

**NHS TERMS AND CONDITIONS FOR THE SUPPLY OF GOODS (CONTRACT VERSION)**

<b>The Authority</b>	<b>The NHS Commissioning Board (operating as NHS England)</b> whose principal office is at <b>4th Floor, Quarry House, Leeds LS2 7UE</b> (the " <b>Authority</b> ", which term includes any successor to it in the exercise of its statutory functions);
<b>The Supplier</b>	<b>[Insert name, address and, where applicable, the company number of the Supplier]</b>
<b>Date</b>	<b>[Insert date when signed by both parties]</b>
<b>Type of Goods</b>	<b>Provision of [a new] / [an existing] antimicrobial to the NHS in England via a subscription-based payment model</b>

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 or any Purchasing Authority, and the Authority or Purchasing Authority (as the case may be) shall receive and the Authority shall pay for, the Goods on the terms of this Contract.

The Definitions in Schedule 4 apply to the use of all capitalised terms in this Contract.

**Schedules**

<b>Schedule 1</b>	Key Provisions
<b>Schedule 2</b>	General Terms and Conditions
<b>Schedule 3</b>	Information and Data Provisions
<b>Schedule 4</b>	Definitions and Interpretations
<b>Schedule 5</b>	Specification and Tender Response Document
<b>Schedule 6</b>	Commercial Schedule
<b>Schedule 7</b>	<b>Not Used</b>
<b>Schedule 8</b>	<b>Not Used</b>
<b>Schedule 9</b>	<b>Not Used</b>
<b>Schedule 10</b>	Performance Levels and Performance Credits
<b>Schedule 11</b>	Change Control Process

**Signed by the authorised representative of THE AUTHORITY**

Name:	.....	Signature:	.....
Position:	.....		

**Signed by the authorised representative of THE SUPPLIER**

Name:	.....	Signature	.....
Position:	.....		

## Schedule 1

### Key Provisions

#### Standard Key Provisions

#### **1 Application of the Key Provisions**

- 1.1 The standard Key Provisions at Clauses 1 to 6 of this Schedule 1 shall apply to this Contract.
- 1.2 The optional Key Provisions at Clauses 7 to 23 of this Schedule 1 shall only apply to this Contract where they have been checked and information completed as applicable.
- 1.3 Extra Key Provisions shall only apply to this Contract where such provisions are set out at the end of this Schedule 1.

#### **2 Term**

- 2.1 This Contract shall commence on the Commencement Date and the Term of this Contract shall expire **three (3)** years from the Commencement Date. The Term may be extended in accordance with Clause 15.2 of Schedule 2 provided that the duration of this Contract shall be no longer than **ten (10)** years in total.

#### **3 Contract Managers**

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

3.1.1 for the Authority:

**[insert name and role]**

3.1.2 for the Supplier:

**[insert name and role].**

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

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

4.1.1 for the Authority:

**[complete name and/or role and address]**

4.1.2 for the Supplier:

**[complete name and/or role and address].**

#### **5 Management levels for escalation and dispute resolution**

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

Level	Authority representative	Supplier representative
1	[Contract Manager]	[Contract Manager]
2	[insert role]	[insert role]
3	[insert role]	[insert role]

## 6 Order of precedence

6.1 Subject always to Clause 1.10 of Schedule 4, should there be a conflict between any other parts of this Contract the order of priority for construction purposes shall be:

6.1.1 the provisions on the front page of this NHS Contract for the Supply of Goods (Contract Version);

6.1.2 Schedule 1: Key Provisions;

6.1.3 Schedule 5: Specification and Tender Response Document (but only in respect of the Authority's requirements);

6.1.4 Schedule 2: General Terms and Conditions;

6.1.5 Schedule 6: Commercial Schedule;

6.1.6 Schedule 3: Information Governance Provisions;

6.1.7 Schedule 4: Definitions and Interpretations;

6.1.8 the order in which all subsequent schedules, if any, appear; and

6.1.9 any other documentation forming part of the Contract in the date order in which such documentation was created with the more recent documentation taking precedence over older documentation to the extent only of any conflict.

6.2 For the avoidance of doubt, the Specification and Tender Response Document shall include, without limitation, the Authority's requirements in the form of its specification and other statements and requirements, the Supplier's responses, proposals and/or method statements to meet those requirements, and any clarifications to the Supplier's responses, proposals and/or method statements as included as part of Schedule 5. Should there be a conflict between these parts of the Specification and Tender Response Document, the order of priority for construction purposes shall be (1) the Authority's requirements; (2) any clarification to the Supplier's responses, proposals and/or method statements, and (3) the Supplier's responses, proposals and/or method statements.

**7 Quality assurance standards  (only applicable to the Contract if this box is checked and the standards are listed)**

7.1 The following quality assurance standards shall apply, as appropriate, to the manufacture, supply, and/or installation of the Goods: **[insert standards]**.

**8 Different levels and/or types of insurance  (only applicable to the Contract if this box is checked and the table sets out the requirements)**

8.1 The Supplier shall put in place and maintain in force the following insurances with the following minimum cover per claim:

Type of insurance required	Minimum cover
Employer's liability insurance	£10,000,000
Public liability insurance	£10,000,000
Product liability insurance	£10,000,000

**9 Guarantee  (only applicable to the Contract if this box is checked)**

9.1 Promptly following the execution of this Contract, the Supplier shall, if it has not already delivered an executed deed of guarantee to the Authority, deliver the executed deed of guarantee to the Authority as required by the procurement process followed by the Authority. Failure to comply with this Key Provision shall be an irremediable breach of this Contract.

**10 Further Authority obligations  (only applicable to the Contract if this box is checked and the Schedule inserted)**

10.1 The Authority's Obligations are set out in Schedule *[insert schedule number]*.

**11 Supplier as Data Processor  (only applicable to the Contract if this box is checked)**

11.1 The Parties acknowledge that the Authority is the Controller and the Supplier is the Processor in respect of Personal Data Processed under this Contract and that paragraph 2.2 of Schedule 3 and the provisions of the Data Protection Protocol must be complied with by the Parties as a term of this Contract.

**12 Purchase Orders  (only applicable to the Contract if this box is checked)**

12.1 The Authority or Purchasing Authority (as the case may be) shall issue a Purchase Order to the Supplier in respect of any Goods to be supplied to the Authority or Purchasing Authority (as the case may be) under this Contract. The Supplier shall comply with the terms of such Purchase Order as 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.

**13 Pre-Acquisition Questionnaire  (only applicable to the Contract if this box is checked)**

13.1 The Supplier warrants and undertakes that its responses to the Pre-Acquisition Questionnaire issued by the Authority are correct and will remain correct and binding on the Supplier until no longer applicable notwithstanding any earlier expiry or termination of this Contract. The Supplier further warrants and undertakes to the Authority that it will inform the Authority in writing immediately upon becoming aware that the foregoing warranty and undertaking in this Clause 13.1 of this Schedule 1 has been breached or there is a risk that it may be breached. Should the Supplier be in breach of this warranty, the Supplier shall take all such actions necessary to put the Authority in such a position as if the Supplier had continued to comply fully with the warranty.

**14 Time of the essence  (only applicable to the Contract if this box is checked)**

14.1 Time is of the essence as to any delivery dates under this Contract and if the Supplier fails to meet any delivery date this shall be deemed to be a breach incapable of remedy for the purposes of Clause 15.4(i) of Schedule 2.

- 15 Specific time periods for inspection  (only applicable to the Contract if this box is checked and Clause 15.1 of this Schedule 1 is completed)**
- 15.1 For the purposes of Clause 4.2 of Schedule 2, the Authority shall visually inspect the Goods within **[insert time period during which any inspection must be carried out]** of the date of delivery of the relevant Goods.
- 16 Specific time periods for rights and remedies under Clause 4.6 of Schedule 2  (only applicable to the Contract if this box is checked and Clause 16.1 of this Schedule 1 is completed)**
- 16.1 The Authority's rights and remedies under Clause 4.6 of Schedule 2 shall cease **[insert period – e.g. 12 months]** from the date of delivery of the relevant Goods.
- 17 Monthly payment profile  (only applicable to the Contract if this box is checked)**
- 17.1 The payment profile for this Contract shall be monthly in arrears.
- 18 Termination for convenience  (only applicable to the Contract if this box is checked and Clause 18.1 of this Schedule 1 is completed)**
- 18.1 The Authority may terminate this Contract by issuing a Termination Notice to the Supplier at any time on six (6) months' written notice.
- 19 Installation and Commissioning Services  (only applicable to the Contract if this box is checked)**
- 19.1 The Supplier shall provide the Installation and Commissioning Services in accordance with the terms set out in Schedule 7.
- 20 Maintenance Services  (only applicable to the Contract if this box is checked)**
- 20.1 The Supplier shall provide the Maintenance Services in accordance with the terms set out in Schedule 8.
- 21 Right to terminate following a specified number of material breaches  (only applicable to the Contract if this box is checked and Clause 21.1 of this Schedule 1 is completed)**
- 21.1 Either Party may terminate this Contract by issuing a Termination Notice to the other Party if such other Party commits a material breach of this Contract in circumstances where it is served with a valid Breach Notice having already been served with at least two (2) previous valid Breach Notices within the last twelve (12) calendar month rolling period 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). The twelve (12) month rolling period is the twelve (12) months immediately preceding the date of the third Breach Notice.
- 22 Expert Determination  (only applicable to the Contract if this box is checked)**
- 22.1 Any Dispute between the Authority and the Supplier shall be dealt in accordance with the expert determination process as specified at Schedule 9.
- 22.2 For the avoidance of doubt, where this Clause 22 of this Schedule 1 is checked, all Disputes shall be dealt in accordance with Clause 22.1 of this Schedule 1 above and the entirety of Clause 22 of Schedule 2 shall be deemed not to apply and deleted in its entirety from this Contract.

