising in contract (to include, without limitation, under any relevant indemnity), tort, negligence, breach of statutory duty or otherwise to the extent that any losses, damages and/or other costs and expenses claimed are in respect of loss of production, loss of business opportunity or are in respect of indirect loss of any nature suffered or alleged. For the avoidance of doubt, without limitation, the Parties agree that for the purposes of this Contract the following costs, expenses and/or loss of income shall be direct recoverable losses (to include under any relevant indemnity) provided such costs, expenses and/or loss of income are properly evidenced by the claiming Party:

18.3.1 extra costs incurred purchasing replacement or alternative goods;

18.3.2 costs incurred in relation to any product recall; and/or

18.3.3 costs associated with advising, screening, testing, treating, re-treating or otherwise providing healthcare to patients;

18.3.4 the costs of extra management time;

18.3.5 loss of income due to an inability to provide healthcare services,

18.4 in each case to the extent to which such costs, expenses and/or loss of income arise or result from the other Party's breach of contract, negligent act or omission, breach of statutory duty, and/or other liability under or in connection with this Contract.

18.5 Each Party shall at all times take all reasonable steps to minimise and mitigate any loss for which that Party is entitled to bring a claim against the other pursuant to this Contract.

18.6 If the total Contract Price paid or payable by the Authority to the Supplier over the Term:

18.6.1 is less than or equal to one million GBP (£1,000,000), then the figure of five million GBP (£5,000,000) at Clause 18.2 of this Schedule 2 shall be replaced with one million GBP (£1,000,000);

18.6.2 is less than or equal to three million GBP (£3,000,000) but greater than one million GBP (£1,000,000), then the figure of five million GBP (£5,000,000) at Clause 18.2 of this Schedule 2 shall be replaced with three million GBP (£3,000,000);

18.6.3 is equal to, exceeds or will exceed ten million GBP (£10,000,000), but is less than fifty million GBP (£50,000,000), then the figure of five million GBP (£5,000,000) at Clause 18.2 of this Schedule 2 shall be replaced with ten million GBP (£10,000,000) and the figure of one hundred and twenty five percent (125%) at Clause 18.2 of this Schedule 2 shall be deemed to have been deleted and replaced with one hundred and fifteen percent (115%); and

18.6.4 is equal to, exceeds or will exceed fifty million GBP (£50,000,000), then the figure of five million GBP (£5,000,000) at Clause 18.2 of this Schedule 2 shall be replaced with fifty million GBP (£50,000,000) and the figure of one hundred and twenty five percent (125%) at Clause 18.2 of this Schedule 2 shall be deemed to have been deleted and replaced with one hundred and five percent (105%).

18.7 This Clause 18 of this Schedule 2 shall survive the expiry of or earlier termination of this Contract for any reason.

19. **Insurance**

19.1 Subject to Clause 19.2 of this Schedule 2 and unless otherwise confirmed in writing by the Authority, as a minimum level of protection, the Supplier shall put in place and/or maintain in force at its own cost with a reputable commercial insurer, insurance arrangements in respect of employer's liability, public liability and product liability in accordance with Good Industry Practice with the minimum cover per claim of the greater of five million GBP (£5,000,000) or any sum as required by Law unless otherwise agreed with the Authority in writing.

19.2 Provided that the Supplier maintains all indemnity arrangements required by Law, the Supplier may self insure in order to meet other relevant requirements referred to at Clause 19.1 of this Schedule 2 on condition that such self insurance arrangements offer the appropriate levels of protection and are approved by the Authority in writing prior to the Commencement Date.

19.3 The amount of any indemnity cover and/or self insurance arrangements shall not relieve the Supplier of any liabilities under this Contract. It shall be the responsibility of the Supplier to determine the amount of indemnity and/or self insurance cover that will be adequate to enable it to satisfy its potential liabilities under this Contract. Accordingly, the Supplier shall be liable to make good any deficiency if the proceeds of any indemnity cover and/or self insurance arrangement is insufficient to cover the settlement of any claim.

19.4 The Supplier warrants that it shall not take any action or fail to take any reasonable action or (in so far as it is reasonable and within its power) permit or allow others to take or fail to take any action, as a result of which its insurance cover may be rendered void, voidable, unenforceable, or be suspended or impaired in whole or in part, or which may otherwise render any sum paid out under such insurances repayable in whole or in part.

19.5 The Supplier shall from time to time and in any event within five (5) Business Days of written demand provide documentary evidence to the Authority that insurance arrangements taken out by the Supplier pursuant to Clause 19 of this Schedule 2 are fully maintained and that any premiums on them and/or contributions in respect of them (if any) are fully paid.

19.6 Upon the expiry or earlier termination of this Contract, the Supplier shall ensure that any ongoing liability it has or may have arising out of this Contract shall continue to be the subject of appropriate indemnity arrangements for the period of twenty one (21) years from termination or expiry of this Contract or until such earlier date as that liability may reasonably be considered to have ceased to exist.

20. **Term and termination**

20.1 This Contract shall commence on the Commencement Date and, unless terminated earlier in accordance with the terms of this Contract or the general law, shall continue until the end of the Term.

20.2 In the case of a breach of any of the terms of this Contract by either Party that is capable of remedy (including, without limitation any breach of any KPI and, subject to Clause 13.8 of this Schedule 2, any breach of any payment obligations, under this Contract), the non-breaching Party may, without prejudice to its other rights and remedies under this Contract, issue a Breach Notice and shall allow the Party in breach the opportunity to remedy such breach in the first instance via a remedial proposal put forward by the Party in breach ("**Remedial Proposal**") before exercising any right to terminate this Contract in accordance with Clause 20.4.2 of this Schedule 2. Such Remedial Proposal must be agreed with the non-breaching Party (such agreement not to be unreasonably withheld or delayed) and must be implemented by the Party in breach in accordance with the timescales referred to in the agreed Remedial Proposal. Once agreed, any changes to a Remedial Proposal must be approved by the Parties in writing. Any failure by the Party in breach to:

20.2.1 put forward and agree a Remedial Proposal with the non-breaching Party in relation to the relevant default or breach within a period of ten (10) Business Days (or such other period as the non-breaching Party may agree in writing) from written notification of the relevant default or breach from the non-breaching Party;

20.2.2 comply with such Remedial Proposal (including, without limitation, as to its timescales for implementation, which shall be thirty (30) days unless otherwise agreed between the Parties); and/or

20.2.3 remedy the default or breach notwithstanding the implementation of such Remedial Proposal in accordance with the agreed timescales for implementation,

20.3 shall be deemed, for the purposes of Clause 20.4.2 of this Schedule 2, a material breach of this Contract by the Party in breach not remedied in accordance with an agreed Remedial Proposal.

20.4 Either Party may terminate this Contract by issuing a Termination Notice to the other Party if such other Party commits a material breach of any of the terms of this Contract which is:

20.4.1 not capable of remedy; or

20.4.2 in the case of a breach capable of remedy, which is not remedied in accordance with a Remedial Proposal.

20.5 The Authority may terminate this Contract by issuing a Termination Notice to the Supplier if:

20.5.1 the Supplier, or any third party guaranteeing the obligations of the Supplier under this Contract, 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) otherwise than as part of, and exclusively for the purpose of, a bona fide reconstruction or amalgamation; 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;

20.5.2 the Licensing Authority, the Commission on Human Medicines or other relevant regulatory body advises the Authority not to use the Goods;

20.5.3 the Supplier undergoes a change of control within the meaning of sections 450 and 451 of the Corporation Tax Act 2010 (other than for an intra-group change of control) without the prior written consent of the Authority and the Authority shall be entitled to withhold such consent if, in the reasonable opinion of the Authority, the proposed change of control will have a material impact on the performance of this Contract or the reputation of the Authority;

20.5.4 the Supplier purports to assign, Sub-contract, novate, create a trust in or otherwise transfer or dispose of this Contract in breach of Clause 34.1 of this Schedule 2;

20.5.5 pursuant to and in accordance with the Key Provisions and Clauses 9.4 of Schedule 1 and 20.6, 29.9; 31.2; 31.4, 33.3 and 35.2 of this Schedule 2; or

the warranty given by the Supplier pursuant to Clause 14.5 of this Schedule 2 is materially untrue, the Supplier commits a material breach of its obligation to notify the Authority of any Occasion of Tax Non-Compliance as required by Clause 14.5 of this Schedule 2, or the Supplier fails to provide details of proposed mitigating factors as required by Clause 14.5 of this Schedule 2 that in the reasonable opinion of the Authority are acceptable.

20.6 If the Authority, acting reasonably, has good cause to believe that there has been a material deterioration in the financial circumstances of the Supplier and/or any third party guaranteeing the obligations of the Supplier under this Contract and/or any material Sub-contractor of the Supplier when compared to any information provided to and/or assessed by the Authority as part of any procurement process or other due diligence leading to the award of this Contract to the Supplier or the entering into a Sub-contract by the Supplier, the following process shall apply:

20.6.1 the Authority may (but shall not be obliged to) give notice to the Supplier requesting adequate financial or other security and/or assurances for due performance of its material obligations under this Contract on such reasonable and proportionate terms as the Authority may require within a reasonable time period as specified in such notice;

20.6.2 a failure or refusal by the Supplier to provide the financial or other security and/or assurances requested in accordance with Clause 20.6 of this Schedule 2 in accordance with any reasonable timescales specified in any such notice issued by the Authority shall be deemed a breach of this Contract by the Supplier and shall be referred to and resolved in accordance with the Dispute Resolution Procedure; and

20.6.3 a failure to resolve such breach in accordance with such Dispute Resolution Procedure by the end of the escalation stage of such process shall entitle, but shall not compel, the Authority to terminate this Contract in accordance with Clause 20.4.1 of this Schedule 2.

20.7 In order that the Authority may act reasonably in exercising its discretion in accordance with Clause 20.6 of this Schedule 2, the Supplier shall provide the Authority with such reasonable and proportionate up-to-date financial or other information relating to the Supplier or any relevant third party entity upon request.

20.8 The Authority may terminate this Contract by issuing a Termination Notice to the Supplier where:

20.8.1 the Contract has been substantially amended to the extent that the Public Contracts Regulations 2015 (as amended) require a new procurement procedure;

20.8.2 the Authority has become aware that the Supplier should have been excluded under Regulation 57(1) or (2) of the Public Contracts Regulations 2015 (as amended) from the procurement procedure leading to the award of this Contract; or

20.8.3 there has been a failure by the Supplier and/or one of its Sub- contractors to comply with legal obligations in the fields of environmental, social, labour or slavery and human trafficking Law. Where the failure to comply with legal obligations in the fields of environmental, social, labour or slavery and human trafficking 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 Contract under this Clause 20.8.3.

20.9 If the Authority novates this Contract to any body that is not a Contracting Authority, from the effective date of such novation, the rights of the Authority to terminate this Contract in accordance with Clauses 20.5.1 and 20.5.3 to 20.5.5 of this Schedule 2 shall be deemed mutual termination rights and the Supplier may terminate this Contract by issuing a Termination Notice to the entity assuming the position of the Authority if any of the circumstances referred to in such Clauses apply to the entity assuming the position of the Authority.

20.10 The Supplier shall be entitled to terminate this Contract by issuing a Termination Notice to the Authority if the Authority fails to pay undisputed invoices within three (3) or more consecutive months of receipt of such undisputed invoices.

21. **Consequences of expiry or early termination of this Contract**

21.1 Upon expiry or earlier termination of this Contract, the Supplier agrees to buy back the remaining Stockpiled Goods at the Buyback Price. For the avoidance of doubt, where the Supplier has failed to replenish the Stockpile to the Quantity Required in accordance with Clause 6.7 of this Schedule 2 the Supplier shall buyback the equivalent of such number of Units that would have been Delivered if it had complied with Clause 6.7.

21.2 The Supplier shall cooperate fully with the Authority or, as the case may be, any replacement supplier during any re-procurement and handover period prior to and following the expiry or earlier termination of this Contract. This cooperation shall extend to providing access to all information relevant to the operation of this Contract, as reasonably required by the Authority to achieve a fair and transparent re-procurement and/or an effective transition without disruption to routine operational requirements.

21.3 The expiry or earlier termination of this Contract for whatever reason shall not affect any rights or obligations of either Party which accrued prior to such expiry or earlier termination.

21.4 The expiry or earlier termination of this Contract shall not affect any obligations which expressly or by implication are intended to come into or continue in force on or after such expiry or earlier termination.

21.5 In the event of termination pursuant to Clause 9.4 of Schedule 1, should the Authority inform the Supplier that the Authority no longer requires Goods which have been delivered but which it has not used, the Supplier shall:

21.5.1 refund to the Authority the price paid for all unused Goods delivered to the Authority as at the date of termination and pay such refund to the Authority within thirty (30) days of the date of the Authority's invoice for the same; and

21.5.2 at its own expense remove all unused Goods delivered to the Authority as at the date of termination within fourteen (14) days of the date of notification by the Authority that the Authority wishes to return unused Goods. The Authority shall not request the Supplier to collect such Goods from a greater number of collection points than the Supplier delivered the Goods to. Notwithstanding Clause 8.3 of this Schedule 2, title in such Goods shall pass to the Supplier on the date of such notification by the Authority and if the Supplier fails to remove the Goods within fourteen (14) days the Authority may return the Goods at the Supplier's expense.

22. **Post termination provisions**

22.1 The Supplier acknowledges and agrees that:

22.1.1 notwithstanding any other term of this Contract, nothing in this Contract shall prevent the Authority from, at any time, using the Contract Price (and/or any information provided to and/or assessed by the Authority as part of any procurement process or other due diligence leading to the award of this Contract to the Supplier) to formulate a benchmark price (or similar) for use in any procurement process for the award of a contract for the supply of goods the same as or similar to the Goods following (or in anticipation of) the termination or expiry of this Contract and publishing the same. Such benchmark price may be the exact value of the Contract Price; and

22.1.2 for the avoidance of doubt, any breach of any KPIs shall not be Confidential Information.

22.2 The Authority and any Central Government Body will not disclose the Contract Price to any Administering Entity (which for the purposes of Clause 22.2 of this Schedule 2 shall not include a Health Service Board constituted under section 2 of the National Health Service (Scotland) Act 1978, a Special Health Board constituted under that section, the NHS Wales or any statutory successors to such entities) without the Supplier's written consent (such consent not to be unreasonably withheld, delayed or conditioned).

22.3 This Clause 22.3 and the following Clauses shall survive the expiry or termination for any reason of this Contract: Schedule 1 (Key Provisions) Clauses 4 (Notices), 5 (Management levels for escalation and dispute resolution), 6 (Order of precedence), Clause 9 (Regulatory and information requirements), Schedule 2 (General Terms and Conditions) Clauses 9 (Authority's right to Inspect Stockpile and Storage Facilities, 16 (Intellectual property), 17 (Indemnity), 18 (Limitation of liability), 29.10 (Force majeure), 30 (Records retention and right of audit), 28 (Dispute resolution), 36.3 (Waiver), 36.4 (Severance), 36.12 (Entire agreement), 36.13 (Governing law), 36.14 (Jurisdiction), Schedule 4 (Information Provisions), Clauses 1 and 2, Schedule 5 (Definitions and Interpretations) and any Clauses and/or Schedules which are expressly or by implication intended to continue.

23. **Changes in the Market**

23.1 If the Supplier becomes aware of:

23.1.1 any changes or potential changes in market requirements for any of the Goods;

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

23.1.3 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 Goods to the supply chain in the UK in accordance with this Contract and any Release Plan or Exit Plan; or

23.1.4 any potential change to its market share in such a way that would impact its ability to rotate the Stockpiled Goods,

it shall promptly give notice in writing to the Authority setting out details of the relevant circumstances.

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

23.3 In the event that any of the circumstances in Clauses 23.1 and 23.2 of Schedule 2 arise, the Parties shall agree in writing any amendments to this Contract in accordance with Clause 27 of Schedule 2.

24. **Packaging, identification and end of use**

24.1 The Supplier shall comply with all obligations imposed on it by Law and Guidance relevant to the Goods in relation to packaging, identification, and obligations following end of use by the Authority.

24.2 Unless otherwise specified in the Specification or otherwise agreed with the Authority in writing, the Goods shall be securely packed in trade packages of a type normally used by the Supplier for deliveries of the same or similar goods in the same quantities within the United Kingdom.

24.3 The Supplier shall comply with any labelling requirements in respect of the Goods: (a) specified in the Specification; (b) agreed with the Authority in writing; and/or (c) required to comply with Law or Guidance.

24.4 The Supplier shall ensure that all Goods that are required by Law or Guidance to bear any safety information, environmental information, any mark, tab, brand, label, serial numbers or other device indicating place of origin, inspection by any government or other body or standard of quality at the point such Goods are delivered shall comply with such requirements at the point of Delivery.

24.5 Unless otherwise set out in the Specification or agreed with the Authority in writing, the Supplier shall collect without charge any returnable containers and/or packages (including pallets) within twenty one (21) days of the date of the relevant delivery. Empty containers and/or packages not so removed may be returned by the Authority at the Supplier's expense or otherwise disposed of at the Authority's discretion. The Supplier shall credit the Authority in full for any containers for which the Authority has been charged upon their collection, return and/or disposal by the Authority.

24.6 Without prejudice to the Supplier's obligation to comply with all applicable Law and Guidance, the Supplier shall comply in all material respects with applicable environmental laws and regulations in force from time to time in relation to the Goods. 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 Specification. Without prejudice to the generality of the foregoing, the Supplier shall:

24.6.1 comply with all reasonable stipulations of the Authority aimed at minimising the packaging in which the Goods are supplied;

24.6.2 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 Goods;

24.6.3 comply with all obligations imposed on it in relation to the Goods by the Producer Responsibility Obligations (Packaging Waste) Regulations 2007 (SI 2007/871) (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 as amended);

24.6.4 without prejudice to the Supplier's other obligations under this Contract, label all units of the Goods, and the packaging of those units, to highlight environmental and safety information as required by applicable Law;

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

24.6.6 where the Goods are imported into the United Kingdom then for the purposes of the Producer Responsibility Obligations (Packaging Waste) Regulations 2007 (SI 2007/871), assume the rolled-up obligations for all the activities performed outside the United Kingdom in relation to the Goods and the packaging which is used for the containment, protection, handling, delivery and presentation of the Goods in addition to any other obligations it may have pursuant to the said Regulations.

