

## TERMS AND CONDITIONS FOR THE SUPPLY OF SUPPLY OF PULMICORT TURBOHALER 400

|               |  |
|---------------|--|
| 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  | AstraZeneca UK Limited, Horizon Place, 600 Capability Green, Luton, Bedfordshire, LU1 3LU, Company Registration Number:03674842  |

|                                     |   |
|-------------------------------------|---|
| Date                                | 23rd February 2022                            |
| Description of Medicine (the Goods) | Pulmicort Turbohaler 400 (Inhaled Budesonide) |

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.

The Supplier shall supply to the Authority, and the Authority shall receive and pay for, the Goods on the terms of this Contract.

Save where the context does not permit, the definitions in Schedule 4 apply to the use of all capitalised terms in this Contract.

### Schedules

|            |                                 |
|------------|---------------------------------|
| Schedule 1 | Key Provisions                  |
| Schedule 2 | General Terms and Conditions    |
| Schedule 3 | Information Provisions          |
| Schedule 4 | Definitions and Interpretations |
| Schedule 5 | Specification                   |
| Schedule 6 | Commercial Schedule             |
| Schedule 7 | Proforma Change Control Note    |
| Schedule 8 | Tender Response Document        |
| Schedule 9 | Business Continuity Plan        |

**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 April 2021** (“**Commencement Date**”) and shall expire on **31 March 2022** (“**Initial Term**”).

#### **3. Contract Managers**

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

- 3.1.1 for the Authority:

**Redacted Under FOIA Section 40, Personal Information**

- 3.1.2 for the Supplier:

**Redacted Under FOIA Section 40, Personal Information**

#### **4. Names and addresses for notices**

- 4.1 Notices served under this Contract are to be delivered to:

- 4.1.1 for the Authority:

**Redacted Under FOIA Section 40, Personal Information**

- 4.1.2 for the Supplier:

**Redacted Under FOIA Section 40, Personal Information**

#### **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 | Redacted Under FOIA Section 40, Personal Information | Redacted Under FOIA Section 40, Personal Information |
| 2 | Redacted Under FOIA Section 40, Personal Information | Redacted Under FOIA Section 40, Personal Information |
| 3 | Redacted Under FOIA Section 40, Personal Information | Redacted Under FOIA Section 40, Personal Information |

## 6. Order of precedence

6.1 Subject always to Clauses 5.1 and **Error! Reference source not found.** of Schedule 2 and Clause 1.11 of Schedule 4, 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 5: Specification;
- 6.1.4 Schedule 2: General Terms and Conditions;
- 6.1.5 Schedule 6: Commercial Schedule;
- 6.1.6 Schedule 4: Definitions and Interpretations;
- 6.1.7 Schedule 8: Tender Response Document;
- 6.1.8 Schedule 3: Information Provisions;
- 6.1.9 Schedule 9: Business Continuity Plan; and
- 6.1.10 Schedule 7: Proforma Change Control Notice.

## 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 for Delivery**

- 8.1 If the Supplier fails to meet any delivery date this shall be addressed in accordance with Clause 5.5 of Schedule 2. 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 (and where applicable being the provisions of Directive 2001/83, the Human Medicines Regulations 2012 and any amended and/or successor legislation applicable to the UK). 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 9.7 of this Schedule 1, if in any circumstances the holder of the Marketing Authorisation is changed from the Supplier to 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 9.7 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

9.7 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 medical devices and/or medicinal products (both 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 medical devices and/or medicinal products. In particular, but without limitation, the Supplier warrants that:

- 9.7.1 at the point such Goods are supplied to the Authority, all such Goods which are medical devices shall have valid CE or UKCA marking as applicable and as required by Law and Guidance and that all relevant marking, authorisation, registration, approval and documentation requirements as required under Law and Guidance relating to the sale, manufacture, assembly, importation, storage, distribution, supply, Delivery, or installation of such Goods shall have been complied with. Without limitation to the foregoing provisions of this Clause 9.7, the Supplier shall, upon written request from the Authority, make available to the Authority evidence of the grant of such valid CE or UKCA marking, and evidence of any other authorisations, registrations, approvals or documentation required;
- 9.7.2 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 9.7, 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

- 9.7.3 it shall maintain or procure the maintenance of 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 and/or UKCA marking and 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**

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
2. Supply of Additional Goods
3. Performance review and delay
4. Quality assurance
5. Delivery
6. Stock Rotation
7. Authorised Release in a Supply Shortage
8. Authority's right to Stockpiled Goods
9. Buyback
10. Exit Phase
11. Passing of risk and ownership
12. Inspection, rejection, return and recall
13. Business continuity
14. Contract management
15. Price and payment
16. Warranties
17. Intellectual property
18. Indemnity
19. Limitation of liability
20. Insurance
21. Term and termination
22. Consequences of expiry or early termination of this Contract
23. Post termination provisions
24. Packaging, identification and end of use
25. Sustainable development
26. Electronic product information
27. Change Control
28. Dispute resolution
29. Force majeure
30. Records retention and right of audit
31. Conflicts of interest and the prevention of fraud

- 32. Equality and human rights
- 33. Notice
- 34. Assignment, novation and Sub-contracting
- 35. Prohibited Acts
- 36. General

## 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, storage, distribution, 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: not previously have left the control of the Supplier nor have deviated from their defined distribution path; be consistent with any sample; have not been rejected by any other entity prior to their supply to the Authority under this Contract; and 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. Supply of Additional Goods**

- 2.1 The Authority may place orders for the Delivery of additional Goods in excess of the Initial Volume ("**Additional Goods Orders**"). Each Additional Goods Order shall be provided to the Supplier in writing and shall carry an authorised purchase order number which the Supplier shall quote on all correspondence relating to such Additional Goods Order. The Supplier shall supply to the Authority the volume requested in any Additional Goods Order. To the extent that the Additional Goods Order is for Goods which do not, in aggregate with the Initial Volume and any previous Additional Goods Orders, exceed the Required Volume, the Authority shall specify the required date for Delivery which shall be no less than 12 weeks from the date of such Additional Goods Order.
- 2.2 The price for all Goods ordered by the Authority in any Additional Goods Order shall be as set out in Schedule 6. Except as expressly stated otherwise, the provisions of this Contract in relation to the Goods shall apply equally to all Goods under an Additional Goods Order in the same way as to Goods forming part of the Initial Volume of Goods as stated at the Commencement Date of this Contract.

## **3. Performance review and delay**

- 3.1 Should the Authority place an Additional Goods Order in accordance with Clause 2.1 of this Schedule 2, 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.
- 3.2 In the event that the Supplier becomes aware that it is or it may become unable to supply the Goods in accordance with any Additional Goods Order the Supplier shall notify the Authority of such fact as soon as reasonably possible.

## **4. Quality assurance**

- 4.1 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. The Supplier shall at all times comply with those standards set out in the QTA.

- 4.2 The Supplier shall maintain the Manufacturing Licence 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:

- 4.2.1 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

- 4.2.2 the relevant Licensing Authority formally approving such change.

## 5. **Delivery**

- 5.1 The Supplier shall deliver the Goods to the Storage and Distribution Facility or as otherwise agreed with the Authority in writing.

- 5.2 Delivery shall be completed either:

- 5.2.1 when the Goods have been unloaded at the Storage and Distribution Facility by the Supplier; or

- 5.2.2 if the Supplier has arranged to maintain stock at the Storage and Distribution Facility, then at the point that the Goods are ordered by the Authority and released to the Authority in order to fulfil an order ("**Delivery**").