**23 Consigned Goods  (only applicable to the Contract if this box is checked)**

- 23.1 Provided that such Consignment Request is consistent with the forecast requirement for the Goods (as set out in the Specification and Tender Response Document and/or as calculated in accordance with any relevant processes set out in this document and/or as otherwise agreed by the Parties in writing), the Supplier shall deliver the Consigned Goods in accordance with Clause 2 of Schedule 2 in response to a Consignment Request for their eventual purchase and use by the Authority in accordance with the terms set out in this Contract.
- 23.2 For the avoidance of doubt, Clause 4 of Schedule 2 shall apply to the inspection, rejection, return and recall of the Consigned Goods.
- 23.3 The Authority shall, or shall procure that its third party provider shall, maintain any storage facilities throughout the term of this Contract where the Consigned Goods are to be stored in such manner that such storage facilities remain suitable to store the Consigned Goods.
- 23.4 Prior to the Consigned Goods being taken into use by the Authority, the Authority shall ensure that:
- 23.4.1 the Consigned Goods are stored at the storage facilities in such a manner as to protect them from damage or deterioration;
  - 23.4.2 the Consigned Goods in its possession remain readily identifiable as the Supplier's property;
  - 23.4.3 any identifying marks or packaging on or relating to the Consigned Goods are not removed, defaced or obscured; and
  - 23.4.4 the Consigned Goods are kept in satisfactory condition in accordance with any reasonable and necessary instructions from the Supplier from time to time.
- 23.5 The Authority shall keep accurate stock records in relation to any Consigned Goods and shall provide the Supplier with a sales report ("**Sales Report**") each [**week/month/quarter/other agreed period**] detailing current stock levels and the Consigned Goods taken into use by the Authority. For the avoidance of doubt, a sale will take place at the point any Consigned Goods are taken into use by the Authority.
- 23.6 On receipt of the Sales Report, the Supplier may invoice the Authority the Contract Price for all of the Consigned Goods taken into use by the Authority (as set out in that Sales Report).
- 23.7 Each [**week/month/quarter/other agreed period**] the Authority shall take into use and purchase at the Contract Price at least the minimum quantity of Consigned Goods specified in the Specification and Tender Response Document for such period (if any) ("**Minimum Quantity**"). If the Supplier fails to supply the Authority with any Consigned Goods required by the Authority (including, without limitation, where the Authority obtains substitute goods from a third party as a result), the Minimum Quantity for the period in question shall be reduced by the quantity of the Consigned Goods that the Supplier fails to supply. Except to the extent that the Authority's failure to purchase the Minimum Quantity during any given period is caused by the Supplier's default or a Force Majeure Event, if the Authority purchases less than the Minimum Quantity for a given period, the Supplier may charge the Authority for any shortfall between:
- 23.7.1 the Contract Price of the Minimum Quantity in the relevant period; and
  - 23.7.2 the Contract Price for Consigned Goods purchased by the Authority in that period.
- 23.8 The Authority (on a first in first out basis) may return to the Supplier any Consigned Goods that it is unable to use ("**Returned Goods**") by giving written notice to that effect ("**Returns Notice**"). Upon receipt of a Returns Notice, the Supplier shall collect the Returned Goods at the Supplier's

risk and expense within ten (10) Business Days of the date of the Returns Notice. If the Supplier requests and the Authority accepts that the Returned Goods should be disposed of by the Authority rather than returned to the Supplier, the Authority may invoice the Supplier for the costs associated with the disposal of the Returned Goods and the Supplier shall pay any such costs.

- 23.9 Risk in respect of any Returned Goods shall pass to the Supplier on the earlier of: (a) collection by the Supplier; or (b) immediately following the expiry of ten (10) Business Days from the date of the Returns Notice related to such Returned Goods. If Returned Goods are not collected within ten (10) Business Days of the date of the relevant Returns Notice, the Authority may return the Returned Goods to the Supplier at the Supplier's risk and expense and/or charge the Supplier for the cost of storage from the expiry of ten (10) Business Days from the date of the relevant Returns Notice. The Authority may invoice the Supplier for such return expenses and/or storage costs and the Supplier shall pay any such expenses or costs.
- 23.10 The Consigned Goods shall at all times be subject to the direction and control of the Supplier, and the Supplier may (at the Supplier's risk and expense), upon (10) Business Days written notice to the Authority, collect (on a first in first out basis) any Consigned Goods that have not been taken into use by the Authority within [*insert period*] of their delivery to the Authority and/or which have a remaining shelf life of less than [*insert period*].
- 23.11 The Authority acknowledges that it holds Consigned Goods in its possession as bailee for the Consignor until such time as ownership passes in accordance with Clause 3.2 of Schedule 2.
- 23.12 On the termination or expiry of this Contract for whatever reason, all Consigned Goods not taken into use by Authority as at the point of such termination or expiry shall be deemed Returned Goods. Such Returned Goods shall be deemed the subject of a Returns Notice that shall be deemed to have been received by the Supplier with a notice date the same as the date of the expiry or earlier termination of this Contract. Clauses 23.8 and 23.9 of this Schedule 1 shall then apply accordingly and this Clause, together with Clauses 23.8 and 23.9 of this Schedule 1, shall survive the expiry or earlier termination of this Contract for these purposes.

### **Extra Key Provisions**

#### **24 Performance**

- 24.1 The parties agree that Schedule 10 shall have effect.
- 24.2 With effect from the Commencement Date the Supplier must ensure that it performs this Contract at all times in a manner which meets or exceeds the Performance Levels.
- 24.3 Notwithstanding any of its other obligations under this Contract, the Supplier must monitor its performance against the Performance Levels in accordance with the Performance Monitoring System. The Supplier must provide the Authority with a report as soon as reasonably practicable (but in any event within four (4) weeks of the end of each Quarter) specifying, , the Supplier's performance against each of the Performance Levels in accordance with the timescales set out in Annex B of Schedule 10, including full details of any failure to meet the Performance Levels and a statement of any Performance Credits due against each Performance Level and in aggregate.
- 24.4 The Authority shall be entitled to audit the Supplier's compliance with clause 24.2 under clause 24 of Schedule 2.
- 24.5 If Supplier's performance of this Contract does not comply with the Key Performance Levels or else if no report (or a report that does not detail all Key Performance Levels that were due to be measured) pursuant to Clause 24.3 of this Schedule 1 is provided by the Supplier (in which case there will be a presumption that all Performance Levels were at Red Level or all such Performance Levels in respect of which the report is incomplete, were at Red Level), the

Authority shall be entitled to a Performance Credit payable by the Supplier in respect of those Performance Levels as set out in Schedule 10.

- 24.6 Performance Credits shall be a debt due by the Supplier to the Authority for the Quarter to which they relate which the Authority may set off against any amount the Authority owes to the Supplier. Performance Credits shall be deducted by the Supplier from the Contract Price in the invoice issued in accordance with Commercial Schedule following the determination of the Performance Credits due in accordance with the reports provided pursuant to clause 24.3. Any Performance Credits not deducted in accordance with this clause 24.6 shall immediately be payable to the Authority as a liquidated debt.
- 24.7 Nothing in this clause 24 shall restrict the Authority's right to claim damages or any other remedy or to terminate this Contract under clause 15 of Schedule 2.
- 24.8 Without prejudice to any of its other rights under this Contract, the Authority shall be entitled to request a draft correction report from the Supplier in the event of a delay or failure in the delivery, completion or performance of any part of the Supplier's obligations under this Contract, including any Amber Level or Red Level rating for any of the Performance Levels (a "Correction Report"). The draft Correction Report must identify the causes of the relevant delay or failure and the steps that the Supplier proposes to take to rectify (where possible) or mitigate the effects of such delay or failure.
- 24.9 The draft Correction Report must be submitted to the Authority for its approval (such approval not to be unreasonably withheld or delayed) promptly after the Supplier becomes aware of any such delay or failure in the delivery, completion or performance of any part of this Contract or promptly following a request from the Authority. The Supplier must incorporate into the revised draft of the Correction Report all reasonable requests or comments raised by the Authority to prevent the recurrence of any delay or failure in the Supplier's performance of this Contract.
- 24.10 The Supplier must, at its own cost, promptly take the steps identified in the Correction Report approved by the Authority to prevent the recurrence of any delay or failure in the Supplier's performance of this Contract.

## **25 Information Requirements**

- 25.1 The Supplier shall provide the information specified in Annex B of Schedule 10 of the Contract in a timely manner and in any event within the applicable time period set out in Annex B of Schedule 10, and shall ensure its accuracy and completeness.
- 25.2 The Supplier shall provide the information specified in Annex B of Schedule 10 in such format as may be prescribed by the Authority from time to time.

## **26 Change Control Process**

- 26.1 Any changes to this Contract, including to the Goods may only be agreed in accordance with the Change Control Process set out in Schedule 11.

## **27 Continuity and Brexit**

- 27.1 The Supplier must ensure, without prejudice to the other provisions of the Contract, that the Goods are available for supply throughout the Term and are licensed for use in England.
- 27.2 Without prejudice to the generality of Key Provision 27.1:
- 27.2.1 Brexit means the withdrawal of the United Kingdom from the European Union and
- 27.2.2 any related circumstances, events, changes or requirements.

- 27.3 The Supplier must take all steps necessary to ensure a seamless transition between any licensing and regulatory regimes which occur in anticipation of, during or as a result of Brexit so that there is no interruption in supply of the Goods.
- 27.4 The Supplier must take all other steps to ensure that there is a continuity of supply of Goods notwithstanding Brexit, including, but without limitation, complying with the Secretary of State for Health and Social Care's letter of 23rd August 2018 headed 'EU Exit – Human medicines supply in a March 2019 'no deal' scenario' and any further relevant guidance published by the UK Government in relation to Brexit.

## **28 Publicity and Announcements**

28.1 The Supplier shall not:

- 28.1.1 make any press announcements or publicise this Contract or its contents in any way; or
- 28.1.2 use the Authority's name or logo in any promotion or marketing or announcement of orders,

except as required by Law, any government or regulatory authority, any court or other authority of competent jurisdiction, without the prior written consent of the Authority, which shall not be unreasonably withheld or delayed.