24.7 The Supplier shall meet all reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of this Clause 23 of Schedule 2.

25. **Sustainable development**

25.1 The Supplier shall comply in all material respects with applicable environmental and social and labour Law requirements in force from time to time in relation to the Goods. Where the provisions of any such Law are implemented by the use of voluntary agreements, the Supplier shall comply with such agreements as if they were incorporated into English law subject to those voluntary agreements being cited in the Specification. Without prejudice to the generality of the foregoing, the Supplier shall:

25.1.1 comply with all Policies and/or procedures and requirements set out in the Specification and/or any applicable Crown Commercial Services' Procurement Policy Note (as may be in force from time to time) in relation to any stated environmental and social and labour requirements, characteristics and impacts of the Goods and the Supplier's supply chain;

25.1.2 maintain relevant policy statements documenting the Supplier's significant labour, social and environmental aspects as relevant to the Goods being supplied and as proportionate to the nature and scale of the Supplier's business operations; and

25.1.3 maintain plans and procedures that support the commitments made as part of the Supplier's significant labour, social and environmental policies, as referred to at Clause 25.1.2 of this Schedule 2.

25.2 The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of Clause 25 of this Schedule 2.

26. **Electronic product information**

26.1 Where requested by the Authority, the Supplier shall provide the Authority the Product Information in such manner and upon such media as agreed between the Supplier and the Authority from time to time for the sole use by the Authority.

26.2 The Supplier warrants that the Product Information is complete and accurate as at the date upon which it is delivered to the Authority and that the Product Information shall not contain any data or statement which gives rise to any liability on the part of the Authority following publication of the same in accordance with Clause 21 of this Schedule 2.

26.3 If the Product Information ceases to be complete and accurate, the Supplier shall promptly notify the Authority in writing of any modification or addition to or any inaccuracy or omission in the Product Information.

26.4 The Supplier grants the Authority a perpetual, non-exclusive, royalty free licence to use and exploit the Product Information and any Intellectual Property Rights in the Product Information for the purpose of illustrating the range of goods and services (including, without limitation, the Goods) available pursuant to the Authority's contracts from time to time. Subject to Clause 26.5 of this Schedule 2, no obligation to illustrate or advertise the Product Information is imposed on the Authority, as a consequence of the licence conferred by this Clause 26.4 of this Schedule 2.

26.5 Before any publication of the Product Information (electronic or otherwise) is made by the Authority, the Authority will submit a copy of the relevant sections of the Authority's product catalogue to the Supplier for approval, such approval not to be unreasonably withheld or delayed. For the avoidance of doubt the Supplier shall have no right to compel the Authority to exhibit the Product Information in any product catalogue as a result of the approval given by it pursuant to this Clause 26.5 of this Schedule 2 or otherwise under the terms of this Contract.

26.6 If requested in writing by the Authority, and to the extent not already agreed as part of the Specification and the Tender Response Document, the Supplier and the Authority shall discuss and seek to agree in good faith arrangements to use any Electronic Trading System.

27. **Change Control**

27.1 The Supplier acknowledges to the Authority that the Authority's requirements for the Goods may change during the Term and the Supplier shall not unreasonably withhold or delay its consent to any reasonable variation or addition to the Specification, as may be requested by the Authority from time to time.

27.2 Either party may submit a written request for Change to the other party in accordance with this Clause 27 of this Schedule 2, but no Change will come into effect until a Change Control Note has been signed by the authorised representatives of both parties.

27.3 If the Authority requests a Change:

27.3.1 the Authority will submit a written request to the Supplier containing as much information as is necessary to enable the Supplier to prepare a Change Control Note; and

27.3.2 within five (5) Business Days of receipt of a request, the Supplier will, unless otherwise agreed, send to the Authority a Change Control Note.

27.4 If the Supplier requests a Change, it will send to the Authority a Change Control Note.

27.5 A Change Control Note will be in the form set out in Schedule 8.

27.6 If, following the Authority's receipt of a Change Control Note pursuant to Clauses 27.3 or 27.4 of this Schedule 2:

27.6.1 the parties agree the terms of the relevant Change Control Note, which, once signed by each of the Parties, shall constitute a binding change to the Contract for the purposes of Clause 27.8 of this Schedule 2; or

27.6.2 either Party does not agree to any term of the Change Control Note, then the other party may refer the disagreement to be dealt with in accordance with the Dispute Resolution Procedure.

27.7 Each party will bear its own costs in relation to compliance with the Change Control Procedure.

27.8 Any change to the Goods or other variation to this Contract shall only be binding once it has been agreed in writing and signed by an authorised representative of both Parties.

27.9 Subject to Clause 13.6 of this Schedule 2, the Supplier shall neither be relieved of its obligations to supply the Goods in accordance with the terms and conditions of this Contract nor be entitled to an increase in the Charges as a result of a Change in Law.

28. **Dispute resolution**

28.1 During any Dispute, including a Dispute as to the validity of this Contract, it is agreed that the Supplier shall continue its performance of the provisions of the Contract (unless the Authority requests in writing that the Supplier does not do so).

28.2 In the case of a Dispute arising out of or in connection with this Contract the Supplier and the Authority shall make every reasonable effort to communicate and cooperate with each other with a view toresolving the Dispute and follow the procedure set out in Clause 28.3 of this Schedule 2 as the first stage in the Dispute Resolution Procedure.

28.3 If any Dispute arises out of the Contract either Party may serve a notice on the other Party to commence formal resolution of the Dispute. The Parties shall first seek to resolve the Dispute by escalation in accordance with the management levels as set out in Clause 5 of the Key Provisions. Respective representatives at each level, as set out in Clause 5 of the Key Provisions, shall have five (5) Business Days at each level during which they will use their reasonable endeavours to resolve the Dispute before escalating the matter to the next level until all levels have been exhausted. Level 1 will commence on the date of service of the Dispute Notice. The final level of the escalation process shall be deemed exhausted on the expiry of five (5) Business Days following escalation to that level unless otherwise agreed by the Parties in writing.

28.4 If the procedure set out in Clause 28.3 of this Schedule 2 above has been exhausted and fails to resolve such Dispute, as part of the Dispute Resolution Procedure, the Parties will attempt to settle it by mediation. The Parties shall, acting reasonably, attempt to agree upon a mediator. In the event that the Parties fail to agree a mediator within five (5) Business Days following the exhaustion of all levels of the escalation procedure at Clause 28.3 of this Schedule 2, the mediator shall be nominated and confirmed by the Centre for Effective Dispute Resolution, London.

28.5 The mediation shall commence within twenty eight (28) days of the confirmation of the mediator in accordance with Clause 28.4 of this Schedule 2 or at such other time as may be agreed by the Parties in writing. Neither Party will terminate such mediation process 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. After this time, either Party may terminate the mediation process by notification to the other Party (such notification may be verbal provided that it is followed up by written confirmation). The Authority and the Supplier will cooperate with any person appointed as mediator providing them with such information and other assistance as they may require and will pay their costs, as they shall determine, or in the absence of such determination such costs will be shared equally.

28.6 Nothing in this Contract shall prevent:

28.6.1 the Authority taking action in any court in relation to any death or personal injury arising or allegedly arising in connection with supply of the Goods; or

28.6.2 either Party seeking from any court any interim or provisional relief that may be necessary to protect the rights or property of that Party or that relates to the safety of patients or the security of Confidential Information, pending resolution of the relevant Dispute in accordance with the Dispute Resolution Procedure.

28.7 Clause 28 of this Schedule 2 shall survive the expiry of or earlier termination of this Contract for any reason.

29. **Force majeure**

29.1 Subject to Clause 29.2 of this Schedule 2 neither Party shall be liable to the other for any failure to perform all or any of its obligations under this Contract nor liable to the other Party for any loss or damage arising out of the failure to perform its obligations to the extent only that such performance is rendered impossible by a Force Majeure Event.

29.2 The Supplier shall only be entitled to rely on a Force Majeure Event and the relief set out in Clause 29 of this Schedule 2 and will not be considered to be in default or liable for breach of any obligations under this Contract if:

29.2.1 the Supplier has fulfilled its obligations pursuant to Clause 11 of this Schedule 2;

29.2.2 the Force Majeure Event does not arise directly or indirectly as a result of any wilful or negligent act or default of the Supplier; and

29.2.3 the Supplier has complied with the procedural requirements set out in Clause 29 of this Schedule 2.

29.3 Where a Party is (or claims to be) affected by a Force Majeure Event it shall use reasonable endeavours to mitigate the consequences of such a Force Majeure Event upon the performance of its obligations under this Contract and shall resume the performance of its obligations affected by the Force Majeure Event as soon as practicable.

29.4 Where the Force Majeure Event affects the Supplier's ability to perform part of its obligations under the Contract the Supplier shall fulfil all such contractual obligations that are not so affected and shall not be relieved from its liability to do so.

29.5 If either Party is prevented or delayed in the performance of its obligations under this Contract by a Force Majeure Event, that Party shall as soon as reasonably practicable serve notice in writing on the other Party specifying the nature and extent of the circumstances giving rise to its failure to perform or any anticipated delay in performance of its obligations.

29.6 Subject to service of such notice, the Party affected by such circumstances shall have no liability for its failure to perform or for any delay in performance of its obligations affected by the Force Majeure Event only for so long as such circumstances continue and for such time after they cease as is necessary for that Party, using its best endeavours, to recommence its affected operations in order for it to perform its obligations.

29.7 The Party claiming relief shall notify the other in writing as soon as the consequences of the Force Majeure Event have ceased and of when performance of its affected obligations can be resumed.

29.8 If the Supplier is prevented from performance of its obligations as a result of a Force Majeure Event, the Authority may at any time if the Force Majeure Event subsists for thirty (30) days or more, terminate this Contract by issuing a Termination Notice to the Supplier.

29.9 Following such termination in accordance with Clause 29.8 of this Schedule 2 and subject to Clause 29.10 of this Schedule 2, neither Party shall have any liability to the other.

29.10 Any rights and liabilities of either Party which have accrued prior to such termination in accordance with Clause 29.8 of this Schedule 2 shall continue in full force and effect unless otherwise specified in this Contract.

30. **Records retention and right of audit**

30.1 Subject to any statutory requirement and Clause 30.2 of this Schedule 2, the Supplier shall keep secure and maintain for the Term and seven (7) years afterwards, or such longer period as may be agreed between the Parties, full and accurate records of all matters relating to this Contract.

30.2 Where any records could be relevant to a claim for personal injury such records shall be kept secure and maintained for a period of twenty one (21) years from the date of expiry or earlier termination of this Contract.

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

30.4 Should the Supplier Sub-contract any of its obligations under this Contract, the Authority shall have the right to audit and inspect such third party. The Supplier shall procure permission for the Authority or its authorised representative during normal business hours no more than once in any twelve (12) months, and having given advance written notice of no less than five (5) Business Days, access to any premises and facilities, books and records used in the performance of the Supplier's obligations under this Contract that are Sub-contracted to such third party. The Supplier shall cooperate with such audit and inspection and accompany the Authority or its authorised representative if requested.

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

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

30.5.2 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.

30.6 The Comptroller and Auditor General may examine such documents as they 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 they consider necessary. Clause 30 of this Schedule 2 does not constitute a requirement or agreement for the examination, certification or inspection of the accounts of the Supplier under sections 6(3)(d) and 6(5) of the National Audit Act 1983.

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

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

31. **Conflicts of interest and the prevention of fraud**

31.1 The Supplier shall take appropriate steps to ensure that neither the Supplier nor any Staff are placed in a position where, in the reasonable opinion of the Authority, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Supplier and the duties owed to the Authority under the provisions of this Contract. The Supplier will disclose to the Authority full particulars of any such conflict of interest which may arise.

31.2 The Authority reserves the right to terminate this Contract immediately by notice in writing and/or to take such other steps it deems necessary where, in the reasonable opinion of the Authority, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Supplier and the duties owed to the Authority under the provisions of this Contract. The actions of the Authority pursuant to this Clause 31.2 of this Schedule 2 shall not prejudice or affect any right of action or remedy which shall have accrued or shall subsequently accrue to the Authority.

31.3 The Supplier shall take all reasonable steps to prevent Fraud by Staff and the Supplier (including its owners, members and directors). 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.

31.4 If the Supplier or its Staff commits Fraud the Authority may terminate this Contract and recover from the Supplier the amount of any direct loss suffered by the Authority resulting from the termination.

32. **Equality and human rights**

32.1 The Supplier shall:

32.1.1 ensure that (a) it does not, whether as employer or as supplier of the Goods and any associated services, engage in any act or omission that would contravene the Equality Legislation, and (b) it complies with all its obligations as an employer or supplier of the Goods and any associated services as set out in the Equality Legislation and take reasonable endeavours to ensure its Staff do not unlawfully discriminate within the meaning of the Equality Legislation;

32.1.2 in the management of its affairs and the development of its equality and diversity policies, cooperate with the Authority in light of the Authority's obligations to comply with its statutory equality duties whether under the Equality Act 2010 or otherwise. The Supplier shall take such reasonable and proportionate steps as the Authority considers appropriate to promote equality and diversity, including race equality, equality of opportunity for disabled people, gender equality, and equality relating to religion and belief, sexual orientation and age; and

32.1.3 the Supplier shall impose on all its Sub-contractors and suppliers, obligations substantially similar to those imposed on the Supplier by Clause 32 of this Schedule 2.

32.2 The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of Clause 32 of this Schedule 2.

33. **Modern Slavery in Government Supply Chains**

33.1 The Supplier:

33.1.1 shall not require any Staff to lodge deposits or identity papers with their employer and shall be free to leave their employer after reasonable notice;

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

33.1.3 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;

33.1.4 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 anti-slavery and human trafficking provisions;

33.1.5 shall implement due diligence procedures to ensure that there is no slavery or human trafficking in any part of its supply chain that is responsible for performing its obligations under this Contract;

33.1.6 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;

33.1.7 shall not use, or allow its Staff 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;

33.1.8 shall not use, or allow its Sub-contractors to use, child or slave labour;

33.1.9 shall report the discovery or suspicion of any slavery, trafficking, forced labour, child labour, involuntary prison labour or labour rights abuses by its Staff or its Sub-contractors to the Authority and Modern Slavery Helpline and relevant national or local law enforcement agencies; and

33.1.10 shall, if the Authority identifies any occurrence of modern slavery connected to this Contract, comply with any request of the Authority to follow the remedial process pursuant to Clause 20.2 of this Schedule 2 to submit a remedial action plan which follows the form set out in Annex D of the Tackling Modern Slavery in Government Supply Chains guidance.

34. Assignment, novation and Sub-contracting

34.1 The Supplier shall not, except where Clause 25.2 of this Schedule 2 applies, assign, Sub-contract, novate, create a trust in, or in any other way dispose of the whole or any part of this Contract without the prior consent in writing of the Authority, such consent not to be unreasonably withheld or delayed. If the Supplier Sub-contracts any of its obligations under this Contract, every act or omission of the Sub-contractor shall for the purposes of this Contract be deemed to be the act or omission of the Supplier and the Supplier shall be liable to the Authority as if such act or omission had been committed or omitted by the Supplier itself.

34.2 Notwithstanding Clause 25.1 of this Schedule 2, the Supplier may assign to a third party ("**Assignee**") the right to receive payment of any sums due and owing to the Supplier under this Contract for which an invoice has been issued. Any assignment under this Clause 25.2 of this Schedule 2 shall be subject to:

34.2.1 the deduction of any sums in respect of which the Authority exercises its right of recovery under Clause 13.9 of this Schedule 2;

34.2.2 all related rights of the Authority in relation to the recovery of sums due but unpaid;

34.2.3 the Authority receiving notification of the assignment and the date upon which the assignment becomes effective together with the Assignee's contact information and bank account details to which the Authority shall make payment;

34.2.4 the provisions of Clause 13 of this Schedule 2 continuing to apply in all other respects after the assignment which shall not be amended without the prior written approval of the Authority; and

34.2.5 payment to the Assignee being full and complete satisfaction of the Authority's obligation to pay the relevant sums in accordance with this Contract.

34.3 Any authority given by the Authority for the Supplier to Sub-contract any of its obligations under this Contract shall not impose any duty on the Authority to enquire as to the competency of any authorised Sub-contractor. 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 Contract.

34.4 Where the Supplier enters into a Sub-contract in respect of any of its obligations under this Contract relating to the manufacture, supply, Delivery or installation of or training in relation to the Goods, the Supplier shall include provisions in each such Sub-contract, unless otherwise agreed with the Authority in writing, which:

34.4.1 contain at least equivalent obligations as set out in this Contract in relation to such manufacture, supply, Delivery or installation of or training in relation to the Goods to the extent relevant to such Sub-contracting;

34.4.2 contain at least equivalent obligations as set out in this Contract in respect of confidentiality, information security, data protection, Intellectual Property Rights, compliance with Law and Guidance and record keeping;

34.4.3 contain a prohibition on the Sub-contractor Sub-contracting, assigning or novating any of its rights or obligations under such Sub-contract without the prior written approval of the Authority (such approval not to be unreasonably withheld or delayed);

34.4.4 contain a right for the Authority to take an assignment or novation of the Sub-contract (or part of it) upon expiry or earlier termination of this Contract;

34.4.5 requires the Supplier or other party receiving goods under the contract to consider and verify invoices under that contract in a timelyfashion;

34.4.6 provides that if the Supplier or other party fails to consider and verify an invoice in accordance with Clause 34.4.5 of this Schedule 2, the invoice shall be regarded as valid and undisputed for the purpose of Clause 34.4.7 after a reasonable time has passed;

34.4.7 requires the Supplier or other party to pay any undisputed sums which are due from it to the Sub-contractor within a specified period not exceeding thirty (30) days of verifying that the invoice is valid and undisputed;

34.4.8 permitting the Supplier to terminate, or procure the termination of, the relevant Sub-contract in the event the Sub-contractor fails to comply in the performance of its Sub-contract with legal obligations in the fields of environmental, social or labour Law where the Supplier is required to replace such Sub-contractor in accordance with Clause 20.8.3 of this Schedule 2;

34.4.9 permitting the Supplier to terminate, or to procure the termination of, the relevant Sub-contract where the Supplier is required to replace such Sub-contractor in accordance with Clause 34.5 of this Schedule 2; and

34.4.10 requires the Sub-contractor to include a clause to the same effect as this Clause 34.4 of this Schedule 2 in any Sub-contract which it awards.