- 5.3 The Supplier shall notify the Authority within 24 hours of any of the Goods:

- 5.3.1 arriving in England;

- 5.3.2 being released by the Licensing Authority, where such release is required by Law or the Licensing Authority; and

- 5.3.3 arriving at the Storage and Distribution Facility.

- 5.4 Following Delivery, the Supplier shall store the Goods at the Storage and Distribution Facility in accordance with Law.

- 5.5 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 the timelines specified in 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:

- 5.5.1 be entitled to refuse or cancel Delivery of any such Goods not Delivered in accordance with the timelines specified in this Contract;
- 5.5.2 cease to have any liability to pay for any such Goods not Delivered in accordance with the timelines specified in this Contract where such Goods have been refused Delivery or had their Delivery cancelled in accordance with Clause 5.5.1 of this Schedule 2;
- 5.5.3 be entitled to charge the Supplier for any costs reasonably and properly 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;

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.
- 5.6 The Supplier's obligations under Clauses 5.6 and 5.7 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:
  - 5.6.1 Delivery address; and
  - 5.6.2 Special direction for storage (if any)
- 5.7 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.
- 5.8 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 of the recipient and their delivery address, a description, weight, measure, batch number and expiry date and quantity of the Goods. All ancillary paperwork and literature (including invoices) shall include the same information.
- 5.9 Unless otherwise agreed with the Authority in writing (including where stated in the Specification or Commercial Schedule), the Supplier shall be responsible for carriage, insurance, transport, all relevant licences, all related

costs, and all other costs associated Delivery. Without limitation to the foregoing provision of this Clause 5.9 of this Schedule 2, unless otherwise agreed with the Authority in writing (including where stated in the Specification or Commercial Schedule), 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.

- 5.10 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 to the Authority.
- 5.11 If the Supplier's performance of its obligations under this Contract is prevented or delayed by any act or omission of the Authority, then, without prejudice to any other right or remedy it may have, the Supplier shall be allowed an extension of time to perform its obligations equal to the delay caused by the Authority.

## **6. Stockpiled Goods**

- 6.1 The Supplier shall not remove any Stockpiled Goods from the Stockpile, save for Authorised Releases.
- 6.2 For the avoidance of doubt the requirements of this Clause 6 shall continue during any Exit Phase.
- 6.3 If changes are required to the 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 Stockpiled Goods to ensure that they are compliant with those changes.

## **7. Authorised Release in a Supply Shortage**

- 7.1 Each party shall promptly notify the other party in writing if it anticipates that there may be a shortage in the supply of the Goods in the UK due to a Supply Shortage.
- 7.2 The Authority and the Supplier shall review together any such anticipated Supply Shortages and the means for minimising such Supply Shortages or their impact.
- 7.3 The Supplier is authorised to release Goods from the Stockpile to minimise the impact of such Supply Shortages and purchase said released Goods from the Authority at the Buyback Price. Such an Authorised Release shall be known as a Supply Shortage Authorised Release.
- 7.4 During a Supply Shortage, the Supplier shall:



- 7.4.1 attend any meetings as reasonably requested by the Authority;
- 7.4.2 provide a report to the Authority following a Supply Shortage Authorised Release on the Business Day of each week to report on the preceding week, or at the frequency required by the Authority, setting out:
  - (a) the number of Units of Stockpiled Goods removed from the Stockpile;
  - (b) the number of Units of Stockpiled Goods remaining within the Stockpile;
  - (c) the identities of the Customers to whom the Supplier has supplied Goods during the previous week; and
  - (d) any other information reasonably requested by the Authority in relation to the distribution of the Goods.

## **8. Authority's right to Stockpiled Goods**

- 8.1 The Supplier shall procure that the Authority shall on reasonable notice be allowed access to the Stockpile for any purpose whatsoever (including the collection, removal and rapid distribution of the Stockpiled Goods and/or supply of the Stockpiled Goods in the UK). The Supplier shall on receipt of such notice, immediately and in any case, no later than 3 business days from the time of the notice, provide to the Authority and any person authorised by the Authority:
  - 8.1.1 unrestricted access to the Stockpile including for the purpose of removing any Stockpiled Goods from the Stockpile;
  - 8.1.2 access to the Storage and Distribution Facility, vehicles and any other premises or facilities where the Stockpiled Goods are stored and/or the Storage Services are carried out;
  - 8.1.3 access to any personnel and information necessary to enable the Authority to exercise its rights under this Clause 8 (including the records held under Clause 5 identifying the Stockpiled Goods);
  - 8.1.4 delivery of the Stockpiled Goods to the Storage and Distribution Facility loading bay in a deliverable state packaged for transportation and load the Goods onto a vehicle as directed by the Authority for transportation by the Authority;
  - 8.1.5 any cooperation and assistance reasonably requested by the Authority in relation to the exercise of the Authority's rights under this Clause 8.

provided that, where the Authority removes any Stockpiled Goods from the Stockpile it will, following this, provide a report to the Supplier providing relevant details of the removed Stockpiled Goods, and any delivery or removal



under this Clause 8 other than as part of a Supply Shortage Authorised Release shall not be deemed to be an Authorised Release.

## **9. Buyback**

- 9.1 For each Authorised Release the Supplier shall purchase the Stockpiled Goods at the Buyback Price.

## **10. Exit Phase**

- 10.1 The Authority and the Supplier agree that the Supplier during the Exit Phase shall buy back all of the Stockpiled Goods at the Buyback Price at the end of the Term.

## **11. Passing of risk and ownership**

- 11.1 Risk in the Goods shall remain with the Supplier until such Goods as are remaining on the expiry or earlier termination of this Contract are delivered to or collected by the Authority in accordance with Clause 22.2 of this Schedule 2.

- 11.2 Ownership of the Goods shall pass to the Authority on the earlier of:

11.2.1 full payment for such Goods; or

11.2.2 where the goods are consumables or are non-recoverable (e.g. used in clinical procedures), at the point such Goods are Delivered as specified in this Contract. For the avoidance of doubt, where ownership passes in accordance with this Clause 11.2.2, 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.

- 11.3 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.

- 11.4 If any Stockpiled Goods are removed from the Stockpile by the Supplier in accordance with Clause 6.1, of this Schedule 2 then title to such Units of the Goods shall pass to the Supplier upon removal in accordance with Clause 6.1 of this Schedule 2 .

- 11.5 If the Supplier removes any Stockpiled Goods from the Stockpile during a Supply Shortage or an Exit Phase then title to such Units of the Goods shall pass to the Supplier on the date of the appropriate Authorised Release.

## **12. Inspection, rejection, return and recall**

- 12.1 As relevant and proportionate to the Goods in question and subject to reasonable written notice, the Supplier shall permit any person authorised by the Authority, to inspect work being undertaken in relation to the Goods and/or the storage facilities used in the storage of the Goods at all reasonable times

at the Supplier's premises or at the premises of any Sub-contractor or agent of the Supplier in order to confirm that the Goods are being manufactured and/or stored in accordance with Good Industry Practice and Good Manufacturing Practice and in compliance with the requirements of this Contract and/or that stock holding and quality assurance processes are in accordance with the requirements of this Contract.