- 28.1.3 The provisions of this Clause shall apply during the continuance of this Contract and indefinitely after its expiry or termination.

## **Schedule 2**

### **General Terms and Conditions**

#### **Contents**

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30. General

## **1 Supply of Goods**

- 1.1 The Supplier shall supply the Goods ordered by the Authority or any Purchasing Authority (as the case may be) 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 all other 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 training to the extent that such installation, works 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 and/or the Specification and Tender Response Document;
  - 1.1.6 in accordance with the Law and with 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.

In complying with its obligations under this Contract, the Supplier shall, and shall procure that all Staff shall, act in accordance with the NHS values as set out in the NHS Constitution from time to time.

- 1.2 The Supplier shall comply fully with its obligations set out in the Specification and Tender Response Document (to include, without limitation, the Performance Levels and all obligations in relation to the quality, performance characteristics, supply, delivery and installation and training in relation to use of the Goods).
- 1.3 Unless otherwise agreed by the Parties in writing, the Goods shall be new, consistent with any sample, and shall 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 Tender Response Document and the Supplier's response to such requirements) 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 or any Purchasing Authority, the Supplier shall cooperate fully with the Authority or any Purchasing Authority (as the case may be) in relation to the Authority's or any Purchasing Authority's (as the case may be) 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 or any Purchasing Authority (as the case may be) 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 and any Purchasing 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 Delivery**

Any reference in this Clause 2 to the Authority shall - where the Goods have been ordered by a Purchasing Authority or the context so requires - be deemed to be a reference to such Purchasing Authority

- 2.1 The Supplier shall deliver the Goods in accordance with any delivery timescales, delivery dates and delivery instructions (to include, without limitation, as to delivery location and delivery times) set out in the Specification and Tender Response Document, a Consignment Request, or a Purchase Order or as otherwise agreed with the Authority in writing.
- 2.2 Delivery shall be completed when the Goods have been unloaded at the location specified by the Authority and such delivery has been received by a duly authorised agent, employee or location representative of the Authority. The Authority shall procure that such duly authorised agent, employee or location representative of the Authority is at the delivery location at the agreed delivery date and times in order to accept such delivery. Any arrangement by which the Goods are collected by the Authority in return for a discount on the Contract Price shall be agreed by the Parties in writing (where due to an emergency such arrangements cannot be committed to writing prior to collection, the Parties shall confirm such arrangements in writing as soon as possible following collection). Where the Authority collects the Goods, collection is deemed delivery for the purposes of the Contract.
- 2.3 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 and Tender Response Document or as otherwise agreed with the Authority in writing. Where such information requirements as to the content of delivery notes are not specified or separately agreed, such delivery notes shall, as a minimum, contain the Authority's order number, the name and address of the Authority, a description and quantity of the Goods, and shall show separately any extra agreed charges for containers and/or any other item not included in the Contract Price or, where no charge is made, whether the containers are required to be returned.
- 2.4 Part deliveries and/or deliveries outside of the agreed delivery times/dates may be refused unless the Authority has previously agreed in writing to accept such deliveries. Where delivery of the Goods is refused by the Authority in accordance with this Clause 2.4 of this Schedule 2, the Supplier shall be responsible for all risks, costs and expenses associated with the re-delivery of the Goods in accordance with the agreed delivery times/dates. Where the Authority accepts delivery more than five (5) days before the agreed delivery date, the Authority shall be entitled to charge the Supplier for the costs of insurance and storage of the Goods until the agreed date for delivery.
- 2.5 Unless otherwise set out in the Specification and Tender Response Document or agreed with the Authority in writing, the Supplier shall be responsible for carriage, insurance, transport, all relevant licences, all related costs, and all other costs associated with the delivery of the Goods to the delivery location and unloading of the Goods at that location. Without limitation to the foregoing provision of this Clause 2.5 of this Schedule 2, unless otherwise stated in the Specification and Tender Response Document or agreed with the Authority in writing, the Supplier shall be responsible for obtaining all export and import licences for the Goods and shall be responsible for any delays to the delivery time due to such licences not being available when required. In the case of any Goods supplied from outside the United Kingdom, the Supplier shall ensure that accurate information is provided to the Authority as to the country of origin of the Goods and shall be liable to the Authority for any extra duties or taxes for which the Authority may be accountable should the country of origin prove to be different from that set out in the Specification and Tender Response Document.

- 2.6 All third party carriers engaged to deliver the Goods shall at no time be an agent 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.

### **3 Passing of risk and ownership**

Any reference in this Clause 3 to the Authority shall - where the Goods have been ordered by a Purchasing Authority or the context so requires - be deemed to be a reference to such Purchasing Authority

- 3.1 Risk in the Goods shall pass to the Authority when the Goods are delivered as specified in this Contract or, in the case of Goods which require installation by the Supplier, when that installation process is complete.
- 3.2 Ownership of the Goods shall pass to the Authority on the earlier of:
- 3.2.1 full payment for such Goods; or
  - 3.2.2 where the goods are consumables or are non-recoverable (e.g. used in clinical procedures), at the point such Goods are taken into use. For the avoidance of doubt, where ownership passes in accordance with this Clause 3.2.2 of this Schedule 2, then the full Contract Price for such Goods shall be recoverable by the Supplier from the Authority as a debt if there is non-payment of a valid undisputed invoice issued by the Supplier to the Authority in relation to such Goods.
- 3.3 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.

### **4 Inspection, rejection, return and recall**

Any reference in this Clause 3 to the Authority shall - where the Goods have been ordered by a Purchasing Authority or the context so requires - be deemed to be a reference to such Purchasing Authority

- 4.1 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 in compliance the requirements of this Contract and/or that stock holding and quality assurance processes are in accordance with the requirements of this Contract.
- 4.2 Without prejudice to the provisions of Clause 4.6 of this Schedule 2 and subject to Clause 4.7 of this Schedule 2, the Authority shall visually inspect the Goods within a reasonable time following delivery (or such other period as may be set out in the Key Provisions, if any) 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.
- 4.3 Without prejudice to the provisions of Clause 4.5 of this Schedule 2, upon the rejection of any Goods in accordance with Clauses 4.2 and/or 4.6 of this Schedule 2, the Supplier shall at the Authority's written request:
- 4.3.1 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

- 4.3.2 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 4.5 of this Schedule 2.

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.

- 4.4 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 4.3 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 and charge the Supplier for the cost of storage from the expiry of ten (10) Business Days from the date of notification of rejection.
- 4.5 Where the Authority rejects any Goods in accordance with Clauses 4.2 and/or 4.6 of this Schedule 2 and the Authority no longer requires replacement Goods, 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.
- 4.6 Without prejudice to any other provisions of this Contract or any other warranties or guarantees applicable to the Goods supplied and subject to Clause 4.7 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:
- 4.6.1 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 repairing such Defective Goods; or
- 4.6.2 upon written notice of rejection from the Authority, treat such Defective Goods as Rejected Goods in accordance with Clauses 4.2 to 4.5 of this Schedule 2.
- 4.7 The Supplier shall be relieved of its liabilities under Clauses 4.2 to 4.5 (inclusive) and/or Clause 4.6 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.
- 4.8 The Authority's rights and remedies under Clause 4.6 of this Schedule 2 shall cease within a reasonable period of time from the date on 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 in no event 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 Tender Response Document.
- 4.9 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:
- 4.9.1 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;

- 4.9.2 from the date of the Requirement to Recall treat the Goods the subject of such recall as Defective Goods in accordance with Clause 4.6 of this Schedule 2;
- 4.9.3 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
- 4.9.4 indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings suffered or incurred by the Authority as a result of such Requirement to Recall.

## **5 Staff and Life Science Industry Accredited Credentialing Register**

- 5.1 The Supplier will employ sufficient Staff to ensure that it complies with its obligations under this Contract. This will include, but not be limited to, the Supplier providing a sufficient reserve of trained and competent Staff during Staff holidays or absence.
- 5.2 The Supplier shall ensure that all Staff are aware of, and at all times comply with, the Policies.
- 5.3 The Supplier shall employ only such persons as are careful, skilled and experienced in the duties required of them, and will ensure that every such person is properly and sufficiently trained and instructed and shall maintain throughout the Term all appropriate licences and registrations with any relevant bodies (at the Supplier's expense) and has the qualifications to carry out their duties.
- 5.4 The Supplier shall comply with the Authority's staff vetting procedures and other staff protocols, as may be relevant to this Contract and which are notified to the Supplier by the Authority in writing.
- 5.5 Unless otherwise confirmed by the Authority in writing, the Supplier shall ensure full compliance (to include with any implementation timelines) with any Guidance issued by the Department of Health and Social Care and/or any requirements and/or Policies issued by the Authority (to include as may be set out as part of any procurement documents leading to the award of this Contract) in relation to the adoption of, and compliance with, any scheme or schemes to verify the credentials of Supplier representatives that visit NHS premises (to include use of the Life Science Industry Accredited Credentialing Register). Once compliance with any notified implementation timelines has been achieved by the Supplier, the Supplier shall, during the Term, maintain the required level of compliance in accordance with any such Guidance, requirements and Policies.