34.5 Where the Authority considers that the grounds for exclusion under Regulation 57 of the Public Contracts Regulations 2015 (as amended) apply to any Sub- contractor, then:

34.5.1 if the Authority finds there are compulsory grounds for exclusion, the Supplier shall ensure, or shall procure, that such Sub-contractor is replaced or not appointed; or

34.5.2 if the Authority finds there are non-compulsory grounds for exclusion, the Authority may require the Supplier to ensure, or to procure, that such Sub-contractor is replaced or not appointed and the Supplier shall comply with such a requirement.

34.6 The Supplier shall pay any undisputed sums which are due from it to a Sub- contractor within thirty (30) days of verifying that the invoice is valid and undisputed. Where the Authority pays the Supplier's valid and undisputed invoices earlier than thirty (30) days from verification in accordance with any applicable government prompt payment targets, the Supplier shall use its reasonable endeavours to pay its relevant Sub-contractors within a comparable timeframe from verifying that an invoice is valid and undisputed.

34.7 The Authority shall upon written request have the right to review any Sub- contract entered into by the Supplier in respect of the provision of the Goods and the Supplier shall provide a certified copy of any Sub-contract within five (5) Business Days of the date of a written request from the Authority.

34.8 For the avoidance of doubt, the Supplier shall have the right to redact any confidential pricing information in relation to such copies of Sub-contracts.

34.9 The Authority may at any time transfer, assign, novate, sub-contract or otherwise dispose of its rights and obligations under this Contract or any part of this Contract and the Supplier warrants that it will carry out all such reasonable further acts required to effect such transfer, assignment, novation, sub-contracting or disposal. If the Authority novates this Contract to any body that is not a Contracting Authority, from the effective date of such novation, the party assuming the position of the Authority shall not further transfer, assign, novate, sub-contract or otherwise dispose of its rights and obligations under this Contract or any part of this Contract without the prior written consent of the Supplier, such consent not to be unreasonably withheld or delayed by the Supplier.

35. **Prohibited Acts**

35.1 The Supplier warrants and represents that:

35.1.1 it has not committed any offence under the Bribery Act 2010 or done any of the following ("**Prohibited Acts**"):

(a) offered, given or agreed to give any officer or employee of the Authority any gift or consideration of any kind as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining or performance of this or any other agreement with the Authority or for showing or not showing favour or disfavour to any person in relation to this or any other agreement with the Authority; or

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

35.1.2 it has in place adequate procedures to prevent bribery and corruption, as contemplated by section 7 of the Bribery Act 2010.

35.2 If the Supplier or its Staff (or anyone acting on its or their behalf) has done or does any of the Prohibited Acts or has committed or commits any offence under the Bribery Act 2010 with or without the knowledge of the Supplier in relation to this or any other agreement with the Authority:

35.2.1 the Authority shall be entitled:

(a) to terminate this Contract and recover from the Supplier the amount of any loss resulting from the termination;

(b) to recover from the Supplier the amount or value of any gift, consideration or commission concerned; and

(c) to recover from the Supplier any other loss or expense sustained in consequence of the carrying out of the Prohibited Act or the commission of the offence under the Bribery Act 2010;

35.2.2 any termination under Clause 35.2.1 of this Schedule 2 shall be without prejudice to any right or remedy that has already accrued, or subsequently accrues, to the Authority; and

35.2.3 notwithstanding the Dispute Resolution Procedure, any Dispute relating to:

(a) the interpretation of Clause 35 of this Schedule 2; or

(b) the amount or value of any gift, consideration or commission,

35.2.4 shall be determined by the Authority, acting reasonably, and the decision shall be final and conclusive.

36. **General**

36.1 Each of the Parties is independent of the other and nothing contained in this Contract shall be construed to imply that there is any relationship between the Parties of partnership or of principal/agent or of employer/employee nor are the Parties hereby engaging in a joint venture and accordingly neither of the Parties shall have any right or authority to act on behalf of the other nor to bind the other by agreement or otherwise, unless expressly permitted by the terms of this Contract.

36.2 Failure or delay by either Party to exercise an option or right conferred by this Contract shall not of itself constitute a waiver of such option or right.

36.3 The delay or failure by either Party to insist upon the strict performance of any provision, term or condition of this Contract or to exercise any right or remedy consequent upon such breach shall not constitute a waiver of any such breach or any subsequent breach of such provision, term or condition.

36.4 Any provision of this Contract which is held to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining provisions of this Contract and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provisions in any other jurisdiction.

36.5 Each Party 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 Contract and therefore irrevocably and unconditionally waives any rights it may have to claim damages against the other Party for any misrepresentation or undertaking (whether made carelessly or not) or for breach of any warranty unless the representation, undertaking or warranty relied upon is set out in this Contract or unless such representation, undertaking or warranty was made fraudulently.

36.6 Each Party shall bear its own expenses in relation to the preparation and execution of this Contract including all costs, legal fees and other expenses so incurred.

36.7 This Contract is not exclusive and accordingly the Authority shall not be restricted from purchasing any products whatsoever including the Goods and any products that are equivalent to or substitutable for the Goods from other parties.

36.8 The Authority may at any time, without notice to the Supplier, set off any liability of the Supplier to the Authority against any liability of the Authority to the Supplier, whether either liability is present or future, liquidated or unliquidated, and whether or not either liability arises under this Contract. If the liabilities to be set off are not expressed in GBP, the Authority may convert either liability at the published Bank of England exchange rate for the purpose of set-off. Any exercise by the Authority of its rights under this Clause 36.8 shall not limit or affect any other rights or remedies available to it under this Contract or otherwise.

36.9 The rights and remedies provided in this Contract are independent, cumulative and not exclusive of any rights or remedies provided by general law, any rights or remedies provided elsewhere under this Contract or by any other contract or document. In this Clause 36.9 of this Schedule 2, right includes any power, privilege, remedy, or proprietary or security interest.

36.10 The Supplier acknowledges that the Authority has entered into this Contract in the context of the exercise of performance of the duties of the Secretary of State for Health and Social Care under the National Health Service Act 2006, and on behalf of the Welsh Ministers under the National Health Service (Wales) Act 2006 (c.42), the Secretary of State under the National Health Service (Scotland) Act 1978 (c.29) and the Minister under the Health and Personal Social Services (Northern Ireland) Order 1972 S.I 1972/1265 (N.I.14). Accordingly, for the purpose of assessing the extent of any liability of the Supplier to the Authority any relevant loss or damage or any liability incurred by any Administering Entity or Devolved Administration shall be deemed to be loss or damage or liability incurred by the Authority.

36.11 A person who is not a party to this Contract shall have no right to enforce any terms of it which confer a benefit on such person. No such person shall be entitled to object to or be required to consent to any amendment to the provisions of this Contract.

36.12 This Contract, any variation in writing signed by an authorised representative of each Party and any document referred to (explicitly or by implication) in this Contract or any variation to this Contract, contain the entire understanding between the Supplier and the Authority relating to the supply of the Goods to the exclusion of all previous agreements, confirmations and understandings and there are no promises, terms, conditions or obligations whether oral or written, express or implied other than those contained or referred to in this Contract. Nothing in this Contract seeks to exclude either Party's liability for Fraud. Any tender conditions and/or disclaimers set out in the Authority's procurement documentation leading to the award of this Contract shall form part of this Contract.

36.13 This Contract, and any Dispute or claim arising out of or in connection with it or its subject matter (including any non-contractual claims), shall be governed by, and construed in accordance with, the laws of England and Wales.

36.14 Subject to Clause 28 of this Schedule 2, the Parties irrevocably agree that the courts of England and Wales shall have non-exclusive jurisdiction to settle any Dispute or claim that arises out of or in connection with this Contract or its subject matter.

36.15 All written and oral communications and all written material referred to under this Contract shall be in English.

36.16 This Contract may be executed in any number of counterparts, each of which when executed and delivered shall constitute a duplicate original, but all the counterparts shall together constitute the one agreement.

36.17 Transmission of the executed signature page of a counterpart of this Contract by email in PDF format shall take effect as delivery of an executed counterpart of this Contract.

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

Schedule 3

Storage Facilities and Storage Provider

Company Name:	Baxter Healthcare Limited

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	Yusen Logistics
Address of storage location	Yusen Logistics Grange Park – GP1 & GP3 Cheaney Drive Northampton NN4 5FB
Wholesale Distribution Authorisation (H) number	20962
Wholesale Distribution Authorisation (H) date	12/2022
WDA(H) Licence Number - Site number (This number is of the facility where the product will be stored.)	Site - 89377
Name of Responsible Person within contracted organisation (this should be filled in even if contracting to a third party storage location)	[redacted]
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]
Name of medicine being offered to be stored at this site in ambient storage conditions	None
Name of medicine being offered to be stored at this site in chilled storage conditions	None

Name of medicine being offered to be stored at this site in controlled storage conditions	HARTMANN BP 1000ML VIAFLO HARTMANN BP 500ML VIAFLO 4% GLUCOSE & 0.18% NACL 1000ML VIAFLO 5% GLUCOSE + 0,45% NACL 500ML VIAFLO 5% GLUCOSE & 0.9% NACL 500ML VIAFLO 5% GLUCOSE 1000ML VIAFLO 5% GLUCOSE 500ML VIAFLO 5% GLUCOSE 100ML VIAFLO UK NP 0.9% NACL 1000ML VIAFLO

Schedule 4

Information Provisions

1. **Confidentiality**

1.1 In respect of any Confidential Information it may receive directly or indirectly from the other Party ("**Discloser**") and subject always to the remainder of Clause 1 of this Schedule 4, each Party ("**Recipient**") undertakes to keep secret and strictly confidential and shall not disclose any such Confidential Information to any third party without the Discloser's prior written consent provided that:

1.1.1 the Recipient shall not be prevented from using any general knowledge, experience or skills which were in its possession prior to the Commencement Date;

1.1.2 the provisions of Clause 1 of this Schedule 4 shall not apply to any Confidential Information:

(a) which is in or enters the public domain other than by breach of this Contract or other act or omissions of the Recipient;

(b) which is obtained from a third party who is lawfully authorised to disclose such information without any obligation of confidentiality;

(c) which is authorised for disclosure by the prior written consent of the Discloser;

(d) which the Recipient can demonstrate was in its possession without any obligation of confidentiality prior to receipt of the Confidential Information from the Discloser; or

(e) which the Recipient is required to disclose purely to the extent to comply with the requirements of any relevant stock exchange.

1.2 Nothing in Clause 1 of this Schedule 4 shall prevent the Recipient from disclosing Confidential Information where it is required to do so by judicial, administrative, governmental or regulatory process in connection with any action, suit, proceedings or claim or otherwise by applicable Law, including the Freedom of Information Act 2000 ("**FOIA**"), Codes of Practice on Access to Government Information, on the Discharge of Public Authorities' Functions or on the Management of Records ("**Codes of Practice**") or the Environmental Information Regulations 2004 ("**Environmental Regulations**").

1.3 The Authority may disclose the Supplier's Confidential Information:

1.3.1 on a confidential basis, to any Contracting Authority (to the extent required for the proper performance of this Contract);

1.3.2 on a confidential basis to a professional adviser, consultant, supplier or other person engaged by any of the entities described in Clause 1.3.1 of this Schedule 4 (including any benchmarking organisation) for any purpose relating to or connected with this Contract;

1.3.3 on a confidential basis, to any consultant, contractor or other person engaged by the Authority and/or the Contracting Authority receiving such information;

1.3.4 to any relevant party for the purpose of the examination and certification of the Authority's accounts;

1.3.5 to any relevant party for any examination pursuant to section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Authority has used its resources;

1.3.6 to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirements; or

1.3.7 on a confidential basis, to a proposed successor body in connection with any proposed or actual, assignment, novation or other disposal of rights, obligations, liabilities or property in connection with this Contract;

1.4 and for the purposes of this Contract, references to disclosure "on a confidential basis" shall mean the Authority making clear the confidential nature of such information and that it must not be further disclosed except in accordance with Law or this Clause 1.3 of this Schedule 4.

1.5 The Supplier may only disclose the Authority's Confidential Information, and any other information provided to the Supplier by the Authority in relation to this Contract, to the Supplier's Staff or professional advisors who are directly involved in the performance of or advising on the Supplier's obligations under this Contract. The Supplier shall ensure that such Staff or professional advisors are aware of and shall comply with the obligations in Clause 1 of this Schedule 4 as to confidentiality and that all information, including Confidential Information, is held securely, protected against unauthorised use or loss and, at the Authority's written discretion, destroyed securely or returned to the Authority when it is no longer required. The Supplier shall not, and shall ensure that the Staff do not, use any of the Authority's Confidential Information received otherwise than for the purposes of performing the Supplier's obligations in this Contract.

1.6 For the avoidance of doubt, save as required by Law or as otherwise set out in this Schedule 4, the Supplier shall not, without the prior written consent of the Authority (such consent not to be unreasonably withheld or delayed), announce that it has entered into this Contract and/or that it has been appointed as a Supplier to the Authority and/or make any other announcements about this Contract.

1.7 Where the Authority sources the Goods (or any other product) from the Supplier under this Contract or any other agreement with the Authority as a result of:

1.7.1 a third party supplier ("**Third Party Supplier**") failing to meet any timescales and/or delivery requirements under its agreement with the Authority ("**Third Party Supplier Agreement**"); and

1.7.2 the Authority exercising its rights under such Third Party Supplier Agreement to source an alternative product from a third party and charge the Third Party Supplier for any costs incurred by the Authority in excess of what would have been paid to the Third Party Supplier had the Third Party Supplier met the timescales and/or delivery requirements set out in the Third Party Supplier Agreement,

the Authority may disclose the Contract Price (or, in the case of another product, the unit price paid by the Authority to the Supplier for such other product) on a confidential basis to the Third Party Supplier for a purpose directly related to or connected with the Authority verifying and/or evidencing to the Third Party Supplier the costs that the Authority has incurred in excess of what would have been paid by the Authority to the Third Party Supplier for delivery of the product(s) in accordance with the timescales and/or delivery requirements set out in the Third Party Supplier Agreement. References to disclosure on a confidential basis in Clause 1.7 of this Schedule 4 shall mean the Authority making clear the confidential nature of such information and that it must not be further disclosed except in accordance with Law.

1.8 Clause 1 of this Schedule 4 shall remain in force:

1.8.1 without limit in time in respect of Confidential Information which comprises Personal Data or which relates to national security; and

1.8.2 for all other Confidential Information for a period of three (3) years after the expiry or earlier termination of this Contract unless otherwise agreed in writing by the Parties.

2. **Freedom of Information and Transparency**

2.1 The Parties acknowledge the duties of Contracting Authorities under the FOIA, Codes of Practice and Environmental Regulations and shall give each other all reasonable assistance as appropriate or necessary to enable compliance with those duties.

2.2 The Supplier shall assist and cooperate with the Authority to enable it to comply with its disclosure obligations under the FOIA, Codes of Practice and Environmental Regulations. The Supplier agrees:

2.2.1 that this Contract and any recorded information held by the Supplier on the Authority's behalf for the purposes of this Contract are subject to the obligations and commitments of the Authority under the FOIA, Codes of Practice and Environmental Regulations;

2.2.2 that the decision on whether any exemption to the general obligations of public access to information applies to any request for information received under the FOIA, Codes of Practice and Environmental Regulations is a decision solely for the Authority;

2.2.3 that where the Supplier receives a request for information under the FOIA, Codes of Practice and Environmental Regulations and the Supplier itself is subject to the FOIA, Codes of Practice and Environmental Regulations it will liaise with the Authority as to the contents of any response before a response to a request is issued and will promptly (and in any event within two (2) Business Days) provide a copy of the request and any response to the Authority;

2.2.4 that where the Supplier receives a request for information under the FOIA, Codes of Practice and Environmental Regulations and the Supplier is not itself subject to the FOIA, Codes of Practice and Environmental Regulations, it will not respond to that request (unless directed to do so by the Authority) and will promptly (and in any event within two (2) Business Days) transfer the request to the Authority;

2.2.5 that the Authority, acting in accordance with the Codes of Practice issued and revised from time to time under both section 45 of FOIA, and regulation 16 of the Environmental Regulations, may disclose information concerning the Supplier and this Contract; and

2.2.6 to assist the Authority in responding to a request for information, by processing information or environmental information (as the same are defined in FOIA and the Environmental Regulations) in accordance with a records management system that complies with all applicable records management recommendations and codes of conduct issued under section 46 of FOIA, and providing copies of all information requested by the Authority within five (5) Business Days of that request and without charge.

2.3 The Parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and Environmental Regulations, the content of this Contract is not Confidential Information.

2.4 Notwithstanding any other term of this Contract, the Supplier consents to the publication of this Contract in its entirety (including variations), subject only to the redaction of information that is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and Environmental Regulations.

2.5 In preparing a copy of this Contract for publication under Clause 2.4 of this Schedule 4, the Authority may consult with the Supplier to inform decision making regarding any redactions but the final decision in relation to the redaction of information will be at the Authority's absolute discretion.

2.6 The Supplier acknowledges that the Authority is subject to the transparency obligations set out in the Crown Commercial Services' Procurement Policy Note 02/17 (as amended or replaced from time time) and shall assist and cooperate with the Authority to enable and facilitate the Authority to comply with its obligations thereunder including but not limited to publishing this Contract.

2.7 Where any information is held by any Sub-contractor of the Supplier in connection with this Contract, the Supplier shall procure that such Sub- contractor shall comply with the relevant obligations set out in Clause 2 of this Schedule 4, as if such Sub-contractor were the Supplier.