- 12.2 Without prejudice to the provisions of Clause 12.8 of this Schedule 2 and subject to Clause 12.9 of this Schedule 2, the Authority shall visually inspect the Goods within 72 hours following Delivery and shall verify the batch numbers, expiry dates and temperature records within seven (7) days following Delivery, and may by written notice reject any Goods found to be damaged or otherwise not in accordance with the requirements of this Contract ("**Rejected Goods**"). The whole of any delivery may be rejected if a reasonable sample of the Goods taken indiscriminately from that delivery is found not to conform in all material respects to the requirements of the Contract.
- 12.3 Without prejudice to the provisions of Clause 12.6 of this Schedule 2, upon the rejection of any Goods in accordance with Clauses 12.2 and/or 12.8 of this Schedule 2, the Supplier shall at the Authority's written request:
- 12.3.1 collect the Rejected Goods at the Supplier's risk and expense within ten (10) Business Days of issue of written notice from the Authority rejecting the Goods; and
- 12.3.2 without extra charge, promptly (and in any event within twenty (20) Business Days or such other time agreed by the Parties in writing acting reasonably) supply replacements for the Rejected Goods to the Authority, subject to the Authority not cancelling its purchase obligations in accordance with Clause 12.6 of this Schedule 2.
- 12.4 If the Supplier requests and the Authority accepts that the Rejected Goods should be disposed of by the Authority rather than returned to the Supplier, the Authority reserves the right to charge the Supplier for the costs associated with the disposal of the Rejected Goods and the Supplier shall promptly pay any such costs.
- 12.5 Risk and title in respect of any Rejected Goods shall pass to the Supplier on the earlier of: (a) collection by the Supplier in accordance with Clause 12.3 of this Schedule 2; or (b) immediately following the expiry of ten (10) Business Days from the Authority issuing written notification rejecting the Goods. If Rejected Goods are not collected within ten (10) Business Days of the Authority issuing written notification rejecting the Goods, the Authority may return the Rejected Goods at the Supplier's risk and expense for the avoidance of doubt which includes the cost of transportation and charge the Supplier for the cost of storage from the expiry of ten (10) Business Days from the date of notification of rejection.
- 12.6 Where the Authority rejects any Goods in accordance with Clauses 12.2 and/or 12.8 of this Schedule 2 and the Authority no longer requires replacement Goods or elects to source replacement Goods or any substitute

of the same from elsewhere, the Authority may by written notice cancel its purchase obligations in relation to such quantity of Rejected Goods. Should the Authority have paid for such Rejected Goods the Supplier shall refund such payment to the Authority within thirty (30) days of the Authority cancelling such purchase obligations and informing the Supplier that the Authority does not require replacements for such Rejected Goods.

- 12.7 The Authority shall be entitled to charge the Supplier for any Loss Costs incurred by the Authority as a result of rejection of any Goods in accordance with this Contract provided that the Authority shall use its reasonable endeavours to mitigate the same. The Supplier shall pay such Loss Costs to the Authority within thirty (30) days of the date of the Authority's invoice for the same.
- 12.8 Without prejudice to any other provisions of this Contract or any other warranties or guarantees applicable to the Goods supplied and subject to Clause 12.10 of this Schedule 2, if at any time following the date of the Delivery of any Goods, all or any part of such Goods are found to be defective or otherwise not in accordance with the requirements of this Contract ("**Defective Goods**"), the Supplier shall, at the Authority's discretion:
- 12.8.1 upon written request and without charge, promptly (and in any event within twenty (20) Business Days or such other time agreed by the Parties in writing acting reasonably) remedy the deficiency by replacing such Defective Goods; or
  - 12.8.2 upon written notice of rejection from the Authority, treat such Defective Goods as Rejected Goods in accordance with Clauses 12.2 to 12.6 of this Schedule 2.
- 12.9 No failure to make a complaint at the time of the Delivery nor any other act or omission of the Authority including in particular taking delivery, 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. For the avoidance of doubt this clause is restricted to Defective Goods only and Rejected Goods shall be governed by clause 12.2 to 12.6 of this Schedule 2.
- 12.10 The Supplier shall be relieved of its liabilities under Clauses 12.2 to 12.6 (inclusive) and/or Clause 12.8 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.
- 12.11 The Authority's rights and remedies under Clause 12.8 of this Schedule 2 shall cease within a reasonable period of time, not to exceed 72 hours, from transfer of stock to the Authority the time at which the Authority discovers or might reasonably be expected to discover that the Goods are Defective Goods or within such other period as may be set out in the Key Provisions, if any. For the avoidance of doubt, Goods not used before their expiry date shall not be considered Defective Goods following the date of expiry provided that at the

point such Goods were Delivered to the Authority they met any shelf life requirements set out in the Specification and/or the Tender Response Document. For the avoidance of doubt, where the Specification and Tender Response Document set out conflicting shelf life periods, the longer of the periods shall apply.

- 12.12 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:

12.12.1 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;

12.12.2 from the date of the Requirement to Recall treat the Goods the subject of such recall as Defective Goods in accordance with Clause 12.8 of this Schedule 2;

12.12.3 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

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

### **13. Business continuity**

- 13.1 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.

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

### **14. Contract management**

- 14.1 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.

- 14.2 Each Party shall ensure that its representatives (to include, without limitation, its Contract Manager) shall attend review meetings on a regular basis 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. Review meetings shall take place at the frequency specified in the Specification. Should the Specification not state the frequency, then the first such meeting shall take place on a date to be agreed on or around the end of the first month after the Commencement Date. Subsequent meetings shall take place at monthly intervals or as may otherwise be agreed in writing between the Parties.

- 14.3 Two weeks prior to each review meeting (or at such time and frequency as may be specified in the Specification) the Supplier shall provide a written contract management report to the Authority regarding the supply of the Goods and the operation of this Contract. Unless otherwise agreed by the Parties in writing, such contract management report shall contain:
- 14.3.1 details of the performance of the Supplier when assessed in accordance with the KPIs since the Commencement Date or the last such performance report (whichever is the earlier);
  - 14.3.2 details of any complaints by the Authority in relation to the supply of Goods, their nature and the way in which the Supplier has responded to such complaints since the contract management report of the last review meeting;
  - 14.3.3 the information specified in the Specification in relation to such a contract management report;
  - 14.3.4 a status report in relation to the implementation of any current Remedial Proposals by either Party; and
  - 14.3.5 such other information as reasonably required by the Authority.
- 14.4 Unless specified otherwise in the Specification, the Authority shall take minutes of each review meeting and shall circulate draft minutes to the Supplier within a reasonable time following such review meeting. The Supplier shall inform the Authority in writing of any suggested amendments to the minutes within five (5) Business Days of receipt of the draft minutes. If the Supplier does not respond to the Authority within such five (5) Business Days the minutes will be deemed to be approved. Where there are any differences in interpretation of the minutes, the Parties will use their reasonable endeavours to reach agreement. If agreement cannot be reached the matter shall be referred to, and resolved in accordance with, the Dispute Resolution Procedure.
- 14.5 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 and such management information that the Authority may request shall include, but is not limited to the information set out in Schedule 5. The Supplier shall supply the management information to the Authority in such form as may be specified by the Authority (acting reasonably) 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.