## **6 Business continuity**

- 6.1 The Supplier shall use reasonable endeavours to ensure its Business Continuity Plan operates effectively alongside the Authority's business continuity plan (and that of each Purchasing Authority) where relevant to the supply of the Goods. The Supplier shall also ensure that its Business Continuity Plan complies on an ongoing basis with any specific business continuity requirements, as may be set out in the Specification and Tender Response Document.
- 6.2 Throughout the Term, the Supplier will ensure its Business Continuity Plan provides for continuity during a Business Continuity Event. The Supplier confirms and agrees such Business Continuity Plan details and will continue to detail robust arrangements that are reasonable and proportionate to:
  - 6.2.1 the criticality of this Contract to the Authority; and

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

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

- 6.3 The Supplier shall test its Business Continuity Plan at reasonable intervals, and in any event no less than once every twelve (12) months or such other period as may be agreed between the Parties taking into account the criticality of this Contract to the Authority and the size and scope of the Supplier's business operations. The Supplier shall promptly provide to the Authority, at the Authority's written request, copies of its Business Continuity Plan, reasonable and proportionate documentary evidence that the Supplier tests its Business Continuity Plan in accordance with the requirements of this Clause 6.3 of this Schedule 2 and reasonable and proportionate information regarding the outcome of such tests. The Supplier shall provide to the Authority a copy of any updated or revised Business Continuity Plan within fourteen (14) Business Days of any material update or revision to the Business Continuity Plan.
- 6.4 The Authority may suggest reasonable and proportionate amendments to the Supplier regarding the Business Continuity Plan at any time. Where the Supplier, acting reasonably, deems such suggestions made by the Authority to be relevant and appropriate, the Supplier will incorporate into the Business Continuity Plan all such suggestions made by the Authority in respect of such Business Continuity Plan. Should the Supplier not incorporate any suggestion made by the Authority into such Business Continuity Plan it will explain the reasons for not doing so to the Authority.
- 6.5 Should a Business Continuity Event occur at any time, the Supplier shall implement and comply with its Business Continuity Plan and provide regular written reports to the Authority on such implementation.
- 6.6 During and following a Business Continuity Event, the Supplier shall use reasonable endeavours to continue to supply the Goods in accordance with this Contract.

## **7 The Authority's obligations**

Any reference in this Clause 7 to the Authority shall - where the Goods have been ordered by a Purchasing Authority or the context so requires - be deemed to be a reference to such Purchasing Authority

- 7.1 Subject to the Supplier supplying the Goods in accordance with this Contract, the Authority will pay the Supplier for the Goods in accordance with Clause 9 of this Schedule 2.
- 7.2 The Authority shall, as appropriate, provide copies of or give the Supplier access to such of the Policies that are relevant to the supply and delivery of the Goods.
- 7.3 The Authority shall comply with the Authority's Obligations, as may be referred to in the Key Provisions.
- 7.4 The Authority shall provide the Supplier with any reasonable and proportionate cooperation necessary to enable the Supplier to comply with its obligations under this Contract. The Supplier shall at all times provide reasonable advance written notification to the Authority of any such cooperation necessary in circumstances where such cooperation will require the Authority to plan for and/or allocate specific resources in order to provide such cooperation.

## **8 Contract management**

- 8.1 Each Party shall appoint and retain a Contract Manager who shall be the 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.

- 8.2 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 and Tender Response Document. Should the Specification and Tender Response Document 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.
- 8.3 Two weeks prior to each review meeting (or at such time and frequency as may be specified in the Specification and Tender Response Document) 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:
- 8.3.1 details of the performance of the Supplier when assessed in accordance with the Performance Levels as set out in Schedule 10 ;
  - 8.3.2 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 last review meeting written report;
  - 8.3.3 the information specified in the Commercial Schedule, Specification and Tender Response Document (as the case may be);
  - 8.3.4 a status report in relation to the implementation of any current Remedial Proposals by either Party; and
  - 8.3.5 such other information as reasonably required by the Authority.
- 8.4 Unless specified otherwise in the Specification and Tender Response Document, 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.
- 8.5 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. The Supplier shall supply the management information to the Authority in such form as may be specified by the Authority and, where requested to do so, the Supplier shall also provide such management information to another 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.

- 8.6 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:
- 8.6.1 storing and analysing the management information and producing statistics; and
  - 8.6.2 sharing the management information or any statistics produced using the management information with any other Contracting Authority.
- 8.7 If the Third Party Body and/or the Authority shares the management information or any other information provided under Clause 8.6 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).
- 8.8 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 written notice of any changes.

## **9 Price and payment**

Any reference in this Clause 9 to the Authority shall - where the Goods have been ordered by a Purchasing Authority or the context so requires - be deemed to be a reference to such Purchasing Authority

- 9.1 The Contract Price shall be calculated as set out in the Commercial Schedule.
- 9.2 Unless otherwise stated in the Commercial Schedule the Contract Price:
- 9.2.1 shall remain fixed during the Term; and
  - 9.2.2 is the entire price payable by the Authority to the Supplier in respect of the provision of the Goods and includes, without limitation:
    - (i) packaging, packing materials, addressing, labelling, loading, delivery to and unloading at the delivery location, the cost of any import or export licences, all appropriate taxes (excluding VAT), duties and tariffs, any expenses arising from import and export administration, any installation costs and associated works, the costs of all associated documentation and information supplied or made accessible to the Authority in any media, and any training in relation to the use, storage, handling or operation of the Goods;
    - (ii) 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 11 of this Schedule 2; and
    - (iii) 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.

- 9.3 Unless stated otherwise in the Commercial Schedule:
- 9.3.1 where the Key Provisions confirm that the payment profile for this Contract is monthly in arrears, the Supplier shall invoice the Authority, within fourteen (14) days of the end of each calendar month, the Contract Price in respect of the Goods supplied in compliance with this Contract in the preceding calendar month;
  - 9.3.2 where Consigned Goods are to be provided by the Supplier in accordance with the Key Provisions, the Supplier shall invoice the Authority in relation to such Consigned Goods in accordance with the relevant Key Provision applicable to such Consigned Goods; or
  - 9.3.3 where Clauses 9.3.1 or 9.3.2 of this Schedule 2 do not apply, the Supplier shall invoice the Authority for Goods at any time following completion of the supply of the Goods in compliance with this Contract.

Each invoice shall contain such information and be addressed to such individual as the Authority may inform the Supplier from time to time.

- 9.4 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.
- 9.5 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.
- 9.6 The Authority shall verify and pay each valid and undisputed invoice received in accordance with Clause 4 of Schedule 6 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 4 of Schedule 6, the invoice shall be regarded as valid and undisputed for the purposes this Clause 9.6 after a reasonable time has passed.
- 9.7 Where the Authority raises a query with respect to an invoice the Parties shall liaise with each other and agree a resolution to such query within thirty (30) days of the query being raised. If the Parties are unable to agree a resolution within thirty (30) days the query shall be referred to dispute resolution in accordance with the Dispute Resolution Procedure. For the avoidance of doubt, the Authority shall not be in breach of any of its payment obligations under this Contract in relation to any queried or disputed invoice sums unless the process referred to in this Clause 9.7 of this Schedule 2 has been followed and it has been determined that the queried or disputed invoice amount is properly due to the Supplier and the Authority has then failed to pay such sum within a reasonable period following such determination.
- 9.8 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 Clause 24.6 of Schedule 1 and the Commercial Schedule. For the avoidance of doubt, the Authority may invoice the Supplier for such sums or deductions at any time in the event that they have not automatically been credited to the Authority in accordance with the provisions of Clause 24.6 of Schedule 1 and the Commercial Schedule. Such invoice shall be paid by the Supplier within 30 days of the date of such invoice.

- 9.9 The Authority reserves the right to set-off:
- 9.9.1 any monies due to the Supplier from the Authority as against any monies due to the Authority from the Supplier under this Contract; and
  - 9.9.2 any monies due to the Authority from the Supplier as against any monies due to the Supplier from the Authority under this Contract.
- 9.10 Where the Authority is entitled to receive any sums (including, without limitation, any costs, charges or expenses) from the Supplier under this Contract, the Authority may invoice the Supplier for such sums. Such invoices shall be paid by the Supplier within 30 days of the date of such invoice.
- 9.11 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.

## **10 Warranties**

Any reference in this Clause 10 to the Authority shall - where the Goods have been ordered by a Purchasing Authority or the context so requires - be deemed to be a reference to such Purchasing Authority

- 10.1 The Supplier warrants and undertakes that:
- 10.1.1 the Goods shall be suitable for the purposes and/or treatments as referred to in the Specification and Tender Response Document, be of satisfactory quality, fit for their intended purpose and shall comply with the standards and requirements set out in this Contract;
  - 10.1.2 unless otherwise confirmed by the Authority in writing (to include, without limitation, as part of the Specification and Tender Response Document), it will ensure that the Goods comply with requirements five (5) to eight (8), as set out in Annex 1 of the Cabinet Office Procurement Policy Note - Implementing Article 6 of the Energy Efficiency Directive (Action Note 07/14 3rd June 2014), to the extent such requirements apply to the relevant Goods;
  - 10.1.3 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;
  - 10.1.4 without prejudice to the generality of the warranty at 10.1.3 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;
  - 10.1.5 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;
  - 10.1.6 it has, or the manufacturer of the Goods has, manufacturing and warehousing capacity sufficient to comply with its obligations under this Contract;
  - 10.1.7 it will ensure sufficient stock levels to comply with its obligations under this Contract;

- 10.1.8 it shall ensure that the transport and delivery of the Goods mean that they are delivered in good and useable condition;
- 10.1.9 where the Goods are required to be stored at a certain temperature, it shall provide, or shall procure the provision of, complete and accurate temperature records for each delivery of the Goods during the period of transport and/or storage of the Goods from the point of manufacture to the point of delivery to the Authority;
- 10.1.10 where there is any instruction information, including without limitation patient information leaflets, that accompany the Goods, it shall provide a sufficient number of copies to the Authority and provide updated copies should the instruction information change at any time during the Term;
- 10.1.11 all Goods delivered to the Authority shall comply with any shelf life requirements set out in the Specification and Tender Response Document;
- 10.1.12 it has and shall maintain a properly documented system of quality controls and processes covering all aspects of its obligations under this Contract and/or under Law and/or Guidance and shall at all times comply with such quality controls and processes;
- 10.1.13 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);
- 10.1.14 it shall not make any significant changes to the Goods without the prior written consent of the Authority, such consent not to be unreasonably withheld or delayed;
- 10.1.15 any equipment it uses in the manufacture, delivery, or installation of the Goods shall comply with all relevant Law and Guidance, be fit for its intended purpose and maintained fully in accordance with the manufacturer's specification;
- 10.1.16 where any act of the Supplier requires the notification to and/or approval by any regulatory or other competent body in accordance with any Law and Guidance, the Supplier shall comply fully with such notification and/or approval requirements;
- 10.1.17 it has and shall as relevant maintain all rights, consents, authorisations, licences and accreditations required to supply the Goods;
- 10.1.18 receipt of the Goods by or on behalf of the Authority and use of the Goods or of any other item or information supplied, or made available, to the Authority will not infringe any third party rights, to include without limitation any Intellectual Property Rights;
- 10.1.19 it will comply with all Law, Guidance, Policies and the Supplier Code of Conduct in so far as is relevant to the supply of the Goods;
- 10.1.20 it will promptly notify the Authority of any health and safety hazard which has arisen, or the Supplier is aware may arise, in connection with the Goods and take such steps as are reasonably necessary to ensure the health and safety of persons likely to be affected by such hazards;
- 10.1.21 it shall: (i) comply with all relevant Law and Guidance and shall use Good Industry Practice to ensure that there is no slavery or human trafficking in its supply chains; and (ii) notify the Authority immediately if it becomes aware of any actual or suspected incidents of slavery or human trafficking in its supply chains;