3. **Information Security**

3.1 Without limitation to any other information governance requirements set out in this Schedule 4, the Supplier shall:

3.1.1 notify the Authority forthwith of any information security breaches or near misses (including without limitation any potential or actual breaches of confidentiality or actual information security breaches) in line with the Authority's information governance Policies; and

3.1.2 fully cooperate with any audits or investigations relating to information security and any privacy impact assessments undertaken by the Authority and shall provide full information as may be reasonably requested by the Authority in relation to such audits, investigations and assessments.

Schedule 5

Definitions and Interpretations

1. **Definitions**

1.1 In this Contract the following words shall have the following meanings unless the context requires otherwise:

"Administering Entity"	means any body administering the Goods including all Health Service Bodies;
"Authority"	means the authority named on the form of Contract on page 1;
"Authorised Release"	an event commencing when the Authority gives notice to the Supplier under Clause 6 or Clause 15 of Schedule 2 to allow a release of the Stockpiled Goods in accordance with an agreed Release Plan or Exit Plan;
"Average UK Price"	means for each week, the mean price of the relevant Good over the week which shall be calculated as follows: (A / B) where: A = the total value of sales (in GBP (£)) of the Good 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 Unit sales 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;
"Breach Notice"	means a written notice of breach given by one Party to the other, notifying the Party receiving the notice of its breach of this Contract;
"Business Continuity Event"	means any event or issue that could impact on the operations of the Supplier and its ability to supply the Goods including, without limitation, an influenza pandemic and any Force Majeure Event but excluding, for the avoidance of doubt, the withdrawal of the United Kingdom (or any part of it) from the European Union and any related circumstances, events, changes or requirements;
"Business	means the Supplier's business continuity plan which includes

Continuity Plan"	its plans for continuity of the supply of the Goods during a Business Continuity Event;
"Business Day"	means any day other than a Saturday, Sunday or bank holiday in England;
"Buyback Price"	means the price at which the Supplier purchases the Goods from the Authority in accordance with the calculation set out in Schedule 16;
"Central Government Body"	means 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;
"Change"	means any change to this Contract;
"Change Control Note"	means the written record of a Change agreed or to be agreed by the Parties pursuant to the procedure set out in Clause 27 of Schedule 2;
"Change in Law"	means any change in Law which impacts on the supply of the Goods (including taxation or duties of any sort affecting the Supplier) which comes into force after the Commencement Date;
"Charges"	means the Contract Price together with any applicable VAT;
"Codes of Practice"	shall have the meaning given to the term in Clause 1.2 of Schedule 4;
"Commencement Date"	shall have the meaning given to it in Clause 2.1 of Schedule 1;
"Commercial Schedule"	means the document set out at Schedule 7;
"Confidential Information"	means information, data and material of any nature, which either Party may receive or obtain in connection with the

	conclusion and/or operation of the Contract, including any procurement process, which is: (a) Personal Data including, without limitation, that which relates to any patient or other service user or his or her treatment or clinical or care history; (b) designated as confidential by either Party or that ought reasonably to be considered as confidential (however it is conveyed or on whatever media it is stored); and/or (c) Policies and such other documents which the Supplier may obtain or have access to through the Authority's intranet;
"Contract"	means the agreement between the Parties in the form of contract at the front of this document and all schedules attached to the form of contract;
"Contracting Authority"	means any contracting authority as defined in regulation 3 of the Public Contracts Regulations 2015 (SI 2015/102) (as amended), other than the Authority;
"Contract Manager"	means for the Authority and for the Supplier the individuals specified in the Key Provisions or such other person notified by a Party to the other Party from time to time in accordance with Clause 12.1 of Schedule 2;
"Contract Price"	means the price exclusive of VAT that is payable to the Supplier by the Authority under the Contract for the full and proper performance by the Supplier of its obligations under the Contract;
"Defective Goods"	has the meaning given under Clause 9.5 of Schedule 2;
"Delivery"	has the meaning given under Clause 7.2 of Schedule 2. "Deliver" and "Delivered" shall be construed accordingly;
"Devolved Administration"	means the devolved administrations of Scotland, Wales and Northern Ireland (the Scottish Parliament, the Welsh Assembly and the Northern Ireland Assembly);
"Directive 2001/83"	means Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use (and any implementing, amended and/or successor legislation applicable to the UK or any part of it);

"Directive 2003/94"	means 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 (and any implementing, amended and/or successor legislation applicable to the UK or any part of it);
"Dispute(s)"	means any dispute, difference or question of interpretation or construction arising out of or in connection with this Contract, including any dispute, difference or question of interpretation relating to the Goods, any matters of contractual construction and interpretation relating to the Contract, or any matter where this Contract directs the Parties to resolve an issue by reference to the Dispute Resolution Procedure;
"Dispute Notice"	means a written notice served by one Party to the other stating that the Party serving the notice believes there is a Dispute;
"Dispute Resolution Procedure"	means the process for resolving Disputes as set out in Clause 28 of Schedule 2. For the avoidance of doubt, the Dispute Resolution Procedure is subject to Clause 35.2.3 of Schedule 2;
"DOTAS"	means the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue and Customs of any specified notifiable arrangements or proposals and to provide prescribed information on those arrangements or proposals within set time limits as contained in Part 7 of the Finance Act 2004 and in secondary legislation made under vires contained in Part 7 of the Finance Act 2004 and as extended to National Insurance Contributions by the National Insurance Contributions (Application of Part 7 of the Finance Act 2004) Regulations 2012, SI 2012/1868 made under s.132A Social Security Administration Act 1992;
"e-Tendering Portal"	means the Atamis Health Family eCommercial System, which is the e-tendering service used by the Authority, or such other e-tendering portal that the Authority uses from time to time;
"Electronic Trading System(s)"	means such electronic data interchange system and/or world wide web application and/or other application with such message standards and protocols as the Authority may specify from time to time;

"EMA"	means the European Medicines Agency (or any statutory successor);
"Emergency"	means a Pandemic or other serious and unexpected situation, in which the Authority decides that the normal supply chain of Stockpiled Goods cannot meet the demand;
"Emergency Authorised Release"	means as defined in Clause 6 of Schedule 2;
"Environmental Regulations"	shall have the meaning given to the term in Clause 1.2 of Schedule 4;
"Equality Legislation"	means any and all legislation, applicable guidance and statutory codes of practice relating to equality, diversity, non-discrimination and human rights as may be in force in England and Wales from time to time including, but not limited to, the Equality Act 2010, the Part-time Workers (Prevention of Less Favourable Treatment) Regulations 2000 and the Fixed-term Employees (Prevention of Less Favourable Treatment) Regulations 2002 (SI 2002/2034) and the Human Rights Act 1998;
"EU References"	has the meaning given to it in Clause 1.3.1 of Schedule 5;
"Exit Day"	has the meaning given to it in the European Union (Withdrawal) Act 2018;
"Exit Phase"	means a period commencing from the earliest of any of the following events: (i) three (3) months before expiry of this Contract; or (ii) from the date of any notice to terminate this Contract or any part of this Contract and continuing for a period of three (3) months or as agreed by both Parties; or (iii) from the date of any agreement to reduce the Quantity Required other than by reason of a Emergency Authorised Release and continuing for a period of three (3) months or as agreed by both Parties;
"Exit Plan"	means the plan setting out the manner in which the Supplier

	shall buyback the Goods during the Exit Phase in accordance with Schedule 14;
"FOIA"	shall have the meaning given to the term in Clause 1.2 of Schedule 4;
"Force Majeure Event"	means any event beyond the reasonable control of the Party in question to include, without limitation: (a) war including civil war (whether declared or undeclared), riot, civil commotion or armed conflict materially affecting either Party's ability to perform its obligations under this Contract; (b) acts of terrorism; (c) flood, storm or other natural disasters; (d) fire; (e) unavailability of public utilities and/or access to transport networks to the extent no diligent supplier could reasonably have planned for such unavailability as part of its business continuity planning; (f) government requisition or impoundment to the extent such requisition or impoundment does not result from any failure by the Supplier to comply with any relevant regulations, laws or procedures (including such laws or regulations relating to the payment of any duties or taxes) and subject to the Supplier having used all reasonable legal means to resist such requisition or impoundment; (g) compliance with any local law or governmental order, rule, regulation or direction applicable outside of England and Wales that could not have been reasonably foreseen; (h) industrial action which affects the ability of the Supplier to supply the Goods, but which is not confined to the workforce of the Supplier or the workforce of any Sub-contractor of the Supplier; and (i) a failure in the Supplier's and/or Authority's supply chain to the extent that such failure is due to any event suffered by a member of such supply chain, which would also qualify as a Force Majeure Event in accordance with this definition had it been suffered by one of the Parties; but excluding, for the avoidance of doubt,

	(a) pandemic or epidemic; (b) the withdrawal of the United Kingdom from the European Union; or (c) the COVID-19 pandemic, except for circumstances caused by or related to the COVID-19 pandemic which are changes in applicable law and/or governmental guidance which mean that the Goods cannot be provided as set out in this Contract (in all material respects) without such Laws and/or government guidance being breached, or if the Supplier can reasonably demonstrate that despite all reasonable endeavours, it is unable to secure non-COVID-19 infected personnel to provide the Goods due to the levels of COVID-19 infections in the population of the United Kingdom.
"Fraud"	means any offence under any law in respect of fraud in relation to this Contract or defrauding or attempting to defraud or conspiring to defraud the government, parliament or any Contracting Authority;
"GDPR"	means the General Data Protection Regulation (Regulation (EU) 2016/679);
"General Anti-Abuse Rule"	means (a) the legislation in Part 5 of the Finance Act 2013; and (b) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid national insurance contributions;
"Good Industry Practice"	means the exercise of that degree of skill, diligence, prudence, risk management, quality management and foresight which would reasonably and ordinarily be expected from a skilled and experienced supplier engaged in the manufacture and/or supply of goods similar to the Goods under the same or similar circumstances as those applicable to this Contract, including in accordance with any codes of practice published by relevant trade associations;
"Good Manufacturing Practice"	shall have the meaning set out in Directive 2003/94 and the QTA;
"Goods"	means all goods, materials or items that the Supplier is required

	to supply to the Authority under this Contract (including, without limitation, under Schedule 6 which sets out the requirements of the Authority as issued to tenderers as part of the procurement process and Schedule 9 which sets out the Supplier's response to these requirements);
"Guidance"	means any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to the Goods, 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 Authority, NHS Improvement, NHS England, the Medicines and Healthcare products Regulatory Agency, the European Medicine Agency or the European Commission (in each case to the extent applicable to the UK), the Care Quality Commission and/or any other regulator or competent body;
"Halifax Abuse Principle"	means the principle explained in the CJEU Case C-255/02 Halifax and others;
"Health Service Bodies"	means: (a) the Department of Health and Social Care and all divisions and agencies thereof and any independent NHS board or similar body that may be established including regional agencies of such board; (b) a GP (being a medical practitioner providing general medical services or personal medical services under the National Health Service Act 2006 (c.41) (whether operating in partnership with others or not)); (c) health service bodies referred to in section 9 of the National Health Service Act 2006 (c.41); (d) the Secretary of State for Health and Social Care; (e) any care trust as defined in section 77 of the National Health Service Act 2006 (c.41); (f) any NHS foundation trust listed in the register of NHS foundation trusts maintained pursuant to section 39 of the National Health Service act 2006 (c.41); (g) any body replacing or providing similar or equivalent services to any of the above in any area of the United Kingdom including any bodies established pursuant to the Health and Social Care Act 2012, including but not limited

	to NHS England; and (h) any statutory successor to any of the above;
"Intellectual Property Rights"	means all patents, copyright, design rights, registered designs, trade marks, know-how, database rights, confidential formulae and any other intellectual property rights and the rights to apply for patents and trade marks and registered designs;
"Key Provisions"	means the key provisions set out in Schedule 1;
"KPI"	means the key performance indicators as set out in Part 2 – Key Performance Indicators of Schedule 7;
"Law"	means any applicable legal requirements including, without limitation: (a) any applicable statute or proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument as applicable in England and Wales; (b) to the extent binding under UK law, any applicable European Union obligation, directive, regulation, decision, law or right (including any such obligations, directives, regulations, decisions, laws or rights that are incorporated into the law of England and Wales or given effect in England and Wales by any applicable statute, proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument); (c) to the extent in force in the UK or any part of it, 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 relevant code of practice as applicable in England and Wales; (g) any relevant collective agreement and/or international law provisions (to include, without limitation, as referred to in (a) to (f) above); and (h) where Goods are to be delivered into Northern Ireland, any of the applicable legal requirements set out in (a) to (g), together with any applicable European Union obligation,

	directive, regulation, decision, law or rights to the extent that these are binding and/or applicable in Northern Ireland in relation to such Goods;
"Licensing Authority"	means the MHRA or EMA as the case may be (in the case of the latter, to the extent that any Marketing Authorisation and/or Manufacturing Licence issued by such entity is valid in the UK);
"Loss Costs"	means to the extent that the Authority and/or Administering Entity and/or Devolved Administration has taken all reasonable steps to mitigate such losses: (a) all costs in connection with receiving and storing Defective Goods; (b) where the Defective Goods have been despatched by or on behalf of the Authority or Devolved Administration, the costs of recalling the Defective Goods; (c) all wasted administrative and personnel costs of the Authority and/or any Administering Entity and/or Devolved Administration relating to Defective Goods; (d) where individuals are required to be given further treatments of the Goods because their initial course was Defective Goods, the costs of providing such further treatments of the Goods to such individuals; (e) all costs in excess of the Charges paid or payable by the Authority for Rejected Goods incurred in sourcing alternative products from third parties; and (f) all costs associated with advising, screening, testing, treating or otherwise providing healthcare to patients in relation to Defective Goods;
"Manufacturing Licence"	means the manufacturing licence in respect of the Goods granted by the Licensing Authority;
"Marketing Authorisation"	means the marketing authorisation number as specified in Schedule 9 for Goods for use in the United Kingdom granted by the Licensing Authority as amended or varied by the Licensing Authority from time to time;
"MHRA"	means the Medicines and Healthcare products Regulatory Agency;

"Modern Slavery Helpline"	means the modern slavery helpline phone number on 08000 121 700 or the online reporting tool which can be found online at https://supplierregistration.cabinetoffice.gov.uk/msat;
"Occasion of Tax Non-Compliance"	means: (a) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 is found on or after 1 April 2013 to be incorrect as a result of: i. a Relevant Tax Authority successfully challenging the Supplier under the General Anti-Abuse Rule or the Halifax Abuse Principle or under any tax rules or legislation that have an effect equivalent or similar to the General Anti-Abuse Rule or the Halifax Abuse Principle; ii. the failure of an avoidance scheme which the Supplier was involved in, and which was, or should have been, notified to a Relevant Tax Authority under the DOTAS or any equivalent or similar regime; and/or (b) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Commencement Date or to a civil penalty for fraud or evasion;
"Party"	means the Authority or the Supplier as appropriate and Parties means both the Authority and the Supplier;
"Personal Data"	shall have the same meaning as set out in Section 3(2) of the Data Protection Act 2018 (as amended) in relation to data processed under this Contract;
"Policies"	means the policies, rules and procedures of the Authority as notified to the Supplier from time to time;
"Product Information"	means information concerning the Goods as may be reasonably requested by the Authority and supplied by the Supplier to the Authority in accordance with Clause 26 of Schedule 2 for inclusion in the Authority's product catalogue from time to time;
"Purchase	means the purchase order required by the Authority's financial

Order"	systems, if a purchase order is referred to in the Key Provisions;
"Quality Technical Agreement" or "QTA"	means the Quality Technical Agreement that will be entered into in the form set out in Schedule 15 as amended and updated from time to time by the parties (to the QTA) noting that a Quality Technical Agreement will be entered into by the Authority and the Supplier, and where relevant between the Supplier and any Sub-Contractor(s) indicated in the Offer Schedule;
"Quantity Required"	means the total quantity of the medication(s) that the Authority has procured as listed in the corresponding "Quantity Required" column(s) of the Medications Catalogue sheet of the Offer Schedule subject to any reductions as specified in the Contract;
"Regulation 726/2004"	means 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 (and any implementing, amended and/or successor legislation applicable to the UK or any part of it);
"Rejected Goods"	has the meaning given under Clause 9.3 of Schedule 2;
"Release Report"	means the report to be provided following an Emergency Authorised Release in accordance with Clause 6.6.4;
"Release Plan"	means the plan setting out how to address shortages as a result of an Emergency in accordance with Schedule 13
"Released Goods"	means the Stockpiled Goods that are the subject of an Authorised Release or Emergency Authorised Release;
"Relevant Tax Authority"	means HM Revenue and Customs, or, if applicable, a tax authority in the jurisdiction in which the Supplier is established;
"Remedial Proposal"	has the meaning given under Clause 20.2 of Schedule 2;

"Replacement Goods"	means the Goods used to replace Stockpiled Goods removed from the Stockpile in accordance with Clause 6.8.5 of Schedule 2;
"Requirement to Recall"	has the meaning given under Clause 9.10 of Schedule 2;
"Responsible Person"	as detailed in Schedule 3;
"Shelf Life"	means the time within which a Good can be administered to patients;
"Specification"	means the document set out in Schedule 6 as amended and/or updated in accordance with this Contract;
"Staff"	means all persons employed or engaged by the Supplier to perform its obligations under this Contract including any Sub-contractors and person employedor engaged by such Sub-contractors;
"Stockpile"	means the designated area that is separate from business as usual stock where the Stockpiled Goods are held within the Storage Facilities;
"Stockpiled Goods"	means Goods held in and stored within the Stockpile, including any Replacement Goods supplied under this Contract;
"Stock Report"	means the report to be provided to the Authority in accordance with Clause 4.4.14 of Schedule 2 to include the information set out in Schedule 12
"Storage and Maintenance"	means the management of Stockpiled Goods held at the Supplier's Storage Facilities and includes storage, turnover, maintenance of Shelf Life, accounting, stock rotation, counting and reporting;
"Storage Facilities"	means the location(s) in the United Kingdom designated by the Supplier for the storage of the Stockpiled Goods, as set out in Schedule 3;
"Storage Provider"	means the provider of the Storage Services where this is not the Supplier;

"Storage Services"	means the storage of the Goods in accordance with Clause 4 of Schedule 2;
"Sub-contract"	means a contract between two or more suppliers, at any stage of remoteness from the Supplier in a sub- contracting chain, made wholly or substantially for the purpose of performing (or contributing to the performance of) the whole or any part of this Contract;
"Sub-contractor"	means a party to a Sub-contract other than the Supplier;
"Summary of Product Characteristics" or "SmPC"	means the summary of product characteristics approved by the Licensing Authority for the Marketing Authorisation;
"Supplier"	means the supplier named on the form of Contract on page 1;
"Supplier Code of Conduct"	means the code of that name published by the Government Commercial Function originally dated September 2017, as may be amended, restated, updated, re-issued or re-named from time to time;
"Tender Response Document"	means the part of the Supplier's response submitted pursuant to the competitive process carried out by the Authority in relation to the Goods, as set out in Schedule 9;
"Term"	means the Term as set out in the Key Provisions;
"Termination Notice"	means a written notice of termination given by one Party to the other notifying the Party receiving the notice of the intention of the Party giving the notice to terminate this Contract on a specified date and setting out the grounds for termination;
"Third Party Body"	has the meaning given under Clause 9.2 of Schedule 2;
"Units"	means a unit of the Goods;
"VAT"	means value added tax chargeable under the Value Added Tax Act 1994 or any similar, replacement or extra tax;
"Volume"	means the total quantity of the Goods to be delivered during the Term; and

"Wholesale Distribution Authorisation"	has the meaning set out in the Human Medicines Regulations 2012/2016 or any replacement regulation.