14.6 Where the Supplier and/or the Authority provide the management information to a Third Party Body pursuant to Clause 14.5 of this Schedule 2 and such management information is subject to obligations of confidentiality under this Contract, the Authority shall ensure that any Third Party Body receiving the management information is bound by obligations of confidentiality no less stringent than those which the Authority is bound by under this Contract in relation to such confidential management information.

14.7 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:

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

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

14.8 If the Third Party Body and/or the Authority shares the management information or any other information provided under Clause 14.7 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).

14.9 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.

## **15. Price and payment**

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

15.2 Unless otherwise stated in the Commercial Schedule, the Contract Price:

15.2.1 shall remain fixed during the Term; and

15.2.2 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, 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 17 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.

- 15.3 The Supplier shall invoice the Authority for the price of the Goods on or at any time after they have been Delivered. Each invoice shall contain such information and be addressed to such individual as the Authority may inform the Supplier from time to time.
- 15.4 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.
- 15.5 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.
- 15.6 The Authority shall verify and pay each valid and undisputed invoice received in accordance with Clause 15.3 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 15.6, the invoice shall be regarded as valid and undisputed for the purposes of this Clause 15.6 after a reasonable time (not to exceed ten (10\_ business days)has passed.
- 15.7 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 ten (10) days of the query being raised. If the Parties are unable to agree a resolution within ten (10) 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 15.7 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.

- 15.8 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.
- 15.9 The Authority reserves the right to set-off:
- 15.9.1 any monies due to the Supplier from the Authority as against any monies due to the Authority from the Supplier under this Contract; and
  - 15.9.2 any monies due to the Authority from the Supplier as against any monies due to the Supplier from the Authority under this Contract.
- 15.10 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 undisputed invoices shall be paid by the Supplier within sixty (60) days of the date of such invoice. Where the Supplier raises a query with respect to an invoice the Parties shall follow the process outlined in clause 15.7 and any reference to "the Authority" shall be read as a reference to "the Supplier" and vice versa in respect of "the Supplier".
- 15.11 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.

## **16. Warranties**

- 16.1 The Supplier warrants and undertakes that:
- 16.1.1 the Goods shall be suitable for the purposes and/or treatments as 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;
  - 16.1.2 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 seven (7), 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;

- 16.1.3 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;
- 16.1.4 without prejudice to the generality of the warranty at Clause 16.1.3 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;
- 16.1.5 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;
- 16.1.6 it has, or the manufacturer of the Goods has, manufacturing and warehousing capacity sufficient to comply with its obligations under this Contract;
- 16.1.7 it shall ensure that the transport and Delivery of the Goods mean that they are Delivered in good and useable condition;
- 16.1.8 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;
- 16.1.9 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;
- 16.1.10 all Goods Delivered to the Authority shall comply with any shelf life requirements set out in the Specification and/or the Tender Response Document. For the avoidance of doubt, where the Specification and Tender Response Document set out conflicting shelf life periods, the longer of the periods shall apply;
- 16.1.11 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;

- 16.1.12 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);
- 16.1.13 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;
- 16.1.14 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;
- 16.1.15 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;
- 16.1.16 it has and shall as relevant maintain all rights, consents, authorisations, licences and accreditations required to supply the Goods;
- 16.1.17 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;
- 16.1.18 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;
- 16.1.19 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;
- 16.1.20 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;
- 16.1.21 it shall at all times conduct its business in a manner that is consistent with anti-slavery legislation 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 16.1.21 and/or as may be requested or otherwise required by the Authority in accordance with its anti-slavery Policy.

- 16.1.22 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);
- 16.1.23 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;
- 16.1.24 when supplying the Goods, it shall comply with all timescales set out in or agreed in accordance with this Contract and the KPIs;
- 16.1.25 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;
- 16.1.26 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;
- 16.1.27 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;
- 16.1.28 all necessary actions to authorise the execution of and performance of its obligations under this Contract have been taken before such execution;
- 16.1.29 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;
- 16.1.30 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;
- 16.1.31 it has and will continue to have the capacity, funding and cash flow to meet all its obligations under this Contract; and
- 16.1.32 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.
- 16.2 The Supplier warrants that all information, data and other records and documents required by the Authority as set out in the Specification and/or 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/or the Tender Response Document.

16.3 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:

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

16.3.2 promptly provide to the Authority:

a) 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

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

16.4 The Supplier further warrants and undertakes to the Authority that it will inform the Authority in writing immediately upon becoming aware that any of the warranties set out in this Clause 16 have been breached or there is a risk that any warranties may be breached.

16.5 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.

## **17. Intellectual property**

17.1 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.

## **18. Indemnity**

18.1 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:

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

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

18.1.3 any breach of Clause 16.1.17 and/or Clause 17 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.

18.2 Liability under Clauses 18.1.1 and 18.1.3 of this Schedule 2 shall be unlimited. Liability under Clauses 12.12.4, **Error! Reference source not found.**, and 18.1.2 of this Schedule 2 shall be subject to the limitation of liability set out in Clause 19 of this Schedule 2.

18.3 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:

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

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

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).

## 19. **Limitation of liability**

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

19.1.1 for death or personal injury resulting from its negligence;

19.1.2 for fraud or fraudulent misrepresentation; or

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

19.2 Subject to Clauses 18.2, 19.1, 19.3 and 19.5 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.

19.3 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 reasonably and properly incurred and properly evidenced by the claiming Party:

19.3.1 extra costs incurred purchasing replacement or alternative goods;

19.3.2 costs incurred in relation to any product recall;

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.

19.4 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.

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

19.5.1 is less than or equal to one million GBP (£1,000,000), then the figure of five million GBP (£5,000,000) at Clause 19.2 of this Schedule 2 shall be replaced with one million GBP (£1,000,000);

19.5.2 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 19.2 of this Schedule 2 shall be replaced with three million GBP (£3,000,000);

19.5.3 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 19.2 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 19.2 of this Schedule 2 shall be deemed to have been deleted and replaced with one hundred and fifteen percent (115%); or

19.5.4 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 19.2 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 19.2 of this Schedule 2 shall be deemed to have been deleted and replaced with one hundred and five percent (105%).

19.6 This Clause 19 shall survive the expiry of or earlier termination of this Contract for any reason.

## **20. Insurance**

20.1 Subject to Clause 20.2 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.

- 20.2 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 20.1 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.
- 20.3 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.
- 20.4 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.
- 20.5 The Supplier shall from time to time and in any event within ten (10) Business Days of written demand provide documentary evidence to the Authority that insurance arrangements taken out by the Supplier pursuant to this Clause 20 are fully maintained and that any premiums on them and/or contributions in respect of them (if any) are fully paid.
- 20.6 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 six (6) 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.

## **21. Term and termination**

- 21.1 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.
- 21.2 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 15.7 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 21.3.2 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:

- 21.2.1 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;
- 21.2.2 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); or
- 21.2.3 remedy the default or breach notwithstanding the implementation of such Remedial Proposal in accordance with the agreed timescales for implementation,

shall be deemed, for the purposes of Clause 21.3.2 of this Schedule 2, a material breach of this Contract by the Party in breach not remedied in accordance with an agreed Remedial Proposal.

- 21.3 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:

- 21.3.1 not capable of remedy; or
- 21.3.2 in the case of a breach capable of remedy, which is not remedied in accordance with a Remedial Proposal.