- 10.1.22 it shall at all times conduct its business in a manner that is consistent with any anti-slavery Policy of the Authority and shall provide to the Authority any reports or other information that the Authority may request as evidence of the Supplier's compliance with this Clause 10.1.22 and/or as may be requested or otherwise required by the Authority in accordance with its anti-slavery Policy.
  - 10.1.23 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);
  - 10.1.24 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 Specification and Tender Response Document and Commercial Schedule) and all accompanying materials is accurate;
  - 10.1.25 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;
  - 10.1.26 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;
  - 10.1.27 all necessary actions to authorise the execution of and performance of its obligations under this Contract have been taken before such execution;
  - 10.1.28 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;
  - 10.1.29 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;
  - 10.1.30 it has and will continue to have the capacity, funding and cash flow to meet all its obligations under this Contract; and
  - 10.1.31 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.
- 10.2 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:
- 10.2.1 at the point such Goods are supplied to the Authority, all such Goods which are medical devices shall have valid CE marking 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 10.2 of this Schedule 2, the Supplier shall, upon written request from the Authority, make available to the Authority evidence of the grant of such valid CE marking, and evidence of any other authorisations, registrations, approvals or documentation required;

- 10.2.2 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 10.2 of this Schedule 2, 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
- 10.2.3 it shall maintain, and no later than any due date when it would otherwise expire, obtain a renewal of, any authorisation, registration or approval (including without limitation CE marking and/or marketing authorisation) required in relation to the Goods in accordance with Law and Guidance until such time as the Goods expire or the Authority notifies the Supplier in writing that it has used or disposed of all units of the Goods supplied under this Contract.
- 10.3 If the Supplier is in breach of Clause 10.2 of this Schedule 2, then, without prejudice to any other right or remedy of the Authority, the Authority shall be entitled to reject and/or return the Goods and the Supplier shall, subject to Clause 13.2 of this Schedule 2, indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings suffered or incurred by the Authority as a result of such breach.
- 10.4 The Supplier agrees to use reasonable endeavours to assign to the Authority upon request the benefit of any warranty, guarantee or similar right which it has against any third party manufacturer or supplier of the Goods in full or part.
- 10.5 The Supplier warrants that all information, data and other records and documents required by the Authority as set out in the Specification and Tender Response Document shall be submitted to the Authority in the format and in accordance with any timescales set out in the Specification and Tender Response Document.
- 10.6 The Supplier warrants and undertakes to the Authority that it shall comply with any eProcurement Guidance as it may apply to the Supplier and shall carry out all reasonable acts required of the Supplier to enable the Authority to comply with such eProcurement Guidance.
- 10.7 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:
- 10.7.1 notify the Authority in writing of such fact within five (5) Business Days of its occurrence; and
- 10.7.2 promptly provide to the Authority:
- (i) 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
  - (ii) such other information in relation to the Occasion of Tax Non-Compliance as the Authority may reasonably require.

10.8 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 Clause 10 of this Schedule 2 have been breached or there is a risk that any warranties may be breached.

10.9 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.

## **11 Intellectual property**

Any reference in this Clause 11 to the Authority shall - where the Goods have been ordered by a Purchasing Authority or the context so requires - be deemed to be a reference to such Purchasing Authority

11.1 Unless specified otherwise in the Specification and Tender Response Document, 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.

## **12 Indemnity**

Any reference in this Clause 12 to the Authority shall - where the Goods have been ordered by a Purchasing Authority or the context so requires - be deemed to be a reference to such Purchasing Authority

12.1 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:

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

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

12.1.3 any breach of Clause 10.1.18 and/or Clause 11 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.

12.2 Liability under Clauses 12.1.1 and 12.1.3 of this Schedule 2 and Clause 2.5 of Schedule 3 shall be unlimited. Liability under Clauses 4.9.4, 10.3, and 12.1.2 of this Schedule 2 shall be subject to the limitation of liability set out in Clause 13 of this Schedule 2.

12.3 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:

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

12.3.2 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).

### **13 Limitation of liability**

Any reference in this Clause 13 to the Authority shall - where the Goods have been ordered by a Purchasing Authority or the context so requires - be deemed to be a reference to such Purchasing Authority

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

13.1.1 for death or personal injury resulting from its negligence;

13.1.2 for fraud or fraudulent misrepresentation; or

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

13.2 Subject to Clauses 12.2, 13.1, 13.3 and 13.5 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.

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

13.3.1 extra costs incurred purchasing replacement or alternative goods;

13.3.2 costs incurred in relation to any product recall;

13.3.3 costs associated with advising, screening, testing, treating, retreating or otherwise providing healthcare to patients;

13.3.4 the costs of extra management time; and/or

13.3.5 loss of income due to an inability to provide health care services,

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.

13.4 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.

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

- 13.5.1 is less than or equal to one million pounds (£1,000,000), then the figure of five million pounds (£5,000,000) at Clause 13.2 of this Schedule 2 shall be replaced with one million pounds (£1,000,000);
  - 13.5.2 is less than or equal to three million pounds (£3,000,000) but greater than one million pounds (£1,000,000), then the figure of five million pounds (£5,000,000) at Clause 13.2 of this Schedule 2 shall be replaced with three million pounds (£3,000,000);
  - 13.5.3 is equal to, exceeds or will exceed ten million pounds (£10,000,000), but is less than fifty million pounds (£50,000,000), then the figure of five million pounds (£5,000,000) at Clause 13.2 of this Schedule 2 shall be replaced with ten million pounds (£10,000,000) and the figure of one hundred and twenty five percent (125%) at Clause 13.2 of this Schedule 2 shall be deemed to have been deleted and replaced with one hundred and fifteen percent (115%); and
  - 13.5.4 is equal to, exceeds or will exceed fifty million pounds (£50,000,000), then the figure of five million pounds (£5,000,000) at Clause 13.2 of this Schedule 2 shall be replaced with fifty million pounds (£50,000,000) and the figure of one hundred and twenty five percent (125%) at Clause 13.2 of this Schedule 2 shall be deemed to have been deleted and replaced with one hundred and five percent (105%).
- 13.6 Clause 13 of this Schedule 2 shall survive the expiry of or earlier termination of this Contract for any reason.

#### **14 Insurance**

Any reference in this Clause 14 to the Authority shall - where the Goods have been ordered by a Purchasing Authority or the context so requires - be deemed to be a reference to such Purchasing Authority

- 14.1 Subject to Clauses 14.2 and 14.3 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 pounds (£5,000,000) or any sum as required by Law unless otherwise agreed with the Authority in writing. These requirements shall not apply to the extent that the Supplier is a member and maintains membership of each of the indemnity schemes run by the NHS Litigation Authority.
- 14.2 Without limitation to any insurance arrangements as required by Law, the Supplier shall put in place and/or maintain the different types and/or levels of indemnity arrangements explicitly required by the Authority, if specified in the Key Provisions.
- 14.3 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 Clauses 14.1 and 14.2 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.
- 14.4 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.
- 14.5 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.

- 14.6 The Supplier shall from time to time and in any event within five (5) Business Days of written demand provide documentary evidence to the Authority that insurance arrangements taken out by the Supplier pursuant to Clause 14 of this Schedule 2 and the Key Provisions are fully maintained and that any premiums on them and/or contributions in respect of them (if any) are fully paid.
- 14.7 Upon the expiry or earlier termination of this Contract, the Supplier shall ensure that any ongoing liability it has or may have arising out of this Contract shall continue to be the subject of appropriate indemnity arrangements for the period of twenty one (21) years from termination or expiry of this Contract or until such earlier date as that liability may reasonably be considered to have ceased to exist.

## **15 Term and termination**

- 15.1 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.

- 15.2 The Parties may, by agreement in writing, extend the Term on one or more occasions no less than three (3) months prior to the date on which this Contract would otherwise have expired, provided that the duration of this Contract shall be no longer than the total term specified in the Key Provisions.

- 15.3 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 Performance Levels and, subject to Clause 9.7 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 15.4(ii) 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:

- 15.3.1 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;
- 15.3.2 comply with such Remedial Proposal (including, without limitation, as to its timescales for implementation, which shall be thirty (30) days unless otherwise agreed between the Parties); and/or
- 15.3.3 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 15.4(ii) of this Schedule 2, a material breach of this Contract by the Party in breach not remedied in accordance with an agreed Remedial Proposal.

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

- (i) not capable of remedy; or
- (ii) in the case of a breach capable of remedy, which is not remedied in accordance with a Remedial Proposal.