1.2 References to any Law shall be deemed to include a reference to that Law as amended, extended, consolidated, re-enacted, restated, implemented or transposed from time to time.

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

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

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

1.4 References to any legal entity shall include any body that takes over responsibility for the functions of such entity.

1.5 References in this Contract to a "Schedule", "Appendix", "Paragraph" or to a "Clause" are to schedules, appendices, paragraphs and clauses of this Contract.

1.6 References in this Contract to a day or to the calculation of time frames are references to a calendar day unless expressly specified as a Business Day.

1.7 Unless set out in the Commercial Schedule as a chargeable item and subject to Clause 36.6 of Schedule 2, the Supplier shall bear the cost of complying with its obligations under this Contract.

1.8 The headings are for convenience only and shall not affect the interpretation of this Contract.

1.9 Words denoting the singular shall include the plural and vice versa.

1.10 Where a term of this Contract provides for a list of one or more items following the word "including" or "includes" then such list is not to be interpreted as an exhaustive list. Any such list shall not be treated as excluding any item that might have been included in such list having regard to the context of the contractual term in question. General words are not to be given a restrictive meaning where they are followed by examples intended to be included within the general words.

1.11 Where there is a conflict between the Supplier's responses to the Authority's requirements (the Supplier's responses being set out in Schedule 9) and any other part of this Contract, such other part of this Contract shall prevail.

1.12 Where a document is required under this Contract, the Parties may agree in writing that this shall be in electronic format only.

1.13 Any Breach Notice issued by a Party in connection with this Contract shall not be invalid due to it containing insufficient information. A Party receiving a Breach Notice ("**Receiving Party**") may ask the Party that issued the Breach Notice ("**Issuing Party**") to provide any further information in relation to the subject matter of the Breach Notice that it may reasonably require to enable it to understand the Breach Notice and/or to remedy the breach. The Issuing Party shall not unreasonably withhold or delay the provision of such further information as referred to above as may be requested by the Receiving Party but no such withholding or delay shall invalidate the Breach Notice.

1.14 Any terms defined as part of a Schedule or other document forming part of this Contract shall have the meaning as defined in such Schedule or document.

1.15 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.

1.16 In this Contract the Authority is acting as part of the Crown.

Schedule 6

Specification

Background

1.1 The Authority's intention in carrying out this procurement exercise is to enter into a Contract(s) for the supply, storage, and management of the Goods as a Stockpile by the Supplier, with the Supplier being responsible for rotating the stock so that the Goods in the Stockpile have a minimum agreed Shelf Life of 18 months throughout the Term. The purpose of the Stockpile is to have the Goods that are routinely used in the NHS available for release into the UK supply chain in the event of an Emergency. The Goods procured will be used in the NHS including within the devolved administrations of Scotland, Wales and Northern Ireland. As ownership of the Stockpiled Goods lies with the Authority, and the Storage Facilities will be listed on the Authority's Wholesale Distribution Authorisation, the Authority requires that all Storage Facilities will be located within Great Britain.

1.2 From the Commencement Date, the Supplier shall be required to build up the Stockpile for each Good listed in Table A to the Quantity Required.

1.3 In the period leading up to expiry of the Contract, the Supplier shall be required, through an agreed Exit Plan, to buy back the Stockpiled Goods. Title to the Stockpiled Goods (prior to any buy back) will remain with the Authority, but the Supplier must store the Stockpiled Goods at their own risk and manage it, to include regular reporting and review meetings with the Authority.

Licensing Requirements

2.1 The Goods must be Licensed for use in the United Kingdom (Great Britain and Northern Ireland).

2.2 The Supplier must have at all times, the requisite Wholesale Distribution Authorisation (H) licence and/or a MIA licence, sufficient for the supply of the Goods and Storage Services in accordance with the terms of the Contract.

Packaging and Labelling

3.1 The pack design must comply with the principles of the "MHRA Best Practice Guidance on Labelling and Packaging"[1] and the "National Patient Safety Agency Guidelines on Packaging and Labelling"[2].The name of the medicine expressed on the packaging must be the same as that which is registered in the Summary of Product Characteristics approved by the MHRA. This will be the brand name for a proprietary product, but the generic name must also be clearly expressed.

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[1] Available online at < https://www.gov.uk/government/publications/best-practice-in-the-labelling-and-packaging-of-medicines

[2] Available online at https://www.gov.uk/guidance/medicines-packaging-labelling-and-patient-information-leaflets

Abbreviations must not be used.

3.2 All critical information must be present, namely:

- the generic name of the medicine;
- the strength of the medicine;
- the form of the medicine;
- the route of administration;
- posology; and
- warnings.

3.3 All packs must include a Patient Information Leaflet in English Language in the form approved by the MHRA. The Patient Information Leaflet must comply with current regulatory requirements.

3.4 The batch number and expiry date must be clearly present and easily legible. Where embossing is used for this purpose then the batch number and expiry date must be clearly discernible under normal reading conditions. The expiry date must be unambiguously expressed.

3.5 Temperature storage conditions must be clearly stated on both the primary and secondary packaging.

3.6 Outer boxes must be robust and provide adequate protection to the inner Good containers.

Shelf Life

4.1 There must be a minimum of 18 months' Shelf Life remaining on the Goods in the Stockpile at all times.

Delivery and Storage

5.1 The Supplier will be required to transport the Goods from the manufacturer's(s') site(s), and deliver them to the Storage Facilities. The Supplier shall also be required to provide details of location(s) where the Goods are to be stored. Such details will include:

(i) Name of storage location

(ii) Address of storage location

(iii) Wholesale Distribution Authorisation (H) number

(iv) Wholesale Distribution Authorisation (H) date

(v) WDA(H) Licence Number - Site number (this number is of the facility where the Goods will be stored)

(vi) Name of the Supplier's Responsible Person (this should be filled in even if contracting to a third-party storage location)

(vii) Name of Responsible Person within the proposed storage location (if different

from above i.e., the stock is being held at a third-party location)

(viii) Name of medicine being supplied and confirmation that the medicine shall be stored at the storage location in ambient storage conditions

5.2 Except in the case of an Authorised Release, the Supplier shall ensure that it maintains the Quantity Required of the Stockpiled Goods.

5.3 The Authority is permitted by the Supplier to visit the Supplier's Storage Facilities for any inspection at agreed scheduled intervals.

Authority Responsibilities

6.1 The Authority will appoint a Contract Manager to manage the relationship with the Supplier under the Contract.

Supplier Responsibilities

7.1 The Supplier shall appoint a Contract Manager to oversee the work and liaise with/report to the Authority's Contract Manager.

Reporting and Contract Management

8.2 Contract review meetings between the Supplier and Authority will take place at least once every six months and at such other times as reasonably requested by the Authority from time to time.

8.3 Any reports required for the purposes of performing or managing this Contract shall be provided to the Authority by the Supplier in accordance with the Contract or at intervals agreed with the Supplier in writing from time to time.

8.4 Further instructions and obligations on the Supplier are set out in Schedule 2 (General Terms and Conditions) of the Conditions of Contract.

Table A

			Volume per Authority's pack*1 size (E)	
Lot	Medicine	Presentation	Units	Quantity Required (Units)
Lot 1	Sodium Lactate	Compound Sodium lactate 1 litre iv	Single bag of fluid	1,392,347

		infusion		
Lot 2	Sodium Lactate	Compound Sodium lactate 500ml iv infusion	Single bag of fluid	254,477
Lot 3	Glucose	Glucose/Sodium chloride 4%/0.18% 1 litre iv infusion	Single bag of fluid	59,773
Lot 4	Glucose	Glucose/Sodium chloride 5%/0.45% 500ml iv infusion	Single bag of fluid	19,709
Lot 5	Glucose	Glucose 5% / Sodium chloride 0.9% 500ml iv infusion	Single bag of fluid	39,740
Lot 8	Glucose	Glucose 5% - 1 litre iv infusion	Single bag of fluid	103,094
Lot 9	Glucose	Glucose 5% - 500ml iv infusion	Single bag of fluid	92,294
Lot 10	Glucose	Glucose 5% - 100ml iv infusion	Single bag of fluid	268,013
Lot 11	Sodium Chloride	Sodium Chloride 0.9% - 1 litre iv infusion	Single bag of fluid	1,471,742

Schedule 7

Commercial Schedule

Part 1 – Price

Product	Quantity	Price per Unit (£) (per single bag of fluid)	Storage costs per Unit per week	Total
Lot 1 - Compound Sodium lactate 1 litre iv infusion	1,392,347	[redacted]	[redacted]	[redacted] excluding VAT
Lot 2 - Compound Sodium lactate 500ml iv infusion	254,477	[redacted]	[redacted]	[redacted] excluding VAT
Lot 3 - Glucose/Sodium chloride 4%/0.18% 1 litre iv infusion	59,773	[redacted]	[redacted]	[redacted] excluding VAT
Lot 4 - Glucose/Sodium chloride 5%/0.45% 500ml iv infusion	19,709	[redacted]	[redacted]	[redacted] excluding VAT
Lot 5 -Glucose 5% / Sodium chloride 0.9%	39,740	[redacted]	[redacted]	[redacted] excluding VAT

500ml iv infusion				
Lot 8 - Glucose 5% - 1 litre iv infusion	103,094	[redacted]	[redacted]	[redacted] VAT
Lot 9 - Glucose 5% - 500ml iv infusion	92,294	£[redacted]	[redacted]	[redacted] excluding VAT
Lot 10 - Glucose 5% - 100ml iv infusion	268,013	[redacted]	[redacted]	[redacted] excluding VAT
Lot 11 - Sodium Chloride 0.9% - 1 litre iv infusion	1,471,742	[redacted]	[redacted]	[redacted] excluding VAT

Part 2 – Key Performance Indicators

1. Goods delivered to contract specification
2. Volume of Goods delivered
3. Date of delivery
4. Shelf Life
5. Production of reports
6. Accuracy of invoices
7. Delivery of social value

	KPI	Contract Schedules and Clauses containing Supplier obligations in relation to this indicator
1	Goods delivered to contract specification	Schedule 1 Key Provisions, Clauses 8 and 9 Schedule 2 General Terms and Conditions, Clauses 1.1, 1.2, 1.3, 3, 7.8, 14.1, 24 and 25. Schedule 5 Definitions and Interpretations, Clause 1.1 Schedule 6 Specification Schedule 9 Tender Response Document
2	Volume of Goods delivered	Schedule 2 General Terms and Conditions, Clause 1.1 Schedule 5 Definitions and Interpretations, Clause 1.1 Schedule 6 Specification
3	Date of Delivery	Schedule 1 Key Provisions, Clauses 8 & 9 Schedule 2 General Terms and Conditions, Clause 1.1, 1.2, 1.3, , 2, 7 and 14.1 Schedule 5 Definitions and Interpretations, Clause 1.1
4	Shelf Life	Schedule 2 General Terms and Conditions, Clause 6.9.2 Schedule 5 Definitions and Interpretations, Clause 1.1 Schedule 6 Specification
5	Production of Reports	Schedule 2 General Terms and Conditions, Clauses 4.4.14, 6.6.4 and 6.8 Schedule 12 Stock Report
6	Accuracy of invoices	Schedule 2 General Terms and Conditions, Clauses 13.3, 13.4, 13.6 and 13.7
7	Delivery of social value	Schedule 9 Tender Response Document

Schedule 8

Proforma Change Control Note

CCN No:	**Contract:**	**Effective date of Change:**
Initiated by: Change requested by [Supplier **OR** Authority]		
Date of request:		
Period of validity: This Change Control Note is valid for acceptance until [DATE].		
Reason for Change:		
Description and impact of the Change (including to delivery and performance):		
Required amendments to wording of Contract or Schedules:		
Adjustment to Contract Price resulting from Change:		
Additional one-off charges and means of determining these (for example, fixed price basis):		
Supporting or additional information:		

SIGNED ON BEHALF OF THE AUTHORITY	**SIGNED ON BEHALF OF THE SUPPLIER**
Signature:	Signature:
Name:	Name:
Position:	Position:
Date:	Date:

Schedule 9

Tender Response Document

Lot 1 Compound Sodium lactate 1litre iv infusion

Document 5 Offer Schedule for the Invitation to offer for The Supply, Storage and Management of Intravenous Fluids.

Offer reference number : CM /EMI/ 22 / C103602

QA Technical Sheet Goods Information

Offeror name :	**Baxter Healthcare Ltd**

- Offerors must not make any deletions to this schedule
- ALL fields must be completed
- The QA Technical Sheet needs to be completed for each Good you offer as part of your submission. If you are applying for more than one Good, then please make a copy of this tab and complete for each Good as required.

OFFICIAL -SENSITIVE COMMERCIAL (WHEN COMPLETE D)

General information:
- QA Technical sheet, packaging and production information.

Table 6.1		**Please input your responses in Column "C"**
Supplier	Supplier Name	Baxter Healthcare Ltd
	Supplier address	Wallingford Road
		Compton
		Berkshire
		RG20 7QW
	Storage Facilities (if different from above)	Baxter - Brackmills Industrial Estate, Salthouse Rd, Northampton NN4 7UF. Yusen UK - Cheaney Drive, Grange Park South, Northamptonshire, NN4 5FB

	WDA (H) Licence Number and/or MIA Licence Number if applicable (provide a copy of the licence(s)), and GDP or GMP certificate if applicable (provide a copy) to cover all activities involved in performing the Contract	WDA (H) Licence number: WDA (H) 116 MIA Licence number: MIA 116 GDP & GMP certificates reference: UK MIA 116 Insp GMP/GDP 116/18507-0050 & UK WDA (H) 116 Insp GMP/ GDP IMP 116/18507-0042 Please refer to: Doc5_Tab6WDAH116_GMPGDP-IMP116 Doc 5_Tab 6_MIA 116 Version 63 Doc5_Tab6MIA116 GMP-GDP-IMP116 Doc 5_Tab 6_WDA(H) Licence V17
	Offered Presentation	
Product details	Description of the Goods (including strength of the Goods)	Compound Sodium lactate 1 litre iv infusion
	Proprietary name (Brand name)	Synonyms: - Hartmann's Solution for Infusion, Ringer Lactate Solution for Infusion
	Countries where the Good is licensed	United Kingdom
	Name and address of the Marketing Authorisation holder (ie the company who owns the licence for the Good)	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
	Dosage form of the Goods (e.g. plastic ampoule, pre-filled syringe)	Viaflo IV Bag
	Storage conditions	No special precautions for storage

	Shelf Life from date of manufacture	36 months
	Shelf-Life after reconstitution or first opening	Contents should be used immediately and should not be stored for a subsequent infusion. Discard after single use. Discard any unused portion.
	Good grade e.g. BP, USP (State whether the Good is listed in British/US/European Pharmacopoeia)	BP
	Route/s of administration	Intravenous infusion
	UK/GB Marketing Authorisation number	PL 00116/0330
	Details of any animal products or animal derived material which may be present in the Good	n/a
	List of excipients	Water for Injections
Manufacturer details	Manufacturer (responsible for batch released of the Goods as shown on the patient information leaflet)	Baxter Healthcare Ltd
	- Manufacturing licence number	MIA116
	- Country in which the manufacture is based	United Kingdom
	- Full address	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
	Manufacturer of bulk product	n/a

	- Manufacturing licence number	n/a
	- Country in which the bulk manufacture is based	n/a
	- Full address	n/a
	API (Active Pharmaceutical Ingredient) supplier	Confidential Information
	- Manufacturing licence number	Confidential Information
	- Country in which the API manufacture is based	The majority of our raw material is sourced from within the EU. All raw material suppliers are fully audited.
	- Full address	Confidential Information
	Company responsible for packaging activity	Baxter Healthcare Ltd
	- Manufacturing licence number	MIA116
	- Country in which the packager is based	United Kingdom
	- Full address	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
Pack details	Packaging type (description)	Bags overwrapped with a protective plastic pouch, Cardboard shipper pack
	Pack size (eg. 10 ml ampoules in a pack of 5, a pack of 100 tablets,...)	10 bags of 1000 ml per outer pack
	Code for the Goods (if from inside UK)	FKE2324
	PIP code (if from inside UK)	n/a

	Tamper evidence - method used.	Bags overwrapped with a protective plastic pouch
	Provide artwork or packaging, labelling, patient information leaflets and Summary of Product Characteristics (SmPC)	Please see attached files in Doc5_Tab6_Lot1_FKE2324-1000ml
	*Does the pack/container meet the following requirements (Y/N) and comment as appropriate**	
	English livery	Y
	Expiry date displayed on the pack	Y
	Patient information leaflet in each pack	Y
	Batch number displayed on pack	Y
Shipping and packaging	Pack dimensions (mm) h x w x d	280 x 154 x 45
	Outer, or shipper pack quantity	10
	Outer pack dimensions (mm) h x w x d	210 x 290 x 390
	Outer pack weight (Kg)	11.20
	Delivery on Europallets?	Y
	Number of outer packs per pallet	64
	Maximum pallet dimensions (mm) h x w x d	1,680 x 800 x 1,200
	Pallet weight (Kg)	716.80
Transport	Current location of Goods offered (full address including name of wholesaler if applicable)	Yusen Logistics, Grange Park, Northampton, NN3 8RG

	Transport route and method used (from current location to place of delivery)	The transport route will depend on the nature of the emergency and the DHSC response. Baxter will work with the DHSC to ensure the most direct and appropriate transport route to used to get product to the designated delivery point/s. Baxters dedicated delivery partner would facilitate the deliveries under instruction from Baxter.
	Full description of supply chain (provide a supply chain map from end to end; from manufacture to end supply point)	Please refer to the process flow map from manufacture to end supply point attached as Doc5_Tab6_In_Replen & Outbound..
	Method of temperature control systems that will be employed, including the records that will be provided to the Authority	Yusen GP1 & GP3, use an Ice spy web based system to monitor their warehouse temperatures. Alarm levels are set at 25 and 15 degrees with alert messages set at 24.5 and 15.5 degrees. Alerts are sent to QA and Operations team members. For out of hours, site security receive alerts and contact nominated person to action.
Verification of the Goods (to be completed by supplier)	Name and role of person that has checked and verified the above information	[redacted], Senior Product Manager
Approved by the Authority		Yes
Name of the Approver		[redacted], RP
Date		24-Jul-23

Lot 2 – Compound Sodium lactate 500ml iv infusion

Document 5 Offer Schedule for the Invitation to offer for The Supply, Storage and Management of Intravenous Fluids.