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

- 21.4.1 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;

- 21.4.2 the Licensing Authority, the Commission on Human Medicines or other relevant regulatory body advises the Authority not to use the Goods;
  - 21.4.3 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;
  - 21.4.4 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;
  - 21.4.5 pursuant to and in accordance with the Key Provisions and Clauses 9.4 of Schedule 1 and 21.5, 29.8; 31.2; 31.4 and 35.2 of this Schedule 2; or
  - 21.4.6 the warranty given by the Supplier pursuant to Clause 16.3 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 16.3 of this Schedule 2, or the Supplier fails to provide details of proposed mitigating factors as required by Clause 16.3 of this Schedule 2 that in the reasonable opinion of the Authority are acceptable.
- 21.5 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:
- 21.5.1 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;
  - 21.5.2 a failure or refusal by the Supplier to provide the financial or other security and/or assurances requested in accordance with this Clause 21.5 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

- 21.5.3 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 21.3.1 of this Schedule 2.
- 21.6 In order that the Authority may act reasonably in exercising its discretion in accordance with Clause 21.5 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.
- 21.7 The Authority may terminate this Contract by issuing a Termination Notice to the Supplier where:
  - 21.7.1 the Contract has been substantially amended to the extent that the Public Contracts Regulations 2015 (as amended) require a new procurement procedure; or
  - 21.7.2 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
  - 21.7.3 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 or labour Law. Where the failure to comply with legal obligations in the fields of environmental, social or labour Law is a failure by one of the Supplier's Sub-contractors, the Authority may request the replacement of such Sub-contractor and the Supplier shall comply with such request as an alternative to the Authority terminating this Contract under this Clause 21.7.3.
- 21.8 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 21.4.1 and 21.4.3 to 21.4.5 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.
- 21.9 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.

## **22. Consequences of expiry or early termination of this Contract**

- 22.1 Upon expiry or earlier termination of this Contract, the Authority agrees to pay the Supplier for the Goods which have been ordered (within 12 weeks of the Authority requested delivery date), supplied and Delivered by the Supplier and not rejected by the Authority in accordance with this Contract prior to expiry or earlier termination of this Contract, provided that this shall be the extent of the compensation due by the Authority to the Supplier upon termination of this Contract for any reason.
- 22.2 In the event that, on expiry of the Term or earlier termination of this Contract for any reason, the Supplier is still holding stocks of the Goods at the Storage and Distribution Facility on behalf of the Authority in accordance with Clause 5.4 of this Schedule 2 and the Authority and Supplier have not agreed that the Supplier will buy back such Goods, the Supplier shall notify the Authority of the volumes of such stocks and shall either, at the Authority's option:
- 22.2.1 deliver such stocks of the Goods to the Authority at such address as the Authority may notify the Supplier;
  - 22.2.2 make such stocks of the Goods available for collection by the Authority at the Storage and Distribution Facility during the normal business hours of the Storage and Distribution Facility; or
  - 22.2.3 dispose of such stocks of the Goods at the Authority's expense.
- For the avoidance of doubt, the Authority shall not be entitled to a refund of the Contract Price for any such stocks of the Goods unless otherwise agreed with the Supplier in writing in accordance with the Specification.
- 22.3 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.
- 22.4 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.
- 22.5 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.
- 22.6 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:
- 22.6.1 pay to the Authority the Buyback price 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

- 22.6.2 at its own expense remove all unused Goods Delivered to the Authority as at the date of termination within thirty (30) 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. Risk and title in such Goods shall pass to the Supplier on collection of the Goods.

### 23. Post termination provisions

- 23.1 The Supplier acknowledges and agrees that:

- 23.1.1 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
- 23.1.2 for the avoidance of doubt, any breach of any KPIs shall not be Confidential Information.

- 23.2 The Authority and any Central Government Body will not disclose the Contract Price to any Administering Entity (which for the purposes of this Clause 23.2 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).

- 23.3 This Clause 23.3 and the following Clauses shall survive the expiry or termination for any reason of this Contract: Schedule 1 (Key Provisions) Clauses 4 (Names and addresses for notices), 5 (Management levels for escalation and dispute resolution), 6 (Order of precedence), Clause **Error! Reference source not found.** (Regulatory and information requirements), Schedule 2 (General Terms and Conditions) Clauses 12 (Inspection, rejection, return and recall), 17 (Intellectual property), 18 (Indemnity), 19 (Limitation of liability), 22 (Consequences of expiry or early termination of this Contract), 28 (Dispute Resolution), 29.10 (Force majeure), 30 (Records retention and right of audit), 31.4 (Conflicts of interest and the prevention of fraud), 36.3 (waiver), 36.4 (severance), 36.11 (entire agreement), 36.12 (Governing law), 36.13 (jurisdiction), Schedule 3 (Information Provisions) Clauses 1 and 2, Schedule 4 (Definitions and Interpretations), and any Clauses and/or Schedules which are expressly or by implication intended to continue.

### 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 The Supplier shall meet all reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of this Clause 24.

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

## **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 this Clause 26.
- 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 , 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.
- 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 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/or 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 Either Party may submit a written request for Change to the other Party in accordance with this Clause 27, but no Change will come into effect until a Change Control Note has been signed by the authorised representatives of both Parties.
- 27.2 If the Authority requests a Change:
- 27.2.1 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
  - 27.2.2 within 5 Business Days of receipt of a request, the Supplier will, unless otherwise agreed, send to the Authority a Change Control Note.
- 27.3 If the Supplier requests a Change, it will send to the Authority a Change Control Note.
- 27.4 A Change Control Note will be in the form set out in Schedule 7.
- 27.5 If, following the receipt of a Change Control Note pursuant to Clauses 27.2 or 27.3 of this Schedule 2:
- 27.5.1 the Parties agree the terms of the relevant Change Control Note, then it shall, once signed by each of the Parties, constitute a binding change to the Contract for the purposes of Clause 27.7 of this Schedule 2; or

- 27.5.2 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.
- 27.6 Each Party will bear its own costs in relation to compliance with the Change Control Procedure.
- 27.7 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.
- 27.8 Subject to Clause 15.5, 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). 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 to resolving the Dispute, and shall follow the procedure set out in Clause 28.2 of this Schedule 2 as the first stage in the Dispute Resolution Procedure.
- 28.2 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 Schedule 1. Respective representatives at each level, as set out in Clause 5 of Schedule 1, 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.
- 28.3 If the procedure set out in Clause 28.2 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 28.2 of this Schedule 2, the mediator shall be nominated and confirmed by the Centre for Effective Dispute Resolution, London.
- 28.4 The mediation shall commence within twenty eight (28) days of the confirmation of the mediator in accordance with Clause 28.3 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.

28.5 Nothing in this Contract shall prevent:

28.5.1 either party 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

28.5.2 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.

28.6 This Clause 28 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 be 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 this Clause 29, and will not be considered to be in default or liable for breach of any obligations under this Contract, if:

29.2.1 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

29.2.2 the Supplier has complied with the procedural requirements set out in this Clause 29.

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) business 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 six (6) 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 six (6) 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 thirty (30) Business Days, to access 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 thirty (30) Business Days, to access 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. This Clause 30 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 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/or 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 takes 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 this Clause 32.
- 32.2 The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of this Clause 32.