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

- 15.5.1 the Supplier, or any third party guaranteeing the obligations of the Supplier under this Contract, ceases or threatens to cease carrying on its business; suspends making payments on any of its debts or announces an intention to do so; is, or is deemed for the purposes of any Law to be, unable to pay its debts as they fall due or insolvent; enters into or proposes any composition, assignment or arrangement with its creditors generally; takes any step or suffers any step to be taken in relation to its winding-up, dissolution, administration (whether out of court or otherwise) or reorganisation (by way of voluntary arrangement, scheme of arrangement or otherwise) otherwise than as part of, and exclusively for the purpose of, a bona fide reconstruction or amalgamation; has a liquidator, trustee in bankruptcy, judicial custodian, compulsory manager, receiver, administrative receiver, administrator or similar officer appointed (in each case, whether out of court or otherwise) in respect of it or any of its assets; has any security over any of its assets enforced; or any analogous procedure or step is taken in any jurisdiction;
  - 15.5.2 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;
  - 15.5.3 the Supplier purports to assign, Sub-contract, novate, create a trust in or otherwise transfer or dispose of this Contract in breach of Clause 28.1 of this Schedule 2;
  - 15.5.4 pursuant to and in accordance with the Key Provisions and Clauses 15.6, 23.8; 25.2; 25.4 and 29.2 of this Schedule 2; or
  - 15.5.5 the warranty given by the Supplier pursuant to Clause 10.7 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 10.7 of this Schedule 2, or the Supplier fails to provide details of proposed mitigating factors as required by Clause 10.7 of this Schedule 2 that in the reasonable opinion of the Authority are acceptable;
  - 15.5.6 the Supplier incurs Performance Credits pursuant to Schedule 10 for two (2) consecutive Quarters; or
  - 15.5.7 the Supplier is obliged to provide 3 Correction Reports in any twelve(12) months;
- 15.6 If the Authority, acting reasonably, has good cause to believe that there has been a material deterioration in the financial circumstances of the Supplier and/or any third party guaranteeing the obligations of the Supplier under this Contract and/or any material Sub-contractor of the Supplier when compared to any information provided to and/or assessed by the Authority as part of any procurement process or other due diligence leading to the award of this Contract to the Supplier or the entering into a Sub-contract by the Supplier, the following process shall apply:
- 15.6.1 the Authority may (but shall not be obliged to) give notice to the Supplier requesting adequate financial or other security and/or assurances for due performance of its material obligations under this Contract on such reasonable and proportionate terms

as the Authority may require within a reasonable time period as specified in such notice;

- 15.6.2 a failure or refusal by the Supplier to provide the financial or other security and/or assurances requested in accordance with Clause 15.6 of this Schedule 2 in accordance with any reasonable timescales specified in any such notice issued by the Authority shall be deemed a breach of this Contract by the Supplier and shall be referred to and resolved in accordance with the Dispute Resolution Procedure; and
- 15.6.3 a failure to resolve such breach in accordance with such Dispute Resolution Procedure by the end of the escalation stage of such process shall entitle, but shall not compel, the Authority to terminate this Contract in accordance with Clause 15.4(i) of this Schedule 2.

In order that the Authority may act reasonably in exercising its discretion in accordance with Clause 15.6 of this Schedule 2, the Supplier shall provide the Authority with such reasonable and proportionate up-to-date financial or other information relating to the Supplier or any relevant third party entity upon request.

- 15.7 The Authority may terminate this Contract by issuing a Termination Notice to the Supplier where:
  - 15.7.1 the Contract has been substantially amended to the extent that the Public Contracts Regulations 2015 require a new procurement procedure;
  - 15.7.2 the Authority has become aware that the Supplier should have been excluded under Regulation 57(1) or (2) of the Public Contracts Regulations 2015 from the procurement procedure leading to the award of this Contract;
  - 15.7.3 the Contract should not have been awarded to the Supplier in view of a serious infringement of obligations under European law declared by the Court of Justice of the European Union under Article 258 of the Treaty on the Functioning of the EU; or
  - 15.7.4 there has been a failure by the Supplier and/or one of its Sub-contractors to comply with legal obligations in the fields of environmental, social or labour Law. Where the failure to comply with legal obligations in the fields of environmental, social or labour Law is a failure by one of the 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 15.7.4.
- 15.8 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 Clause 15.5.1 to Clause 15.5.3 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.

## **16 Consequences of expiry or early termination of this Contract**

- 16.1 Upon expiry or earlier termination of this Contract, the Authority agrees to pay the Supplier for the Goods which have been supplied by the Supplier and not rejected by the Authority in accordance with this Contract prior to expiry or earlier termination of this Contract.
- 16.2 The Supplier shall cooperate fully with the Authority or, as the case may be, any replacement supplier during any re-procurement and handover period prior to and following the expiry or earlier termination of this Contract. This cooperation shall extend to providing access to all information relevant to the operation of this Contract, as reasonably required by the Authority

to achieve a fair and transparent re-procurement and/or an effective transition without disruption to routine operational requirements. Any Personal Data Processed by the Supplier on behalf of the Authority shall be returned to the Authority or destroyed in accordance with the relevant provisions of the Data Protection Protocol.

- 16.3 The expiry or earlier termination of this Contract for whatever reason shall not affect any rights or obligations of either Party which accrued prior to such expiry or earlier termination.
- 16.4 The expiry or earlier termination of this Contract shall not affect any obligations which expressly or by implication are intended to come into or continue in force on or after such expiry or earlier termination.

## **17 Packaging, identification and end of use**

Any reference in this Clause 17 to the Authority shall - where the Goods have been ordered by a Purchasing Authority or the context so requires - be deemed to be a reference to such Purchasing Authority

- 17.1 The Supplier shall comply with all obligations imposed on it by Law relevant to the Goods in relation to packaging, identification, and obligations following end of use by the Authority.
- 17.2 Unless otherwise specified in the Specification and Tender Response Document 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.
- 17.3 The Supplier shall comply with any labelling requirements in respect of the Goods: (a) specified in the Specification and Tender Response Document; (b) agreed with the Authority in writing; and/or (c) required to comply with Law or Guidance.
- 17.4 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.
- 17.5 Unless otherwise set out in the Specification and Tender Response Document or agreed with the Authority in writing, the Supplier shall collect without charge any returnable containers and/or packages (including pallets) within twenty one (21) days of the date of the relevant delivery. Empty containers and/or packages not so removed may be returned by the Authority at the Supplier's expense or otherwise disposed of at the Authority's discretion. The Supplier shall credit the Authority in full for any containers for which the Authority has been charged upon their collection, return and/or disposal by the Authority in accordance with Clause 17.5 of this Schedule 2.

## **18 Coding requirements**

- 18.1 Unless otherwise confirmed and/or agreed by the Authority in writing and subject to Clause 18.2 of this Schedule 2, the Supplier shall ensure full compliance with any Guidance issued by the Department of Health in relation to the adoption of GS1 and PEPPOL standards (to include, without limitation, any supplier compliance timeline and other policy requirements published by the Department of Health in relation to the adoption of GS1 and PEPPOL standards for master data provision and exchange, barcode labelling and purchase to pay transacting).
- 18.2 Once compliance with any published timelines has been achieved by the Supplier pursuant to Clause 18.1 of this Schedule 2, the Supplier shall, during the Term, maintain the required level of compliance relating to the Goods in accordance with any such requirements and Guidance referred to as part of this Contract.

- 18.3 Once product information relating to Goods is placed by the Supplier into a GS1 certified data pool, the Supplier shall, during the Term, keep such information updated with any changes to the product data relating to the Goods.

## **19 Sustainable development**

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

19.1.1 comply with all Policies and/or procedures and requirements set out in the Specification and Tender Response Document in relation to any stated environmental and social and labour requirements, characteristics and impacts of the Goods and the Supplier's supply chain;

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

19.1.3 maintain plans and procedures that support the commitments made as part of the Supplier's significant labour, social and environmental policies, as referred to at Clause 19.1.2 of this Schedule 2.

- 19.2 The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of Clause 19 of this Schedule 2.

## **20 Electronic product information**

- 20.1 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.

- 20.2 The Supplier warrants that the Product Information is complete and accurate as at the date upon which it is delivered to the Authority and that the Product Information shall not contain any data or statement which gives rise to any liability on the part of the Authority following publication of the same in accordance with Clause 20 of this Schedule 2.

- 20.3 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.

- 20.4 The Supplier grants the Authority a perpetual, non-exclusive, royalty free licence to use and exploit the Product Information and any Intellectual Property Rights in the Product Information for the purpose of illustrating the range of goods and services (including, without limitation, the Goods) available pursuant to the Authority's contracts from time to time. Subject to Clause 20.5 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 20.4 of this Schedule 2.

- 20.5 The Authority may reproduce for its sole use the Product Information provided by the Supplier in the Authority's product catalogue from time to time which may be made available on any NHS communications networks in electronic format and/or made available on the Authority's external website and/or made available on other digital media from time to time.

- 20.6 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 20.6 of this Schedule 2 or otherwise under the terms of this Contract.
- 20.7 If requested in writing by the Authority, and to the extent not already agreed as part of the Specification and Tender Response Document, the Supplier and the Authority shall discuss and seek to agree in good faith arrangements to use any Electronic Trading System.

## **21 Change management**

- 21.1 The Supplier acknowledges to the Authority that the Authority's requirements for the Goods may change during the Term and the Supplier shall not unreasonably withhold or delay its consent to any reasonable variation or addition to the Specification and Tender Response Document, as may be requested by the Authority from time to time.
- 21.2 Subject to Clause 21.3 of this Schedule 2, any change to the Goods or other variation to this Contract shall only be binding once it has been agreed either: (a) in accordance with the Change Control Process if the Key Provisions specify that changes are subject to a formal change control process; or (b) if the Key Provisions make no such reference, in writing and signed by an authorised representative of both Parties
- 21.3 Any change to the Data Protection Protocol shall be made in accordance with the relevant provisions of that protocol.