Offer reference number : CM /EMI/ 22 / C103602

QA Technical Sheet Goods Information

Offeror name :	**Baxter Healthcare Ltd**

- Offerors must not make any deletions to this schedule
- ALL fields must be completed
- The QA Technical Sheet needs to be completed for each Good you offer as part of your submission. If you are applying for more than one Good, then please make a copy of this tab and complete for each Good as required.

OFFICIAL -SENSITIVE COMMERCIAL (WHEN COMPLETE D)

General information:
- QA Technical sheet, packaging and production information.

Table 6.1		**Please input your responses in Column "C"**
Supplier	Supplier Name	Baxter Healthcare Ltd
	Supplier address	Wallingford Road
		Compton
		Berkshire
		RG20 7QW
	Storage Facilities (if different from above)	Baxter - Brackmills Industrial Estate, Salthouse Rd, Northampton NN4 7UF. Yusen UK - Cheaney Drive, Grange Park South, Northamptonshire, NN4 5FB

	WDA (H) Licence Number and/or MIA Licence Number if applicable (provide a copy of the licence(s)), and GDP or GMP certificate if applicable (provide a copy) to cover all activities involved in performing the Contract	WDA (H) Licence number: WDA (H) 116 MIA Licence number: MIA 116 GDP & GMP certificates reference: UK MIA 116 Insp GMP/GDP 116/18507-0050 & UK WDA (H) 116 Insp GMP/ GDP IMP 116/18507-0042 Please refer to: Doc5_Tab6WDAH116_GMPGDP-IMP116 Doc 5_Tab 6_MIA 116 Version 63 Doc5_Tab6MIA116 GMP-GDP-IMP116 Doc 5_Tab 6_WDA(H) Licence V17
	Offered Presentation	
Product details	Description of the Goods (including strength of the Goods)	Compound Sodium lactate 500ml iv infusion
	Proprietary name (Brand name)	Synonyms: - Hartmann's Solution for Infusion, Ringer Lactate Solution for Infusion
	Countries where the Good is licensed	United Kingdom
	Name and address of the Marketing Authorisation holder (ie the company who owns the licence for the Good)	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
	Dosage form of the Goods (e.g. plastic ampoule, pre-filled syringe)	Viaflo IV Bag
	Storage conditions	No special precautions for storage

	Shelf Life from date of manufacture	24 months
	Shelf-Life after reconstitution or first opening	Contents should be used immediately and should not be stored for a subsequent infusion. Discard after single use. Discard any unused portion.
	Good grade e.g. BP, USP (State whether the Good is listed in British/US/European Pharmacopoeia)	BP
	Route/s of administration	Intravenous infusion
	UK/GB Marketing Authorisation number	PL 00116/0330
	Details of any animal products or animal derived material which may be present in the Good	n/a
	List of excipients	Water for Injections
Manufacturer details	Manufacturer (responsible for batch released of the Goods as shown on the patient information leaflet)	Baxter Healthcare Ltd
	- Manufacturing licence number	MIA116
	- Country in which the manufacture is based	United Kingdom
	- Full address	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
	Manufacturer of bulk product	n/a

	- Manufacturing licence number	n/a
	- Country in which the bulk manufacture is based	n/a
	- Full address	n/a
	API (Active Pharmaceutical Ingredient) supplier	Confidential Information
	- Manufacturing licence number	Confidential Information
	- Country in which the API manufacture is based	The majority of our raw material is sourced from within the EU. All raw material suppliers are fully audited.
	- Full address	Confidential Information
	Company responsible for packaging activity	Baxter Healthcare Ltd
	- Manufacturing licence number	MIA116
	- Country in which the packager is based	United Kingdom
	- Full address	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
Pack details	Packaging type (description)	Bags overwrapped with a protective plastic pouch, Cardboard shipper pack
	Pack size (eg. 10 ml ampoules in a pack of 5, a pack of 100 tablets,...)	20 bags of 500 ml per outer pack
	Code for the Goods (if from inside UK)	FKE2323
	PIP code (if from inside UK)	n/a

	Tamper evidence - method used.	Bags overwrapped with a protective plastic pouch
	Provide artwork or packaging, labelling, patient information leaflets and Summary of Product Characteristics (SmPC)	Please see attached files in Doc5_Tab6_Lot2_FKE2323-500ml
	*Does the pack/container meet the following requirements (Y/N) and comment as appropriate**	
	English livery	Y
	Expiry date displayed on the pack	Y
	Patient information leaflet in each pack	Y
	Batch number displayed on pack	Y
Shipping and packaging	Pack dimensions (mm) h x w x d	280 x 120 x 25
	Outer, or shipper pack quantity	20
	Outer pack dimensions (mm) h x w x d	210 x 290 x 390
	Outer pack weight (Kg)	11.54
	Delivery on Europallets?	Y
	Number of outer packs per pallet	64
	Maximum pallet dimensions (mm) h x w x d	1,680 x 800 x 1,200
	Pallet weight (Kg)	738.56
Transport	Current location of Goods offered (full address including name of wholesaler if applicable)	Yusen Logistics, Grange Park, Northampton, NN3 8RG

	Transport route and method used (from current location to place of delivery)	The transport route will depend on the nature of the emergency and the DHSC response. Baxter will work with the DHSC to ensure the most direct and appropriate transport route to used to get product to the designated delivery point/s. Baxters dedicated delivery partner would facilitate the deliveries under instruction from Baxter.
	Full description of supply chain (provide a supply chain map from end to end; from manufacture to end supply point)	Please refer to the process flow map from manufacture to end supply point attached as Doc5_Tab6_In_Replen & Outbound.
	Method of temperature control systems that will be employed, including the records that will be provided to the Authority	Yusen GP1 & GP3, use an Ice spy web based system to monitor their warehouse temperatures. Alarm levels are set at 25 and 15 degrees with alert messages set at 24.5 and 15.5 degrees. Alerts are sent to QA and Operations team members. For out of hours, site security receive alerts and contact nominated person to action.
Verification of the Goods (to be completed by supplier)	Name and role of person that has checked and verified the above information	[redacted] Senior Product Manager
Approved by the Authority		Yes
Name of the Approver		[redacted] RP
Date		24-Jul-23

Comments:	

Lot 3 - Glucose/Sodium chloride 4%/0.18% 1 litre iv infusion

Document 5 Offer Schedule for the Invitation to offer for The Supply, Storage and Management of Intravenous Fluids.

Offer reference number : CM /EMI/ 22 / C103602

QA Technical Sheet Goods Information

Offeror name :	**Baxter Healthcare Ltd**

- Offerors must not make any deletions to this schedule
- ALL fields must be completed
- The QA Technical Sheet needs to be completed for each Good you offer as part of your submission. If you are applying for more than one Good, then please make a copy of this tab and complete for each Good as required.

OFFICIAL -SENSITIVE COMMERCIAL (WHEN COMPLETE D)

General information:
- QA Technical sheet, packaging and production information.

Table 6.1		**Please input your responses in Column "C"**
Supplier	Supplier Name	Baxter Healthcare Ltd
	Supplier address	Wallingford Road
		Compton
		Berkshire
		RG20 7QW
	Storage Facilities (if different from above)	Baxter - Brackmills Industrial Estate, Salthouse Rd, Northampton NN4 7UF. Yusen UK - Cheaney Drive, Grange Park South, Northamptonshire, NN4 5FB

	WDA (H) Licence Number and/or MIA Licence Number if applicable (provide a copy of the licence(s)), and GDP or GMP certificate if applicable (provide a copy) to cover all activities involved in performing the Contract	WDA (H) Licence number: WDA (H) 116 MIA Licence number: MIA 116 GDP & GMP certificates reference: UK MIA 116 Insp GMP/GDP 116/18507-0050 & UK WDA (H) 116 Insp GMP/ GDP IMP 116/18507-0042 Please refer to: Doc5_Tab6WDAH116_GMPGDP-IMP116 Doc 5_Tab 6_MIA 116 Version 63 Doc5_Tab6MIA116 GMP-GDP-IMP116 Doc 5_Tab 6_WDA(H) Licence V17
	Offered Presentation	
Product details	Description of the Goods (including strength of the Goods)	Glucose/Sodium chloride 4%/0.18% 1 litre iv infusion
	Proprietary name (Brand name)	n/a
	Countries where the Good is licensed	United Kingdom
	Name and address of the Marketing Authorisation holder (ie the company who owns the licence for the Good)	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
	Dosage form of the Goods (e.g. plastic ampoule, pre-filled syringe)	Viaflo IV Bag
	Storage conditions	No special precautions for storage
	Shelf Life from date of manufacture	36 months

	Shelf-Life after reconstitution or first opening	Additives: From a microbiological point of view, the diluted product must be used immediately unless dilution has taken place in controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions are the responsibility of the user.
	Good grade e.g. BP, USP (State whether the Good is listed in British/US/European Pharmacopoeia)	BP
	Route/s of administration	Intravenous infusion
	UK/GB Marketing Authorisation number	PL 00116/0342
	Details of any animal products or animal derived material which may be present in the Good	n/a
	List of excipients	Water for injections
Manufacturer details	Manufacturer (responsible for batch released of the Goods as shown on the patient information leaflet)	Baxter Healthcare Ltd
	- Manufacturing licence number	MIA116
	- Country in which the manufacture is based	United Kingdom
	- Full address	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
	Manufacturer of bulk product	n/a

	- Manufacturing licence number	n/a
	- Country in which the bulk manufacture is based	n/a
	- Full address	n/a
	API (Active Pharmaceutical Ingredient) supplier	Confidential Information
	- Manufacturing licence number	Confidential Information
	- Country in which the API manufacture is based	The majority of our raw material is sourced from within the EU. All raw material suppliers are fully audited.
	- Full address	Confidential Information
	Company responsible for packaging activity	Baxter Healthcare Ltd
	- Manufacturing licence number	MIA116
	- Country in which the packager is based	United Kingdom
	- Full address	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
Pack details	Packaging type (description)	Bags overwrapped with a protective plastic pouch, Cardboard shipper pack
	Pack size (eg. 10 ml ampoules in a pack of 5, a pack of 100 tablets,...)	10 bags of 1000 ml per outer pack
	Code for the Goods (if from inside UK)	FKE1254
	PIP code (if from inside UK)	n/a

	Tamper evidence - method used.	Bags overwrapped with a protective plastic pouch
	Provide artwork or packaging, labelling, patient information leaflets and Summary of Product Characteristics (SmPC)	Please see attached files in Doc5_Tab6_Lot3_FKE1254-1000ml
	*Does the pack/container meet the following requirements (Y/N) and comment as appropriate**	
	English livery	Y
	Expiry date displayed on the pack	Y
	Patient information leaflet in each pack	Y
	Batch number displayed on pack	Y
Shipping and packaging	Pack dimensions (mm) h x w x d	280 x 154 x 45
	Outer, or shipper pack quantity	10
	Outer pack dimensions (mm) h x w x d	210 x 290 x 390
	Outer pack weight (Kg)	11.30
	Delivery on Europallets?	Y
	Number of outer packs per pallet	64
	Maximum pallet dimensions (mm) h x w x d	1,680 x 800 x 1,200
	Pallet weight (Kg)	698.2
Transport	Current location of Goods offered (full address including name of wholesaler if applicable)	Yusen Logistics, Grange Park, Northampton, NN3 8RG

	Transport route and method used (from current location to place of delivery)	The transport route will depend on the nature of the emergency and the DHSC response. Baxter will work with the DHSC to ensure the most direct and appropriate transport route to used to get product to the designated delivery point/s. Baxters dedicated delivery partner would facilitate the deliveries under instruction from Baxter.
	Full description of supply chain (provide a supply chain map from end to end; from manufacture to end supply point)	Please refer to the process flow map from manufacture to end supply point attached as Doc5_Tab6_In_Replen & Outbound.
	Method of temperature control systems that will be employed, including the records that will be provided to the Authority	Yusen GP1 & GP3, use an Ice spy web based system to monitor their warehouse temperatures. Alarm levels are set at 25 and 15 degrees with alert messages set at 24.5 and 15.5 degrees. Alerts are sent to QA and Operations team members. For out of hours, site security receive alerts and contact nominated person to action.
Verification of the Goods (to be completed by supplier)	Name and role of person that has checked and verified the above information	[redacted], Senior Product Manager
Approved by the Authority		Yes
Name of the Approver		[redacted], RP
Date		24th Jul 2023

Comments:	

Lot 4 - Glucose/Sodium chloride 5%/0.45% 500ml iv infusion

Document 5 Offer Schedule for the Invitation to offer for The Supply, Storage and Management of Intravenous Fluids.

Offer reference number : CM /EMI/ 22 / C103602

QA Technical Sheet Goods Information

Offeror name :	**Baxter Healthcare Ltd**

- Offerors must not make any deletions to this schedule
- ALL fields must be completed
- The QA Technical Sheet needs to be completed for each Good you offer as part of your submission. If you are applying for more than one Good, then please make a copy of this tab and complete for each Good as required.

OFFICIAL -SENSITIVE COMMERCIAL (WHEN COMPLETE D)

General information:
- QA Technical sheet, packaging and production information.

Table 6.1		**Please input your responses in Column "C"**
Supplier	Supplier Name	Baxter Healthcare Ltd
	Supplier address	Wallingford Road
		Compton
		Berkshire
		RG20 7QW
	Storage Facilities (if different from above)	Baxter - Brackmills Industrial Estate, Salthouse Rd, Northampton NN4 7UF. Yusen UK - Cheaney Drive, Grange Park South, Northamptonshire, NN4 5FB

	WDA (H) Licence Number and/or MIA Licence Number if applicable (provide a copy of the licence(s)), and GDP or GMP certificate if applicable (provide a copy) to cover all activities involved in performing the Contract	WDA (H) Licence number: WDA (H) 116 MIA Licence number: MIA 116 GDP & GMP certificates reference: UK MIA 116 Insp GMP/GDP 116/18507-0050 & UK WDA (H) 116 Insp GMP/ GDP IMP 116/18507-0042 Please refer to: Doc5_Tab6WDAH116_GMPGDP-IMP116 Doc 5_Tab 6_MIA 116 Version 63 Doc5_Tab6MIA116 GMP-GDP-IMP116 Doc 5_Tab 6_WDA(H) Licence V17
	Offered Presentation	
Product details	Description of the Goods (including strength of the Goods)	Glucose/Sodium chloride 5%/0.45% 500ml iv infusion
	Proprietary name (Brand name)	n/a
	Countries where the Good is licensed	United Kingdom
	Name and address of the Marketing Authorisation holder (ie the company who owns the licence for the Good)	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
	Dosage form of the Goods (e.g. plastic ampoule, pre-filled syringe)	Viaflo IV Bag
	Storage conditions	No special precautions for storage
	Shelf Life from date of manufacture	24 months

	Shelf-Life after reconstitution or first opening	It is recommended that the product is used immediately once opened
	Good grade e.g. BP, USP (State whether the Good is listed in British/US/European Pharmacopoeia)	BP
	Route/s of administration	Intravenous infusion
	UK/GB Marketing Authorisation number	PL 00116/0655
	Details of any animal products or animal derived material which may be present in the Good	n/a
	List of excipients	Water for Injections
Manufacturer details	Manufacturer (responsible for batch released of the Goods as shown on the patient information leaflet)	Baxter Healthcare Ltd
	- Manufacturing licence number	MIA116
	- Country in which the manufacture is based	United Kingdom
	- Full address	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
	Manufacturer of bulk product	n/a
	- Manufacturing licence number	n/a
	- Country in which the bulk manufacture is based	n/a
	- Full address	n/a