## **33. Notice**

- 33.1 Subject to Clause 28.4 of Schedule 2, any notice required to be given by either Party under this Contract shall be in writing quoting the date of the Contract and shall be delivered by hand or sent by prepaid first class recorded delivery or by email to the person referred to in the Key Provisions or such other person as a Party may inform the other Party in writing from time to time.
- 33.2 A notice shall be treated as having been received:
- 33.2.1 if delivered by hand within normal business hours when so delivered, or, if delivered by hand outside normal business hours, at the next start of normal business hours; or

- 33.2.2 if sent by first class recorded delivery mail on a normal 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
- 33.2.3 if sent by email, if sent within normal business hours when so sent, or, if sent outside normal business hours, at the next start of normal business hours, provided the sender has either received an electronic confirmation of delivery or has telephoned the recipient to inform the recipient that the email has been sent.

#### **34. Assignment, novation and Sub-contracting**

- 34.1 The Supplier shall not, except where Clause 34.2 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 34.1 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 34.2 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 15.9 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 15 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; and
  - 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.
- 34.5 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.
- 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 ten (10) Business Days of the date of a written request from the Authority. For the avoidance of doubt, the Supplier shall have the right to redact any information it deems to be commercially sensitive, including but not limited to. confidential pricing information in relation to such copies of Sub-contracts. 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 Both Parties warrant and represent 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 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 or for showing or not showing favour or disfavour to any person in relation to this or any other agreement; 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 Party; 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 a Party ("the Breaching Party") 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 other Party ("the Non-breaching Party") in relation to this or any other agreement:

35.2.1 the Non-breaching Party shall be entitled:

- a) to terminate this Contract and recover the amount of any loss resulting from the termination;
- b) to recover 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 parties.

### 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 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 36.8, right includes any power, privilege, remedy, or proprietary or security interest.
- 36.9 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.

- 36.10 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.
  
- 36.11 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.
  
- 36.12 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.
  
- 36.13 Subject to Clause 28 of this Schedule 2, the Parties irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any Dispute or claim that arises out of or in connection with this Contract or its subject matter.
  
- 36.14 All written and oral communications and all written material referred to under this Contract shall be in English.
  
- 36.15 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 contract.
  
- 36.16 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.
  
- 36.17 No counterpart shall be effective until each Party has executed and delivered at least one counterpart.

### SCHEDULE 3

#### 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 this Clause 1, 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 this Clause 1 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 this Clause 1 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 3 (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 where reasonably required, to any relevant party for the purpose of the examination and certification of the Authority's accounts;
- 1.3.5 where reasonably required, 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 where reasonably required, 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;

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.

- 1.4 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 this Clause 1 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.
- 1.5 For the avoidance of doubt, save as required by Law or as otherwise set out in this Schedule 3, 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.

1.6 This Clause 1 shall remain in force:

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

1.6.2 for all other Confidential Information for a period of ten (10) 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 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 subject to clause 2.2.2 of this Schedule 3 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
- 2.3 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. 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 3, 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 to 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 this Clause 2, 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 3, the Supplier shall:



- 3.1.1 notify the Authority forthwith of any information security breaches (including, without limitation, any actual breaches of confidentiality or actual information security breaches); 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 4

### Definitions and Interpretations

#### 1. Definitions

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

|                                    |  |
|------------------------------------|--|
| <b>“AAH”</b>                       | means AAH Pharmaceuticals Limited (company registration number 0123458) whose registered office is Sapphire Court, Walsgrave Triangle, Coventry, CV2 2TX;  |
| <b>“Additional Goods Order”</b>    | has the meaning set out in Clause 2.1 of Schedule 2;   |
| <b>“Additional Volume”</b>         | means the volume of Goods to be Delivered under Additional Goods Orders in accordance with Clause 2 of Schedule 2;   |
| <b>“Administering Entity”</b>      | means any body administering the Goods including all Health Service Bodies;  |
| <b>“Authorised Release”</b>        | means a release of Goods from the Stockpile as a result of a Supply Shortage in accordance with Clause 7   |
| <b>“Authority”</b>                 | means the authority named on the form of Contract on page 1;   |
| <b>“Breach Notice”</b>             | 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;   |
| <b>“Business Continuity Event”</b> | 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;   |
| <b>“Business Continuity Plan”</b>  | means the Supplier’s business continuity plan which includes its plans for continuity of its supply chain operations in the United Kingdom during a Business Continuity Event;   |
| <b>“Business Day”</b>              | means any day other than a Saturday, Sunday or bank holiday in England;  |
| <b>“Buyback Price”</b>             | Means <b>Redacted Under FOIA Section 43(2), Commercial Interests</b> per Unit;   |
| <b>“Central Government Body”</b>   | 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:<br>(a) Government Department; |

|                                   |  |
|-----------------------------------|--|
|                                   | (b) Non-Departmental Public Body or Assembly Sponsored Public Body (advisory, executive, or tribunal);<br>(c) Non-Ministerial Department; or<br>(d) Executive Agency;  |
| <b>“Change”</b>                   | means any change to this Contract;   |
| <b>“Change Control Note”</b>      | 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;   |
| <b>“Change in Law”</b>            | 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;   |
| <b>“Charges”</b>                  | means the Contract Price together with any applicable VAT;   |
| <b>“Codes of Practice”</b>        | shall have the meaning given to the term in Clause 1.2 of Schedule 3;  |
| <b>“Commencement Date”</b>        | shall have the meaning given to it in Clause 2.1 of Schedule 1;  |
| <b>“Commercial Schedule”</b>      | means the document set out at Schedule 6;  |
| <b>“Confidential Information”</b> | 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:<br>(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;<br>(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<br>(c) Policies and such other documents which the Supplier may obtain or have access to through the Authority’s intranet; |
| <b>“Contract”</b>                 | 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;  |
| <b>“Contracting Authority”</b>    | means any contracting authority as defined in regulation 3 of the Public Contracts Regulations 2015 (SI 2015/102) (as amended), other than the Authority;  |
| <b>“Contract Manager”</b>         | 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 14.1 of Schedule 2;  |
| <b>“Contract Price”</b>          | 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;   |
| <b>“Customer”</b>                | means all pharmacies in the UK as specified by the Authority, together with such other customers in the UK as the Authority may reasonably require in writing from time to time;  |
| <b>“Defective Goods”</b>         | has the meaning given under Clause 12.8 of Schedule 2;  |
| <b>“Delivery”</b>                | has the meaning given under Clause 5.2 of Schedule 2 and “Deliver” and “Delivered” shall be construed accordingly;  |
| <b>“Delivery Period”</b>         | means the month(s) during the Term that the Authority requires the supply of the Goods as set out in Schedule 6;  |
| <b>“Devolved Administration”</b> | means the devolved administrations of Scotland, Wales and Northern Ireland (the Scottish Parliament, the Welsh Assembly and the Northern Ireland Assembly);   |
| <b>“Directive 2001/83”</b>       | means Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use (and any amended and/or successor legislation applicable to the UK);   |
| <b>“Directive 2003/94”</b>       | 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 amended and/or successor legislation applicable to the UK);  |
| <b>“Discloser”</b>               | has the meaning given under Clause 1.1 of Schedule 3;   |
| <b>“Dispute(s)”</b>              | 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; |