## **22 Dispute resolution**

Any reference in this Clause 22 to the Authority shall - where the Goods have been ordered by a Purchasing Authority or the context so requires - be deemed to be a reference to such Purchasing Authority

- 22.1 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).
- 22.2 In the case of a Dispute arising out of or in connection with this Contract the Supplier and the Authority shall make every reasonable effort to communicate and cooperate with each other with a view to resolving the Dispute and follow the procedure set out in Clause 22.3 of this Schedule 2 as the first stage in the Dispute Resolution Procedure.
- 22.3 If any Dispute arises out of the Contract either Party may serve a notice on the other Party to commence formal resolution of the Dispute. The Parties shall first seek to resolve the Dispute by escalation in accordance with the management levels as set out in Clause 5 of the Key Provisions. Respective representatives at each level, as set out in Clause 5 of the Key Provisions, shall have five (5) Business Days at each level during which they will use their reasonable endeavours to resolve the Dispute before escalating the matter to the next level until all levels have been exhausted. Level 1 will commence on the date of service of the Dispute Notice. The final level of the escalation process shall be deemed exhausted on the expiry of five (5) Business Days following escalation to that level unless otherwise agreed by the Parties in writing.
- 22.4 If the procedure set out in Clause 22.3 of this Schedule 2 above has been exhausted and fails to resolve such Dispute, as part of the Dispute Resolution Procedure, the Parties will attempt to settle it by mediation. The Parties shall, acting reasonably, attempt to agree upon a mediator. In the event that the Parties fail to agree a mediator within five (5) Business Days following the exhaustion of all levels of the escalation procedure at Clause 22.3 of this Schedule 2, the

mediator shall be nominated and confirmed by the Centre for Effective Dispute Resolution, London.

- 22.5 The mediation shall commence within twenty eight (28) days of the confirmation of the mediator in accordance with Clause 22.4 of this Schedule 2 or at such other time as may be agreed by the Parties in writing. Neither Party will terminate such mediation process until each Party has made its opening presentation and the mediator has met each Party separately for at least one hour or one Party has failed to participate in the mediation process. After this time, either Party may terminate the mediation process by notification to the other Party (such notification may be verbal provided that it is followed up by written confirmation). The Authority and the Supplier will cooperate with any person appointed as mediator providing them with such information and other assistance as they shall require and will pay their costs, as they shall determine, or in the absence of such determination such costs will be shared equally.
- 22.6 Nothing in this Contract shall prevent:
- 22.6.1 the Authority taking action in any court in relation to any death or personal injury arising or allegedly arising in connection with supply of the Goods; or
- 22.6.2 either Party seeking from any court any interim or provisional relief that may be necessary to protect the rights or property of that Party or that relates to the safety of patients or the security of Confidential Information, pending resolution of the relevant Dispute in accordance with the Dispute Resolution Procedure.
- 22.7 Clause 22 of this Schedule 2 shall survive the expiry of or earlier termination of this Contract for any reason.

### **23 Force majeure**

- 23.1 Subject to Clause 23.2 of this Schedule 2 neither Party shall be liable to the other for any failure to perform all or any of its obligations under this Contract nor liable to the other Party for any loss or damage arising out of the failure to perform its obligations to the extent only that such performance is rendered impossible by a Force Majeure Event.
- 23.2 The Supplier shall only be entitled to rely on a Force Majeure Event and the relief set out in Clause 23 of this Schedule 2 and will not be considered to be in default or liable for breach of any obligations under this Contract if:
- 23.2.1 the Supplier has fulfilled its obligations pursuant to Clause 6 of this Schedule 2;
- 23.2.2 the Force Majeure Event does not arise directly or indirectly as a result of any wilful or negligent act or default of the Supplier; and
- 23.2.3 the Supplier has complied with the procedural requirements set out in Clause 23 of this Schedule 2.
- 23.3 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 to resume the performance of its obligations affected by the Force Majeure Event as soon as practicable.
- 23.4 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.
- 23.5 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.

- 23.6 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.
- 23.7 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.
- 23.8 If the Supplier is prevented from performance of its obligations as a result of a Force Majeure Event, the Authority may at any time if the Force Majeure Event subsists for thirty (30) days or more, terminate this Contract by issuing a Termination Notice to the Supplier.
- 23.9 Following such termination in accordance with Clause 23.8 of this Schedule 2 and subject to Clause 23.10 of this Schedule 2, neither Party shall have any liability to the other.
- 23.10 Any rights and liabilities of either Party which have accrued prior to such termination in accordance with Clause 23.8 of this Schedule 2 shall continue in full force and effect unless otherwise specified in this Contract.

#### **24 Records retention and right of audit**

- 24.1 Subject to any statutory requirement and Clause 24.2 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.
- 24.2 Where any records could be relevant to a claim for personal injury such records shall be kept secure and maintained for a period of twenty one (21) years from the date of expiry or earlier termination of this Contract.
- 24.3 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 having given advance written notice of no less than five (5) Business Days, access to any premises and facilities, books and records reasonably required to audit the Supplier's compliance with its obligations under this Contract.
- 24.4 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, having given advance written notice of no less than five (5) Business Days, access to any premises and facilities, books and records used in the performance of the Supplier's obligations under this Contract that are Sub-contracted to such third party. The Supplier shall cooperate with such audit and inspection and accompany the Authority or its authorised representative if requested.
- 24.5 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:
- 24.5.1 the examination and certification of the Authority's accounts; or

- 24.5.2 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.
- 24.6 The Comptroller and Auditor General may examine such documents as they may reasonably require which are owned, held or otherwise within the control of the Supplier and may require the Supplier to provide such oral and/or written explanations as they consider necessary. Clause 24 of this Schedule 2 does not constitute a requirement or agreement for the examination, certification or inspection of the accounts of the Supplier under sections 6(3)(d) and 6(5) of the National Audit Act 1983.
- 24.7 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.
- 24.8 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.

## **25 Conflicts of interest and the prevention of fraud**

- 25.1 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.
- 25.2 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 25.2 of this Schedule 2 shall not prejudice or affect any right of action or remedy which shall have accrued or shall subsequently accrue to the Authority.
- 25.3 The Supplier shall take all reasonable steps to prevent Fraud by Staff and the Supplier (including its owners, members and directors). The Supplier shall notify the Authority immediately if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur.
- 25.4 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.

## **26 Equality and human rights**

- 26.1 The Supplier shall:
- 26.1.1 ensure that (a) it does not, whether as employer or as supplier of the Goods and any associated services, engage in any act or omission that would contravene the Equality Legislation, and (b) it complies with all its obligations as an employer or supplier of the Goods and any associated services as set out in the Equality Legislation and take reasonable endeavours to ensure its Staff do not unlawfully discriminate within the meaning of the Equality Legislation;
- 26.1.2 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

- 26.1.3 the Supplier shall impose on all its Sub-contractors and suppliers, obligations substantially similar to those imposed on the Supplier by Clause 26 of this Schedule 2.
- 26.2 The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of Clause 26 of this Schedule 2.

## **27 Notice**

Any reference in this Clause 27 to the Authority shall - where the context so requires - be deemed to be a reference to a Purchasing Authority

- 27.1 Subject to Clause 22.5 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 one Party may inform the other Party in writing from time to time.
- 27.2 A notice shall be treated as having been received:
- 27.2.1 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
- 27.2.2 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
- 27.2.3 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.

## **28 Assignment, novation and Sub-contracting**

- 28.1 The Supplier shall not, except where Clause 28.2 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.
- 28.2 Notwithstanding Clause 28.1 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 28.2 of this Schedule 2 shall be subject to:
- 28.2.1 the deduction of any sums in respect of which the Authority exercises its right of recovery under Clause 9.9 of this Schedule 2;
- 28.2.2 all related rights of the Authority in relation to the recovery of sums due but unpaid;

- 28.2.3 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;
  - 28.2.4 the provisions of Clause 9 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
  - 28.2.5 payment to the Assignee being full and complete satisfaction of the Authority's obligation to pay the relevant sums in accordance with this Contract.
- 28.3 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.
- 28.4 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:
- 28.4.1 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;
  - 28.4.2 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;
  - 28.4.3 contain a prohibition on the Sub-contractor Sub-contracting, assigning or novating any of its rights or obligations under such Sub-contract without the prior written approval of the Authority (such approval not to be unreasonably withheld or delayed);
  - 28.4.4 contain a right for the Authority to take an assignment or novation of the Sub-contract (or part of it) upon expiry or earlier termination of this Contract;
  - 28.4.5 requires the Supplier or other party receiving goods under the contract to consider and verify invoices under that contract in a timely fashion;
  - 28.4.6 provides that if the Supplier or other party fails to consider and verify an invoice in accordance with Clause 28.4.5 of this Schedule 2, the invoice shall be regarded as valid and undisputed for the purpose of Clause 28.4.7 after a reasonable time has passed;
  - 28.4.7 requires the Supplier or other party to pay any undisputed sums which are due from it to the Sub-contractor within a specified period not exceeding thirty (30) days of verifying that the invoice is valid and undisputed;
  - 28.4.8 permitting the Supplier to terminate, or procure the termination of, the relevant Sub-contract in the event the Sub-contractor fails to comply in the performance of its Sub-contract with legal obligations in the fields of environmental, social or labour Law where the Supplier is required to replace such Sub-contractor in accordance with Clause 15.7.4 of this Schedule 2;

- 28.4.9 permitting the Supplier to terminate, or to procure the termination of, the relevant Sub-contract where the Supplier is required to replace such Sub-contractor in accordance with Clause 28.5 of this Schedule 2; and
- 28.4.10 requires the Sub-contractor to include a clause to the same effect as this Clause 28.4 of this Schedule 2 in any Sub-contract which it awards.
- 28.5 Where the Authority considers that the grounds for exclusion under Regulation 57 of the Public Contracts Regulations 2015 apply to any Sub-contractor, then:
- 28.5.1 if the Authority finds there are compulsory grounds for exclusion, the Supplier shall ensure, or shall procure, that such Sub-contractor is replaced or not appointed; or
- 28.5.2 if the Authority finds there are non-compulsory grounds for exclusion, the Authority may require the Supplier to ensure, or to procure, that such Sub-contractor is replaced or not appointed and the Supplier shall comply with such a requirement.
- 28.6 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.
- 28.7 The Authority shall upon written request have the right to review any Sub-contract entered into by the Supplier in respect of the provision of the Goods and the Supplier shall provide a certified copy of any Sub-contract within five (5) Business Days of the date of a written request from the Authority. For the avoidance of doubt, the Supplier shall have the right to redact any confidential pricing information in relation to such copies of Sub-contracts.
- 28.8 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.