	API (Active Pharmaceutical Ingredient) supplier	Confidential Information
	- Manufacturing licence number	Confidential Information
	- Country in which the API manufacture is based	The majority of our raw material is sourced from within the EU. All raw material suppliers are fully audited.
	- Full address	Confidential Information
	Company responsible for packaging activity	Baxter Healthcare Ltd
	- Manufacturing licence number	MIA116
	- Country in which the packager is based	United Kingdom
	- Full address	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
Pack details	Packaging type (description)	Bags overwrapped with a protective plastic pouch, Cardboard shipper pack
	Pack size (eg. 10 ml ampoules in a pack of 5, a pack of 100 tablets,...)	20 bags of 500 ml per outer pack
	Code for the Goods (if from inside UK)	FE1073
	PIP code (if from inside UK)	n/a
	Tamper evidence - method used.	Bags overwrapped with a protective plastic pouch
	Provide artwork or packaging, labelling, patient information leaflets	Please see attached files in Doc5_Tab6_Lot4_FE1073-500ml

	and Summary of Product Characteristics (SmPC)	
	*Does the pack/container meet the following requirements (Y/N) and comment as appropriate**	
	English livery	Y
	Expiry date displayed on the pack	Y
	Patient information leaflet in each pack	Y
	Batch number displayed on pack	Y
Shipping and packaging	Pack dimensions (mm) h x w x d	280 x 120 x 25
	Outer, or shipper pack quantity	20
	Outer pack dimensions (mm) h x w x d	210 x 290 x 380
	Outer pack weight (Kg)	11.68
	Delivery on Europallets?	Y
	Number of outer packs per pallet	64
	Maximum pallet dimensions (mm) h x w x d	1,712 x 800 x 1,200
	Pallet weight (Kg)	747.52
Transport	Current location of Goods offered (full address including name of wholesaler if applicable)	Yusen Logistics, Grange Park, Northampton, NN3 8RG
	Transport route and method used (from current location to place of delivery)	The transport route will depend on the nature of the emergency and the DHSC response. Baxter will work with the DHSC to ensure the most direct and appropriate transport route to

		used to get product to the designated delivery point/s. Baxters dedicated delivery partner would facilitate the deliveries under instruction from Baxter.
	Full description of supply chain (provide a supply chain map from end to end; from manufacture to end supply point)	Please refer to the process flow map from manufacture to end supply point attached as Doc5_Tab6_In_Replen & Outbound.
	Method of temperature control systems that will be employed, including the records that will be provided to the Authority	Yusen GP1 & GP3, use an Ice spy web based system to monitor their warehouse temperatures. Alarm levels are set at 25 and 15 degrees with alert messages set at 24.5 and 15.5 degrees. Alerts are sent to QA and Operations team members. For out of hours, site security receive alerts and contact nominated person to action.
Verification of the Goods (to be completed by supplier)	Name and role of person that has checked and verified the above information	[redacted] Senior Product Manager
Approved by the Authority		Yes
Name of the Approver		[redacted] RP
Date		24th Jul 2023
Comments:		

Lot 5 - Glucose 5% / Sodium chloride 0.9% 500ml iv infusion

Document 5 Offer Schedule for the Invitation to offer for The Supply, Storage and Management of Intravenous Fluids.

Offer reference number : CM /EMI/ 22 / C103602

QA Technical Sheet Goods Information

Offeror name :	**Baxter Healthcare Ltd**

- Offerors must not make any deletions to this schedule
- ALL fields must be completed
- The QA Technical Sheet needs to be completed for each Good you offer as part of your submission. If you are applying for more than one Good, then please make a copy of this tab and complete for each Good as required.

OFFICIAL -SENSITIVE COMMERCIAL (WHEN COMPLETE D)

General information:
- QA Technical sheet, packaging and production information.

Table 6.1		**Please input your responses in Column "C"**
Supplier	Supplier Name	Baxter Healthcare Ltd
	Supplier address	Wallingford Road
		Compton
		Berkshire
		RG20 7QW
	Storage Facilities (if different from above)	Baxter - Brackmills Industrial Estate, Salthouse Rd, Northampton NN4 7UF. Yusen UK - Cheaney Drive, Grange Park South, Northamptonshire, NN4 5FB

	WDA (H) Licence Number and/or MIA Licence Number if applicable (provide a copy of the licence(s)), and GDP or GMP certificate if applicable (provide a copy) to cover all activities involved in performing the Contract	WDA (H) Licence number: WDA (H) 116 MIA Licence number: MIA 116 GDP & GMP certificates reference: UK MIA 116 Insp GMP/GDP 116/18507-0050 & UK WDA (H) 116 Insp GMP/ GDP IMP 116/18507-0042 Please refer to: Doc5_Tab6WDAH116_GMPGDP-IMP116 Doc 5_Tab 6_MIA 116 Version 63 Doc5_Tab6MIA116 GMP-GDP-IMP116 Doc 5_Tab 6_WDA(H) Licence V17
	Offered Presentation	
Product details	Description of the Goods (including strength of the Goods)	Glucose 5% / Sodium chloride 0.9% 500ml iv infusion
	Proprietary name (Brand name)	n/a
	Countries where the Good is licensed	United Kingdom
	Name and address of the Marketing Authorisation holder (ie the company who owns the licence for the Good)	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
	Dosage form of the Goods (e.g. plastic ampoule, pre-filled syringe)	Viaflo IV Bag
	Storage conditions	No special precautions for storage
	Shelf Life from date of manufacture	24 months

	Shelf-Life after reconstitution or first opening	It is recommended that the product is used immediately once opened
	Good grade e.g. BP, USP (State whether the Good is listed in British/US/European Pharmacopoeia)	BP
	Route/s of administration	Intravenous infusion
	UK/GB Marketing Authorisation number	PL 00116/0343
	Details of any animal products or animal derived material which may be present in the Good	n/a
	List of excipients	Water for Injections
Manufacturer details	Manufacturer (responsible for batch released of the Goods as shown on the patient information leaflet)	Baxter Healthcare Ltd
	- Manufacturing licence number	MIA116
	- Country in which the manufacture is based	United Kingdom
	- Full address	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
	Manufacturer of bulk product	n/a
	- Manufacturing licence number	n/a
	- Country in which the bulk manufacture is based	n/a
	- Full address	n/a

	API (Active Pharmaceutical Ingredient) supplier	Confidential Information
	- Manufacturing licence number	Confidential Information
	- Country in which the API manufacture is based	The majority of our raw material is sourced from within the EU. All raw material suppliers are fully audited.
	- Full address	Confidential Information
	Company responsible for packaging activity	Baxter Healthcare Ltd
	- Manufacturing licence number	MIA116
	- Country in which the packager is based	United Kingdom
	- Full address	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
Pack details	Packaging type (description)	Bags overwrapped with a protective plastic pouch, Cardboard shipper pack
	Pack size (eg. 10 ml ampoules in a pack of 5, a pack of 100 tablets,...)	20 bags of 500 ml per outer pack
	Code for the Goods (if from inside UK)	FKE1063
	PIP code (if from inside UK)	n/a
	Tamper evidence - method used.	Bags overwrapped with a protective plastic pouch
	Provide artwork or packaging, labelling, patient information leaflets	Please see attached files in Doc5_Tab6_Lot5_FKE1063-500ml

	and Summary of Product Characteristics (SmPC)	
	*Does the pack/container meet the following requirements (Y/N) and comment as appropriate**	
	English livery	Y
	Expiry date displayed on the pack	Y
	Patient information leaflet in each pack	Y
	Batch number displayed on pack	Y
Shipping and packaging	Pack dimensions (mm) h x w x d	280 x 120 x 25
	Outer, or shipper pack quantity	20
	Outer pack dimensions (mm) h x w x d	210 x 290 x 390
	Outer pack weight (Kg)	11.74
	Delivery on Europallets?	Y
	Number of outer packs per pallet	64
	Maximum pallet dimensions (mm) h x w x d	1,712 x 800 x 1,200
	Pallet weight (Kg)	751.36
Transport	Current location of Goods offered (full address including name of wholesaler if applicable)	Yusen Logistics, Grange Park, Northampton, NN3 8RG
	Transport route and method used (from current location to place of delivery)	The transport route will depend on the nature of the emergency and the DHSC response. Baxter will work with the DHSC to ensure the most direct and appropriate transport route to

		used to get product to the designated delivery point/s. Baxters dedicated delivery partner would facilitate the deliveries under instruction from Baxter.
	Full description of supply chain (provide a supply chain map from end to end; from manufacture to end supply point)	Please refer to the process flow map from manufacture to end supply point attached as Doc5_Tab6_In_Replen & Outbound.
	Method of temperature control systems that will be employed, including the records that will be provided to the Authority	Yusen GP1 & GP3, use an Ice spy web based system to monitor their warehouse temperatures. Alarm levels are set at 25 and 15 degrees with alert messages set at 24.5 and 15.5 degrees. Alerts are sent to QA and Operations team members. For out of hours, site security receive alerts and contact nominated person to action.
Verification of the Goods (to be completed by supplier)	Name and role of person that has checked and verified the above information	[redacted] Senior Product Manager
Approved by the Authority		Yes
Name of the Approver		[redacted] RP
Date		24-Jul-23
Comments:		

Lot 8 - Glucose 5% - 1 litre iv infusion

Document 5 Offer Schedule for the Invitation to offer for The Supply, Storage and Management of Intravenous Fluids.

Offer reference number : CM /EMI/ 22 / C103602

QA Technical Sheet Goods Information

Offeror name :	**Baxter Healthcare Ltd**

- Offerors must not make any deletions to this schedule
- ALL fields must be completed
- The QA Technical Sheet needs to be completed for each Good you offer as part of your submission. If you are applying for more than one Good, then please make a copy of this tab and complete for each Good as required.

OFFICIAL -SENSITIVE COMMERCIAL (WHEN COMPLETE D)

General information:
- QA Technical sheet, packaging and production information.

Table 6.1		**Please input your responses in Column "C"**
Supplier	Supplier Name	Baxter Healthcare Ltd
	Supplier address	Wallingford Road
		Compton
		Berkshire
		RG20 7QW
	Storage Facilities (if different from above)	Baxter - Brackmills Industrial Estate, Salthouse Rd, Northampton NN4 7UF. Yusen UK - Cheaney Drive, Grange Park South, Northamptonshire, NN4 5FB

	WDA (H) Licence Number and/or MIA Licence Number if applicable (provide a copy of the licence(s)), and GDP or GMP certificate if applicable (provide a copy) to cover all activities involved in performing the Contract	WDA (H) Licence number: WDA (H) 116 MIA Licence number: MIA 116 GDP & GMP certificates reference: UK MIA 116 Insp GMP/GDP 116/18507-0050 & UK WDA (H) 116 Insp GMP/ GDP IMP 116/18507-0042 Please refer to: Doc5_Tab6WDAH116_GMPGDP-IMP116 Doc 5_Tab 6_MIA 116 Version 63 Doc5_Tab6MIA116 GMP-GDP-IMP116 Doc 5_Tab 6_WDA(H) Licence V17
	Offered Presentation	
Product details	Description of the Goods (including strength of the Goods)	Glucose 5% - 1 litre iv infusion
	Proprietary name (Brand name)	n/a
	Countries where the Good is licensed	United Kingdom
	Name and address of the Marketing Authorisation holder (ie the company who owns the licence for the Good)	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
	Dosage form of the Goods (e.g. plastic ampoule, pre-filled syringe)	Viaflo IV Bag
	Storage conditions	This medicinal product does not require any special storage conditions.

	Shelf Life from date of manufacture	36 months
	Shelf-Life after reconstitution or first opening	Additives: From a microbiological point of view, the diluted product must be used immediately unless dilution has taken place in controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions are the responsibility of the user.
	Good grade e.g. BP, USP (State whether the Good is listed in British/US/European Pharmacopoeia)	BP
	Route/s of administration	Intravenous infusion
	UK/GB Marketing Authorisation number	PL 00116/0335
	Details of any animal products or animal derived material which may be present in the Good	n/a
	List of excipients	Water for Injections
Manufacturer details	Manufacturer (responsible for batch released of the Goods as shown on the patient information leaflet)	Baxter Healthcare Ltd
	- Manufacturing licence number	MIA116
	- Country in which the manufacture is based	United Kingdom
	- Full address	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom

	Manufacturer of bulk product	n/a
	- Manufacturing licence number	n/a
	- Country in which the bulk manufacture is based	n/a
	- Full address	n/a
	API (Active Pharmaceutical Ingredient) supplier	Confidential Information
	- Manufacturing licence number	Confidential Information
	- Country in which the API manufacture is based	The majority of our raw material is sourced from within the EU. All raw material suppliers are fully audited.
	- Full address	Confidential Information
	Company responsible for packaging activity	Baxter Healthcare Ltd
	- Manufacturing licence number	MIA116
	- Country in which the packager is based	United Kingdom
	- Full address	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
Pack details	Packaging type (description)	Bags overwrapped with a protective plastic pouch, Cardboard shipper pack
	Pack size (eg. 10 ml ampoules in a pack of 5, a pack of 100 tablets,...)	10 bags of 1000 ml per outer pack
	Code for the Goods (if from inside UK)	FKE0064

	PIP code (if from inside UK)	n/a
	Tamper evidence - method used.	Bags overwrapped with a protective plastic pouch
	Provide artwork or packaging, labelling, patient information leaflets and Summary of Product Characteristics (SmPC)	Please see attached files in Doc5_Tab6_Lot8_FKE0064-1000ml
	*Does the pack/container meet the following requirements (Y/N) and comment as appropriate**	
	English livery	Y
	Expiry date displayed on the pack	Y
	Patient information leaflet in each pack	Y
	Batch number displayed on pack	Y
Shipping and packaging	Pack dimensions (mm) h x w x d	280 x 154 x 45
	Outer, or shipper pack quantity	10
	Outer pack dimensions (mm) h x w x d	210 x 290 x 390
	Outer pack weight (Kg)	11.30
	Delivery on Europallets?	Y
	Number of outer packs per pallet	64
	Maximum pallet dimensions (mm) h x w x d	1,680 x 800 x 1,200
	Pallet weight (Kg)	723.20
Transport	Current location of Goods offered (full address	Yusen Logistics, Grange Park, Northampton, NN3 8RG

	including name of wholesaler if applicable)	
	Transport route and method used (from current location to place of delivery)	The transport route will depend on the nature of the emergency and the DHSC response. Baxter will work with the DHSC to ensure the most direct and appropriate transport route to used to get product to the designated delivery point/s. Baxters dedicated delivery partner would facilitate the deliveries under instruction from Baxter.
	Full description of supply chain (provide a supply chain map from end to end; from manufacture to end supply point)	Please refer to the process flow map from manufacture to end supply point attached as Doc5_Tab6_In_Replen & Outbound.
	Method of temperature control systems that will be employed, including the records that will be provided to the Authority	Yusen GP1 & GP3, use an Ice spy web based system to monitor their warehouse temperatures. Alarm levels are set at 25 and 15 degrees with alert messages set at 24.5 and 15.5 degrees. Alerts are sent to QA and Operations team members. For out of hours, site security receive alerts and contact nominated person to action.
Verification of the Goods (to be completed by supplier)	Name and role of person that has checked and verified the above information	[redacted] Senior Product Manager
Approved by the Authority		Yes

Name of the Approver	[redacted]
Date	24th Jul 2023
Comments:	

Lot 9 – Glucose 5% - 500ml iv infusion

Document 5 Offer Schedule for the Invitation to offer for The Supply, Storage and Management of Intravenous Fluids.

Offer reference number : CM /EMI/ 22 / C103602

QA Technical Sheet Goods Information

Offeror name :	**Baxter Healthcare Ltd**

- Offerors must not make any deletions to this schedule
- ALL fields must be completed
- The QA Technical Sheet needs to be completed for each Good you offer as part of your submission. If you are applying for more than one Good, then please make a copy of this tab and complete for each Good as required.

OFFICIAL -SENSITIVE COMMERCIAL (WHEN COMPLETE D)

General information:
- QA Technical sheet, packaging and production information.

Table 6.1		**Please input your responses in Column "C"**
Supplier	Supplier Name	Baxter Healthcare Ltd
	Supplier address	Wallingford Road
		Compton
		Berkshire
		RG20 7QW
	Storage Facilities (if different from above)	Baxter - Brackmills Industrial Estate, Salthouse Rd, Northampton NN4 7UF. Yusen UK - Cheaney Drive, Grange Park South, Northamptonshire, NN4 5FB

	WDA (H) Licence Number and/or MIA Licence Number if applicable (provide a copy of the licence(s)), and GDP or GMP certificate if applicable (provide a copy) to cover all activities involved in performing the Contract	WDA (H) Licence number: WDA (H) 116 MIA Licence number: MIA 116 GDP & GMP certificates reference: UK MIA 116 Insp GMP/GDP 116/18507-0050 & UK WDA (H) 116 Insp GMP/ GDP IMP 116/18507-0042 Please refer to: Doc5_Tab6WDAH116_GMPGDP-IMP116 Doc 5_Tab 6_MIA 116 Version 63 Doc5_Tab6MIA116 GMP-GDP-IMP116 Doc 5_Tab 6_WDA(H) Licence V17
	Offered Presentation	
Product details	Description of the Goods (including strength of the Goods)	Glucose 5% - 500ml iv infusion
	Proprietary name (Brand name)	n/a
	Countries where the Good is licensed	United Kingdom
	Name and address of the Marketing Authorisation holder (ie the company who owns the licence for the Good)	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
	Dosage form of the Goods (e.g. plastic ampoule, pre-filled syringe)	Viaflo IV Bag
	Storage conditions	This medicinal product does not require any special storage conditions.