|                                       |   |
|---------------------------------------|---|
| <b>“Dispute Notice”</b>               | means a written notice served by one Party to the other stating that the Party serving the notice believes there is a Dispute;  |
| <b>“Dispute Resolution Procedure”</b> | 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 <b>Error! Reference source not found.</b> of Schedule 2;  |
| <b>“DOTAS”</b>                        | 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; |
| <b>“Electronic Trading System(s)”</b> | 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;  |
| <b>“EMA”</b>                          | means the European Medicines Agency (or any statutory successor);   |
| <b>“Environmental Regulations”</b>    | shall have the meaning given to the term in Clause 1.2 of Schedule 3;   |
| <b>“Equality Legislation”</b>         | 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, the Fixed-term Employees (Prevention of Less Favourable Treatment) Regulations 2002 (SI 2002/2034), and the Human Rights Act 1998;  |
| <b>“EU References”</b>                | has the meaning given to it in Clause 1.3.1 of Schedule 4;  |
| <b>“Exit Day”</b>                     | shall have the meaning in the European Union (Withdrawal) Act 2018;   |

|                              |  |
|------------------------------|--|
| <b>“Exit Phase”</b>          | <p>means a period commencing from the earliest of any of the following events:</p> <p>(i) three (3) months before expiry of this Contract;</p> <p>or</p> <p>(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;</p> <p>or</p> <p>(iii) from the date of any agreement to reduce the Required Volume other than by reason of a Supply Shortage Authorised Release and continuing for a period of three (3) months or as agreed by both Parties;</p>  |
| <b>“FOIA”</b>                | <p>shall have the meaning given to the term in Clause 1.2 of Schedule 3;</p>   |
| <b>“Force Majeure Event”</b> | <p>means any event beyond the reasonable control of the Party in question to include, without limitation:</p> <p>(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;</p> <p>(b) acts of terrorism;</p> <p>(c) flood, storm or other natural disasters;</p> <p>(d) fire;</p> <p>(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;</p> <p>(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;</p> <p>(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;</p> <p>(h) industrial action which affects the ability of the Supplier to supply the Goods, but which is not</p> |



|                                  |  |
|----------------------------------|--|
|                                  | <p>confined to the workforce of the Supplier or the workforce of any Sub-contractor of the Supplier; and</p> <p>(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;</p> <p>but excluding, for the avoidance of doubt, any event or other consequence arising as a result of or in connection with:</p> <p>(i) the withdrawal of the United Kingdom from the European Union; or</p> <p>(ii) 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;</p> |
| <b>"Fraud"</b>                   | 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;  |
| <b>"General Anti-Abuse Rule"</b> | <p>means</p> <p>(a) the legislation in Part 5 of the Finance Act 2013; and</p> <p>(b) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid national insurance contributions;</p>  |

|                                      |   |
|--------------------------------------|---|
| <b>“Good Industry Practice”</b>      | 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;  |
| <b>“Good Manufacturing Practice”</b> | shall have the meaning set out in Directive 2003/94;  |
| <b>“Goods”</b>                       | means all goods, materials or items that the Supplier is required to supply to the Authority under this Contract (including, without limitation, under Schedule 5 which sets out the requirements of the Authority as issued to tenderers as part of the procurement process and Schedule 8 which sets out the Supplier's response to these requirements);  |
| <b>“Guidance”</b>                    | 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 MHRA, the EMA 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;                      |
| <b>“Halifax Abuse Principle”</b>     | means the principle explained in the CJEU Case C-255/02 Halifax and others;   |
| <b>“Health Service Bodies”</b>       | means: <ul style="list-style-type: none"> <li>(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;</li> <li>(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));</li> <li>(c) health service bodies referred to in section 9 of the National Health Service Act 2006 (c.41);</li> </ul> |

|                                       |  |
|---------------------------------------|--|
|                                       | <ul style="list-style-type: none"> <li>(d) the Secretary of State for Health and Social Care;</li> <li>(e) any care trust as defined in section 77 of the National Health Service Act 2006 (c.41);</li> <li>(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);</li> <li>(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</li> <li>(h) any statutory successor to any of the above;</li> </ul>                                  |
| <b>“Initial Term”</b>                 | shall have the meaning given to the term in Clause 2.1 of Schedule 1;  |
| <b>“Initial Volume”</b>               | means 40,000 units which will be Delivered in the first delivery under this Contract;  |
| <b>“Intellectual Property Rights”</b> | 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;   |
| <b>“Issuing Party”</b>                | has the meaning given to it in Clause 1.13 of Schedule 4;  |
| <b>“Key Provisions”</b>               | means the key provisions set out in Schedule 1;  |
| <b>“KPI”</b>                          | means the key performance indicators as set out in Part 3 of Schedule 6;   |
| <b>“Law”</b>                          | <p>means any applicable legal requirements including, without limitation:</p> <ul style="list-style-type: none"> <li>(a) any applicable statute or proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument as applicable in England and Wales;</li> <li>(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);</li> </ul> |

|   |  |
|---|--|
|   | <p>(c) to the extent in force in the UK, any enforceable community right within the meaning of section 2(1) European Communities Act 1972;</p> <p>(d) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales;</p> <p>(e) requirements set by any regulatory body as applicable in England and Wales;</p> <p>(f) any relevant code of practice as applicable in England and Wales; and</p> <p>(g) any relevant collective agreement and/or international law provisions (to include, without limitation, as referred to in (a) to (f) above);</p> |
| <b>“Licensing Authority”</b>            | 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);  |
| <b>“Loss Costs”</b>                     | <p>means to the extent that the Authority and/or Administering Entity and/or Devolved Administration has taken all reasonable steps to mitigate such losses:</p> <p>(a) all costs in connection with receiving and storing Defective Goods;</p> <p>(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; and</p> <p>(c) all costs in excess of the Charges paid or payable by the Authority for Rejected Goods incurred in sourcing alternative products from third parties.</p>         |
| <b>“Manufacturing Licence”</b>          | means the manufacturing licence in respect of the Goods granted by the Licensing Authority;  |
| <b>“Marketing Authorisation”</b>        | means the marketing authorisation in respect of the Goods granted by the Licensing Authority as amended or varied by the Licensing Authority from time to time;  |
| <b>“MHRA”</b>                           | means the Medicines and Healthcare products Regulatory Agency;   |
| <b>“Occasion of Tax Non-Compliance”</b> | <p>means:</p> <p>(a) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 that is found on or after 1 April 2013 to be incorrect as a result of:</p>  |

|                                      |   |
|--------------------------------------|---|
|                                      | <ul style="list-style-type: none"> <li>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;</li> <li>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</li> </ul> <p>(b) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 that 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;</p> |
| <b>Pandemic</b>                      | means any period of time in respect of which the 'Pandemic Phase' alert pursuant to the Revised WHO Classification System applies, or such other categorisation the World Health Organization may give to a pandemic from time to time;   |
| <b>"Party"</b>                       | means the Authority or the Supplier as appropriate and Parties means both the Authority and the Supplier;   |
| <b>"Patient Information Leaflet"</b> | shall have the meaning as set out in Part 13, Chapter 1 of the Human Medicines Regulations 2012;  |
| <b>"Personal Data"</b>               | 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;  |
| <b>"Policies"</b>                    | means the policies, rules and procedures of the Authority as notified to the Supplier from time to time;  |
| <b>"Product Information"</b>         | 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;   |
| <b>"Prohibited Acts"</b>             | has the meaning given under Clause 35.1.1 of Schedule 2;  |
| <b>"Purchase Order"</b>              | means the purchase order required by the Authority's financial systems;;  |

|  |  |
|--|--|
| <b>“QTA”</b>                               | means the Quality Technical Agreement dated 23rd February 2022 between the Authority and the Supplier as amended and updated from time to time by the Parties (to the QTA);                |
| <b>“Recipient”</b>                         | has the meaning given under Clause 1.1 of Schedule 3;  |
| <b>“Receiving Party”</b>                   | has the meaning given to it in Clause 1.13 of Schedule 4;  |
| <b>“Rejected Goods”</b>                    | has the meaning given under Clause 12.2 of Schedule 2;   |
| <b>“Relevant Tax Authority”</b>            | means HM Revenue and Customs, or, if applicable, a tax authority in the jurisdiction in which the Supplier is established;   |
| <b>“Remedial Proposal”</b>                 | has the meaning given under Clause 21.2 of Schedule 2;   |
| <b>“Replacement Goods”</b>                 | means Goods used to replace:<br>(a) Stockpiled Goods removed from the Stockpile in accordance with Clause 6; and<br>(b) Rejected Goods;  |
| <b>“Required Volume”</b>                   | means 40,000 Units, unless otherwise agreed in writing between both parties  |
| <b>“Requirement to Recall”</b>             | has the meaning given under Clause 12.12 of Schedule 2;  |
| <b>“Specification”</b>                     | means the document set out in Schedule 5 as amended and/or updated in accordance with this Contract;   |
| <b>“Staff”</b>                             | means all persons employed or engaged by the Supplier to perform its obligations under this Contract including any Sub-contractors and person employed or engaged by such Sub-contractors; |
| <b>“Standard Direct to Pharmacy”</b>       | Means the supplier retains ownership of their products through the supply chain  |
| <b>“Stockpile”</b>                         | means the designated area that is separate from business as usual stock where the Stockpiled Goods are held within the Storage and Distribution Facility;                                  |
| <b>“Stockpiled Goods”</b>                  | means Goods held in and stored within the Stockpile, including any Replacement Goods supplied under this Contract;   |
| <b>“Storage and Distribution Facility”</b> | means Movianto Haydock   |



|   |   |
|---|---|
| <b>“Storage Services”</b>                   | means the storage of the Goods in accordance with Clause 5 of Schedule 2;   |
| <b>“Sub-contract”</b>                       | 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; |
| <b>“Sub-contractor”</b>                     | means a party to a Sub-contract other than the Supplier;  |
| <b>“Summary of Product Characteristics”</b> | means the summary of product characteristics approved by the Licensing Authority for the Marketing Authorisation;   |
| <b>“Supplier”</b>                           | means the supplier named on the form of Contract on page 1;   |
| <b>“Supplier Code of Conduct”</b>           | 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;   |
| <b>“Supply Shortage”</b>                    | means a situation where the normal supply of the Goods cannot meet the demand in the UK   |
| <b>“Tender Response Document”</b>           | 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 8;  |
| <b>“Term”</b>                               | means the Initial Term as set out in the Key Provisions and any extension to this made in accordance with the terms of this Contract;   |
| <b>“Termination Notice”</b>                 | 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;          |
| <b>“Third Party Body”</b>                   | has the meaning given under Clause 14.5 of Schedule 2;  |
| <b>“Units”</b>                              | means a unit of the Goods;  |
| <b>“VAT”</b>                                | means value added tax chargeable under the Value Added Tax Act 1994 or any similar, replacement or extra tax; and   |
| <b>“Volume”</b>                             | means the total quantity of the Goods to be Delivered during the Initial Term.  |

- 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 on and after Exit Day 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 EU body shall be read on and after Exit Day 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 5) 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 5**

### **Specification**

In so far as the context allows, defined terms in this Specification are in accordance with Schedule 4 of the Contract

#### **1 Introduction**

- 1.1 The Authority's intention is to enter into a Contract for the supply and storage of Pulmicort Turbohaler 400 (the Goods), which will be purchased by the Authority and held by the Supplier on behalf of the Authority.

#### **2 Mandatory Requirements:**

- 2.1 The Goods must be as described in paragraph 1.1. above. The Goods must have Marketing Authorisation applicable to their use in the UK.

#### **3 Volume required**

- 3.1 The Supplier shall supply to the Authority the Goods at the price agreed in Schedule 6 of the Contract.
- 3.2 The Required Volume during the Term of the contract is for o **REDACTED** with each inhaler containing - 50 Doses.
- 3.3 The Authority will be responsible for ensuring sufficient Goods are ordered to maintain buffer stock and the Supplier shall ensure that the business as usual ("BAU") stock is not impacted as a result of increased Covid prescriptions of the Goods

#### **4 Storage, onward distribution and sale with buy back process**

- 4.1 The Supplier shall use their comprehensive stock management system (SAP) to provide a stock level report to the Authority on a weekly basis.
- 4.2 The Supplier shall buy back stock from the Authority at the Buyback Price in order to cover the Supplier's storage and distribution costs.
- 4.3 The Supplier shall generate a credit note to the Authority which will apply on buyback of the Goods by the Supplier.

- 4.4 Standard Direct to Pharmacy supply model will be used by the Supplier to distribute to Customers using AAH under their BAU contract.

## 5 Stock Management

- 5.1 The Authority will ensure that at least **REDACTED** Units of the Goods, remains in the UK.
- 5.2 The Supplier shall provide weekly stock level reports.
- 5.3 The Supplier shall provide the Authority with updates on surges and associated insights to changes that could impact supply.
- 5.4 The report format and any changes to reporting must be agreed by both parties in writing.
- 5.5 Delivery shall be made on:  
Euro Pallet
- 1200mm (L) x 800mm (W) x 150mm (H)
  - Two way accessible
  - 1400mm Height inclusive of pallet
  - Total weight, 500Kg inclusive of pallet
  - Pharma Heat treated
  - No over-hang of Goods outside the pallet foot print.
  - Goods to be secured to the pallet to minimise any movement in transit.
- 5.6 Further instructions and obligations on the Supplier as to Delivery are set out in Clause 5 of Schedule 2 (General Terms and Conditions) of the Contract.

## 6 Medicines packaging, labelling and information

- 6.1 All Goods must include a Patient Information Leaflet. The Patient Information Leaflet must comply with current regulatory requirements.
- 6.2 The batch number and expiry date must be present and legible, particularly when embossing is used rather than print. The expiry date must be unambiguously expressed.
- 6.3 Temperature storage conditions must be clearly stated on both the primary and secondary packaging. Where tamper evident

packaging is used, this must comply with relevant guidance and rules as may be in force at the time.

Outer boxes must be robust and offer adequate protection to the inner Goods containers.

## **7 Termination and exit**

Upon expiry or earlier termination of the contract, both parties should have agreed the following:

- (a) Goods' storage location under the Authority's control
- (b) Possibility of selling back stock to the Supplier at an agreed price for incorporation into the Supplier's business-as-usual supply chain



## **SCHEDULE 6**

### **Commercial Schedule**

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



## SCHEDULE 7

### Proforma Change Control Note

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

| <b>SIGNED ON BEHALF OF THE<br/>AUTHORITY</b> | <b>SIGNED ON BEHALF OF THE SUPPLIER</b> |
|--|---|
| Signature:                                   | Signature:                              |
| Name:  | Name:                                   |
| Position:                                    | Position:                               |
| Date:  | Date:                                   |

## **SCHEDULE 8**

### **Response Document**

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

## **SCHEDULE 9**

### **Business Continuity Plan**

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