	Shelf Life from date of manufacture	24 months
	Shelf-Life after reconstitution or first opening	Additives: From a microbiological point of view, the diluted product must be used immediately unless dilution has taken place in controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions are the responsibility of the user.
	Good grade e.g. BP, USP (State whether the Good is listed in British/US/European Pharmacopoeia)	BP
	Route/s of administration	Intravenous infusion
	UK/GB Marketing Authorisation number	PL 00116/0335
	Details of any animal products or animal derived material which may be present in the Good	n/a
	List of excipients	Water for Injections
Manufacturer details	Manufacturer (responsible for batch released of the Goods as shown on the patient information leaflet)	Baxter Healthcare Ltd
	- Manufacturing licence number	MIA116
	- Country in which the manufacture is based	United Kingdom
	- Full address	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom

	Manufacturer of bulk product	n/a
	- Manufacturing licence number	n/a
	- Country in which the bulk manufacture is based	n/a
	- Full address	n/a
	API (Active Pharmaceutical Ingredient) supplier	Confidential Information
	- Manufacturing licence number	Confidential Information
	- Country in which the API manufacture is based	The majority of our raw material is sourced from within the EU. All raw material suppliers are fully audited.
	- Full address	Confidential Information
	Company responsible for packaging activity	Baxter Healthcare Ltd
	- Manufacturing licence number	MIA116
	- Country in which the packager is based	United Kingdom
	- Full address	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
Pack details	Packaging type (description)	Bags overwrapped with a protective plastic pouch, Cardboard shipper pack
	Pack size (eg. 10 ml ampoules in a pack of 5, a pack of 100 tablets,...)	20 bags of 500 ml per outer pack
	Code for the Goods (if from inside UK)	FKE0063

	PIP code (if from inside UK)	n/a
	Tamper evidence - method used.	Bags overwrapped with a protective plastic pouch
	Provide artwork or packaging, labelling, patient information leaflets and Summary of Product Characteristics (SmPC)	Please see attached files in Doc5_Tab6_Lot9_FKE0063-500ml
	*Does the pack/container meet the following requirements (Y/N) and comment as appropriate**	
	English livery	Y
	Expiry date displayed on the pack	Y
	Patient information leaflet in each pack	Y
	Batch number displayed on pack	Y
Shipping and packaging	Pack dimensions (mm) h x w x d	280 x 120 x 25
	Outer, or shipper pack quantity	20
	Outer pack dimensions (mm) h x w x d	210 x 300 x 380
	Outer pack weight (Kg)	11.70
	Delivery on Europallets?	Y
	Number of outer packs per pallet	64
	Maximum pallet dimensions (mm) h x w x d	1,680 x 800 x 1,200
	Pallet weight (Kg)	748.50
Transport	Current location of Goods offered (full address	Yusen Logistics, Grange Park, Northampton, NN3 8RG

	including name of wholesaler if applicable)	
	Transport route and method used (from current location to place of delivery)	The transport route will depend on the nature of the emergency and the DHSC response. Baxter will work with the DHSC to ensure the most direct and appropriate transport route to used to get product to the designated delivery point/s. Baxters dedicated delivery partner would facilitate the deliveries under instruction from Baxter.
	Full description of supply chain (provide a supply chain map from end to end; from manufacture to end supply point)	Please refer to the process flow map from manufacture to end supply point attached as Doc5_Tab6_In_Replen & Outbound.
	Method of temperature control systems that will be employed, including the records that will be provided to the Authority	Yusen GP1 & GP3, use an Ice spy web based system to monitor their warehouse temperatures. Alarm levels are set at 25 and 15 degrees with alert messages set at 24.5 and 15.5 degrees. Alerts are sent to QA and Operations team members. For out of hours, site security receive alerts and contact nominated person to action.
Verification of the Goods (to be completed by supplier)	Name and role of person that has checked and verified the above information	[redacted] Senior Product Manager
Approved by the Authority		Yes

Name of the Approver	[redacted] RP
Date	24th Jul 2023
Comments:	

Lot 10 - Glucose 5% - 100ml iv infusion

Document 5 Offer Schedule for the Invitation to offer for The Supply, Storage and Management of Intravenous Fluids.

Offer reference number : CM /EMI/ 22 / C103602

QA Technical Sheet Goods Information

Offeror name :	**Baxter Healthcare Ltd**

- Offerors must not make any deletions to this schedule
- ALL fields must be completed
- The QA Technical Sheet needs to be completed for each Good you offer as part of your submission. If you are applying for more than one Good, then please make a copy of this tab and complete for each Good as required.

OFFICIAL -SENSITIVE COMMERCIAL (WHEN COMPLETE D)

General information:
- QA Technical sheet, packaging and production information.

Table 6.1		**Please input your responses in Column "C"**
Supplier	Supplier Name	Baxter Healthcare Ltd
	Supplier address	Wallingford Road
		Compton
		Berkshire
		RG20 7QW
	Storage Facilities (if different from above)	Baxter - Brackmills Industrial Estate, Salthouse Rd, Northampton NN4 7UF. Yusen UK - Cheaney Drive, Grange Park South, Northamptonshire, NN4 5FB

	WDA (H) Licence Number and/or MIA Licence Number if applicable (provide a copy of the licence(s)), and GDP or GMP certificate if applicable (provide a copy) to cover all activities involved in performing the Contract	WDA (H) Licence number: WDA (H) 116 MIA Licence number: MIA 116 GDP & GMP certificates reference: UK MIA 116 Insp GMP/GDP 116/18507-0050 & UK WDA (H) 116 Insp GMP/ GDP IMP 116/18507-0042 Please refer to: Doc5_Tab6WDAH116_GMPGDP-IMP116 Doc 5_Tab 6_MIA 116 Version 63 Doc5_Tab6MIA116 GMP-GDP-IMP116 Doc 5_Tab 6_WDA(H) Licence V17
	Offered Presentation	
Product details	Description of the Goods (including strength of the Goods)	Glucose 5% - 100ml iv infusion
	Proprietary name (Brand name)	n/a
	Countries where the Good is licensed	United Kingdom
	Name and address of the Marketing Authorisation holder (ie the company who owns the licence for the Good)	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
	Dosage form of the Goods (e.g. plastic ampoule, pre-filled syringe)	Viaflo IV Bag
	Storage conditions	Do not store above 30°C

	Shelf Life from date of manufacture	24 months
	Shelf-Life after reconstitution or first opening	Additives: From a microbiological point of view, the diluted product must be used immediately unless dilution has taken place in controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions are the responsibility of the user.
	Good grade e.g. BP, USP (State whether the Good is listed in British/US/European Pharmacopoeia)	BP
	Route/s of administration	Intravenous infusion
	UK/GB Marketing Authorisation number	PL 00116/0335
	Details of any animal products or animal derived material which may be present in the Good	n/a
	List of excipients	Water for Injections
Manufacturer details	Manufacturer (responsible for batch released of the Goods as shown on the patient information leaflet)	Baxter Healthcare Ltd
	- Manufacturing licence number	M00167/00001
	- Country in which the manufacture is based	United Kingdom
	- Full address	Baxter Healthcare S.A., Moneen Rd, Drumconlan,

		Castlebar, Co. Mayo, F23 XR63, Ireland
	Manufacturer of bulk product	n/a
	- Manufacturing licence number	n/a
	- Country in which the bulk manufacture is based	n/a
	- Full address	n/a
	API (Active Pharmaceutical Ingredient) supplier	Confidential Information
	- Manufacturing licence number	Confidential Information
	- Country in which the API manufacture is based	The majority of our raw material is sourced from within the EU. All raw material suppliers are fully audited.
	- Full address	Confidential Information
	Company responsible for packaging activity	Baxter Healthcare Ltd
	- Manufacturing licence number	M00167/00001
	- Country in which the packager is based	United Kingdom
	- Full address	Baxter Healthcare S.A., Moneen Rd, Drumconlan, Castlebar, Co. Mayo, F23 XR63, Ireland
Pack details	Packaging type (description)	Bags overwrapped with a protective plastic pouch, Cardboard shipper pack
	Pack size (eg. 10 ml ampoules in a pack of 5, a pack of 100 tablets,...)	60 bags of 100 ml per outer pack

	Code for the Goods (if from inside UK)	FE0087G
	PIP code (if from inside UK)	n/a
	Tamper evidence - method used.	Bags overwrapped with a protective plastic pouch
	Provide artwork or packaging, labelling, patient information leaflets and Summary of Product Characteristics (SmPC)	Please see attached files in Doc5_Tab6_Lot10_FE0087G-100ml
	*Does the pack/container meet the following requirements (Y/N) and comment as appropriate**	
	English livery	Y
	Expiry date displayed on the pack	Y
	Patient information leaflet in each pack	Y
	Batch number displayed on pack	Y
Shipping and packaging	Pack dimensions (mm) h x w x d	155 x 91 x 13
	Outer, or shipper pack quantity	60
	Outer pack dimensions (mm) h x w x d	240 x 230 x 390
	Outer pack weight (Kg)	7.82
	Delivery on Europallets?	Y
	Number of outer packs per pallet	70
	Maximum pallet dimensions (mm) h x w x d	1,680 x 800 x 1,200
	Pallet weight (Kg)	547.40

Transport	Current location of Goods offered (full address including name of wholesaler if applicable)	Yusen Logistics, Grange Park, Northampton, NN3 8RG
	Transport route and method used (from current location to place of delivery)	The transport route will depend on the nature of the emergency and the DHSC response. Baxter will work with the DHSC to ensure the most direct and appropriate transport route to used to get product to the designated delivery point/s. Baxters dedicated delivery partner would facilitate the deliveries under instruction from Baxter.
	Full description of supply chain (provide a supply chain map from end to end; from manufacture to end supply point)	Please refer to the process flow map from manufacture to end supply point attached as Doc5_Tab6_In_Replen & Outbound.
	Method of temperature control systems that will be employed, including the records that will be provided to the Authority	Yusen GP1 & GP3, use an Ice spy web based system to monitor their warehouse temperatures. Alarm levels are set at 25 and 15 degrees with alert messages set at 24.5 and 15.5 degrees. Alerts are sent to QA and Operations team members. For out of hours, site security receive alerts and contact nominated person to action.
Verification of the Goods (to be completed by supplier)	Name and role of person that has checked and verified the above information	[redacted] Senior Product Manager

Approved by the Authority	Yes
Name of the Approver	[redacted] RP
Date	24th Jul 2023
Comments:	

Lot 11 - Sodium Chloride 0.9% - 1 litre iv infusion

Document 5 Offer Schedule for the Invitation to offer for The Supply, Storage and Management of Intravenous Fluids.

Offer reference number : CM /EMI/ 22 / C103602

QA Technical Sheet Goods Information

Offeror name :	**Baxter Healthcare Ltd**

- Offerors must not make any deletions to this schedule
- ALL fields must be completed
- The QA Technical Sheet needs to be completed for each Good you offer as part of your submission. If you are applying for more than one Good, then please make a copy of this tab and complete for each Good as required.

OFFICIAL -SENSITIVE COMMERCIAL (WHEN COMPLETE D)

General information:
- QA Technical sheet, packaging and production information.

Table 6.1		**Please input your responses in Column "C"**
Supplier	Supplier Name	Baxter Healthcare Ltd
	Supplier address	Wallingford Road
		Compton
		Berkshire
		RG20 7QW
	Storage Facilities (if different from above)	Baxter - Brackmills Industrial Estate, Salthouse Rd, Northampton NN4 7UF. Yusen UK - Cheaney Drive, Grange

		Park South, Northamptonshire, NN4 5FB
	WDA (H) Licence Number and/or MIA Licence Number if applicable (provide a copy of the licence(s)), and GDP or GMP certificate if applicable (provide a copy) to cover all activities involved in performing the Contract	WDA (H) Licence number: WDA (H) 116 MIA Licence number: MIA 116 GDP & GMP certificates reference: UK MIA 116 Insp GMP/GDP 116/18507-0050 & UK WDA (H) 116 Insp GMP/ GDP IMP 116/18507-0042 Please refer to: Doc5_Tab6WDAH116_GMPGDP-IMP116 Doc 5_Tab 6_MIA 116 Version 63 Doc5_Tab6MIA116 GMP-GDP-IMP116 Doc 5_Tab 6_WDA(H) Licence V17
	Offered Presentation	
Product details	Description of the Goods (including strength of the Goods)	Sodium Chloride 0.9% - 1 litre iv infusion
	Proprietary name (Brand name)	n/a
	Countries where the Good is licensed	United Kingdom
	Name and address of the Marketing Authorisation holder (ie the company who owns the licence for the Good)	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
	Dosage form of the Goods (e.g. plastic ampoule, pre-filled syringe)	Viaflo IV Bag

	Storage conditions	This medicinal product does not require any special storage conditions
	Shelf Life from date of manufacture	36 months
	Shelf-Life after reconstitution or first opening	Additives: From a microbiological point of view, the diluted product must be used immediately unless dilution has taken place in controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions are the responsibility of the user
	Good grade e.g. BP, USP (State whether the Good is listed in British/US/European Pharmacopoeia)	BP
	Route/s of administration	Intravenous infusion
	UK/GB Marketing Authorisation number	PL 00116/0334
	Details of any animal products or animal derived material which may be present in the Good	n/a
	List of excipients	Water for Injections
Manufacturer details	Manufacturer (responsible for batch released of the Goods as shown on the patient information leaflet)	Baxter Healthcare Ltd
	- Manufacturing licence number	MIA116
	- Country in which the manufacture is based	United Kingdom

	- Full address	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
	Manufacturer of bulk product	n/a
	- Manufacturing licence number	n/a
	- Country in which the bulk manufacture is based	n/a
	- Full address	n/a
	API (Active Pharmaceutical Ingredient) supplier	Confidential Information
	- Manufacturing licence number	Confidential Information
	- Country in which the API manufacture is based	The majority of our raw material is sourced from within the EU. All raw material suppliers are fully audited.
	- Full address	Confidential Information
	Company responsible for packaging activity	Baxter Healthcare Ltd
	- Manufacturing licence number	MIA116
	- Country in which the packager is based	United Kingdom
	- Full address	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
Pack details	Packaging type (description)	Bags overwrapped with a protective plastic pouch, Cardboard shipper pack

	Pack size (eg. 10 ml ampoules in a pack of 5, a pack of 100 tablets,...)	10 bags of 1000 ml per outer pack
	Code for the Goods (if from inside UK)	FKE1324
	PIP code (if from inside UK)	n/a
	Tamper evidence - method used.	Bags overwrapped with a protective plastic pouch
	Provide artwork or packaging, labelling, patient information leaflets and Summary of Product Characteristics (SmPC)	Please see attached files in Doc5_Tab6_Lot11_FKE1324-1000ml
	*Does the pack/container meet the following requirements (Y/N) and comment as appropriate**	
	English livery	Y
	Expiry date displayed on the pack	Y
	Patient information leaflet in each pack	Y
	Batch number displayed on pack	Y
Shipping and packaging	Pack dimensions (mm) h x w x d	280 x 154 x 45
	Outer, or shipper pack quantity	10
	Outer pack dimensions (mm) h x w x d	210 x 290 x 390
	Outer pack weight (Kg)	11.22
	Delivery on Europallets?	Y
	Number of outer packs per pallet	64

	Maximum pallet dimensions (mm) h x w x d	1,680 x 800 x 1,200
	Pallet weight (Kg)	718.08
Transport	Current location of Goods offered (full address including name of wholesaler if applicable)	Yusen Logistics, Grange Park, Northampton, NN3 8RG
	Transport route and method used (from current location to place of delivery)	The transport route will depend on the nature of the emergency and the DHSC response. Baxter will work with the DHSC to ensure the most direct and appropriate transport route to used to get product to the designated delivery point/s. Baxters dedicated delivery partner would facilitate the deliveries under instruction from Baxter.
	Full description of supply chain (provide a supply chain map from end to end; from manufacture to end supply point)	Please refer to the process flow map from manufacture to end supply point attached as Doc5_Tab6_In_Replen & Outbound.
	Method of temperature control systems that will be employed, including the records that will be provided to the Authority	Yusen GP1 & GP3, use an Ice spy web based system to monitor their warehouse temperatures. Alarm levels are set at 25 and 15 degrees with alert messages set at 24.5 and 15.5 degrees. Alerts are sent to QA and Operations team members. For out of hours, site security receive alerts and contact nominated person to action.

Verification of the Goods (to be completed by supplier)	Name and role of person that has checked and verified the above information	[redacted] Senior Product Manager
Approved by the Authority		Yes
Name of the Approver		[redacted], RP
Date		24th Jul 2023
Comments:		

Schedule 10

Business Continuity Plan

Baxter_BCP.pdf

Schedule 11 [Not Used]

Parent Company Guarantee

Schedule 12

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] 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 (Units/ packs)
- 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

Schedule 13

Release Plan

IV 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 Intravenous Fluids Goods. 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. 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]

e. When will the supplier receive sufficient stock for the Intravenous Fluid not to be needed

[Please provide a forecast of when Intravenous Fluid 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) 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 14

Exit Plan

INTRAVENOUS FLUIDS STOCKPILE EXIT PLAN

Date [Please insert the date of subsequent submission]

(a) Introduction

This plan is provided in order that both parties have a documented and agreed record of volume of stock held at the exit phase of the Intravenous Fluids contract.

The exit will be managed by the Authority and [insert name], as detailed in the contract.

(b) List of products exiting

[Please list here]

(c) Plan dates

[Notice period request date – to be filled in when exit plan submitted]

[Exit plan agreed date – to be filled in when exit plan agreed]

(d) Any other relevant information regarding the exit plan

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

(e) Risk register

[Please provide here details of any risks to either party with the exit plan]

(f) Distribution

Exit Plan to be sent to [redacted] or such other person(s) notified to the Supplier by the Authority.

Schedule 15

Quality Technical Agreement

QTA Template

Schedule 16

Buybback Price

1. The Buyback Price will be applied to Authorised Releases during the Exit Phase in accordance with Clause 15 of Schedule 2 and subject to the following:

    1.1. 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 Exit Plan 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:

    [redacted]

    1.2. Where no sales of the Goods 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 Goods within the UK, and the Authority shall calculate the Average UK Price for such week.

    1.3. The parties agree the calculations in Annex 1 of this Schedule 16 represent an example of the operation of this Paragraph 1 of Schedule 16.

Annex 1

Buyback Worked Example

1. The following calculation represents a worked example of a calculation of the Buyback Price.

Worked example of the buyback process

Product A is sold to the market in week one at an average price on all UK sales of [redacted]. In week two it is sold at an average price on all UK sales of [redacted]. Week three at an average price on all UK sales of [redacted], and week four at an average price on all UK sales of [redacted].

This information should be provided to the Authority in the Release Plan or Exit Plan. The Authority will then calculate the buyback price in the following way:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

[redacted]

[redacted]