## **29 Prohibited Acts**

- 29.1 The Supplier warrants and represents that:
- 29.1.1 it has not committed any offence under the Bribery Act 2010 or done any of the following ("**Prohibited Acts**"):
- (i) offered, given or agreed to give any officer or employee of the Authority or any Purchasing Authority (as the case may be) any gift or consideration of any kind as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining or performance of this or any other agreement with the Authority or any Purchasing Authority (as the case may be) for showing or not showing favour or disfavour to any person in relation to this or any other agreement with the Authority or any Purchasing Authority (as the case may be); or

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

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

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

29.2.1 the Authority shall be entitled:

- (i) to terminate this Contract and recover from the Supplier the amount of any loss resulting from the termination;
- (ii) to recover from the Supplier the amount or value of any gift, consideration or commission concerned; and
- (iii) to recover from the Supplier any other loss or expense sustained in consequence of the carrying out of the Prohibited Act or the commission of the offence under the Bribery Act 2010;

29.2.2 any termination under Clause 29.2.1 of this Schedule 2 shall be without prejudice to any right or remedy that has already accrued, or subsequently accrues, to the Authority; and

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

- (i) the interpretation of Clause 29 of this Schedule 2; or
- (ii) the amount or value of any gift, consideration or commission,

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

### **30 General**

Any reference in this Clause 30 to the Authority shall - where the Goods have been ordered by a Purchasing Authority or the context so requires - be deemed to be a reference to such Purchasing Authority

30.1 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.

30.2 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.

30.3 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.

- 30.4 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.
- 30.5 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.
- 30.6 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.
- 30.7 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 30.7 of this Schedule 2, right includes any power, privilege, remedy, or proprietary or security interest.
- 30.8 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.
- 30.9 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.
- 30.10 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.
- 30.11 Subject to Clause 22 of this Schedule 2, the Parties irrevocably agree that the courts of England and Wales shall have non-exclusive jurisdiction to settle any Dispute or claim that arises out of or in connection with this Contract or its subject matter.
- 30.12 All written and oral communications and all written material referred to under this Contract shall be in English.

## Schedule 3

### Information and Data Provisions

#### **1 Confidentiality**

- 1.1 In respect of any Confidential Information it may receive directly or indirectly from the other Party ("**Discloser**") and subject always to the remainder of Clause 1 of this Schedule 3, each Party ("**Recipient**") undertakes to keep secret and strictly confidential and shall not disclose any such Confidential Information to any third party without the Discloser's prior written consent provided that:
- 1.1.1 the Recipient shall not be prevented from using any general knowledge, experience or skills which were in its possession prior to the Commencement Date;
- 1.1.2 the provisions of Clause 1 of this Schedule 3 shall not apply to any Confidential Information:
- (i) which is in or enters the public domain other than by breach of this Contract or other act or omissions of the Recipient;
  - (ii) which is obtained from a third party who is lawfully authorised to disclose such information without any obligation of confidentiality;
  - (iii) which is authorised for disclosure by the prior written consent of the Discloser;
  - (iv) 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
  - (v) which the Recipient is required to disclose purely to the extent to comply with the requirements of any relevant stock exchange.
- 1.2 Nothing in Clause 1 of this Schedule 3 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 (the Parties agree that all Contracting Authorities receiving such Confidential Information shall be entitled to further disclose the Confidential Information to other Contracting Authorities on the basis that the information is confidential and is not to be disclosed to a third party which is not part of any Contracting Authority);
  - 1.3.2 on a confidential basis, to any consultant, contractor or other person engaged by the Authority and/or the Contracting Authority receiving such information;
  - 1.3.3 to any relevant party for the purpose of the examination and certification of the Authority's accounts;

- 1.3.4 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;
- 1.3.5 to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirements; or
- 1.3.6 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 of this Schedule 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 Clause 1 of this Schedule 3 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 Clause 1 of this Schedule 3 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 three (3) years after the expiry or earlier termination of this Contract unless otherwise agreed in writing by the Parties.

## **2 Data protection**

- 2.1 The Parties acknowledge their respective duties under Data Protection Legislation and shall give each other all reasonable assistance as appropriate or necessary to enable each other to comply with those duties. For the avoidance of doubt, the Supplier shall take reasonable steps to ensure it is familiar with the Data Protection Legislation and any obligations it may have under such Data Protection Legislation and shall comply with such obligations.
- 2.2 Where the Supplier is Processing Personal Data under or in connection with this Contract, the Parties shall comply with the Data Protection Protocol.
- 2.3 The Supplier and the Authority shall ensure that Personal Data is safeguarded at all times in accordance with the Law, and this obligation will include (if transferred electronically) only transferring Personal Data (a) if essential, having regard to the purpose for which the transfer is conducted; and (b) that is encrypted in accordance with any international data encryption standards for healthcare, and as otherwise required by those standards applicable to the

Authority under any Law and Guidance (this includes, data transferred over wireless or wired networks, held on laptops, CDs, memory sticks and tapes).

- 2.4 Where any Personal Data is Processed by any Sub-contractor of the Supplier in connection with this Contract, the Supplier shall procure that such Sub-contractor shall comply with the relevant obligations set out in Clause 2 of this Schedule 3, as if such Sub-contractor were the Supplier.
- 2.5 The Supplier shall indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings whatsoever or howsoever arising from the Supplier's unlawful or unauthorised Processing, destruction and/or damage to Personal Data in connection with this Contract.

### **3 Freedom of Information and Transparency**

- 3.1 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.
- 3.2 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:
- 3.2.1 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;
- 3.2.2 that the decision on whether any exemption to the general obligations of public access to information applies to any request for information received under the FOIA, Codes of Practice and Environmental Regulations is a decision solely for the Authority;
- 3.2.3 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;
- 3.2.4 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;
- 3.2.5 that the Authority, acting in accordance with the Codes of Practice issued and revised from time to time under both section 45 of FOIA, and regulation 16 of the Environmental Regulations, may disclose information concerning the Supplier and this Contract; and
- 3.2.6 to assist the Authority in responding to a request for information, by processing information or environmental information (as the same are defined in FOIA and the Environmental Regulations) in accordance with a records management system that complies with all applicable records management recommendations and codes of conduct issued under section 46 of FOIA, and providing copies of all information requested by the Authority within five (5) Business Days of that request and without charge.

- 3.3 The Parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and Environmental Regulations, the content of this Contract is not Confidential Information.
- 3.4 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.
- 3.5 In preparing a copy of this Contract for publication under Clause 3.4 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.
- 3.6 The Supplier shall assist and cooperate with the Authority to enable the Authority to publish this Contract.
- 3.7 Where any information is held by any Sub-contractor of the Supplier in connection with this Contract, the Supplier shall procure that such Sub-contractor shall comply with the relevant obligations set out in Clause 3 of this Schedule 3, as if such Sub-contractor were the Supplier.

#### **4 Information Security**

- 4.1 Without limitation to any other information governance requirements set out in this Schedule 3, the Supplier shall:
- 4.1.1 notify the Authority forthwith of any information security breaches or near misses (including without limitation any potential or actual breaches of confidentiality or actual information security breaches) in line with the Authority's information governance Policies; and
  - 4.1.2 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.

#### *Annex - Data Protection Protocol*

## 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>“Amber Level”</b>	means the service standards identified as “amber” in Annex A to Part II of Schedule 10;
<b>“Authority”</b>	means the authority named on the form of Contract on the first page;
<b>“Authority Confirmation”</b>	means the written confirmation provided (or deemed to be provided) by the Authority that the Goods appear to have been correctly supplied, installed and commissioned ready for use;
<b>“Authority’s Obligations”</b>	means the Authority’s further obligations, if any, referred to in the Key Provisions;
<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>“Brexit Legislation”</b>	means the European Union (Withdrawal) Act 2018, the European Union (Withdrawal) Act 2019, the European Union (Withdrawal) (No 2) Act 2019; any other legislation made by the UK Parliament and any delegated or secondary legislation made by Ministers of the UK Government concerning the withdrawal of the UK from the European Union;
<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 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 the supply of the Goods during a Business Continuity Event;
<b>“Business Day”</b>	means any day other than Saturday, Sunday, Christmas Day, Good Friday or a statutory bank holiday in England and Wales;
<b>“Change”</b>	means any change to the Goods or to this Contract initiated through the Change Control Process;
<b>“Change Control Note”</b>	the written record of a Change agreed or to be agreed by the Parties pursuant to the Change Control Process;
<b>“Change Control Process”</b>	means the change control process, set out in Schedule 11;
<b>“Codes of Practice”</b>	shall have the meaning given to the term in Clause 1.2 of Schedule 3;
<b>“Commencement Date”</b>	means [1 April 2022];

<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: <ul style="list-style-type: none"> <li>(a) Personal Data including without limitation which relates to any patient or other service user or his or her treatment or clinical or care history;</li> <li>(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</li> <li>(c) Policies and such other documents which the Supplier may obtain or have access to through the Authority’s intranet;</li> </ul>
<b>“Consigned Goods”</b>	means Goods delivered by the Supplier in response to a Consignment Request prior to their use by the Authority;
<b>“Consignment Request”</b>	the Authority’s request for Goods to be delivered on a consignment basis;
<b>“Contract”</b>	means the form of contract at the front of this document and all schedules attached to the form of contract;
<b>“Contract Year”</b>	means any 12-month period starting on the Commencement Date and on each anniversary of the Commencement Date;
<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 8.1 of Schedule 2;
<b>“Contract Price”</b>	means the sum of [£xxx] per annum 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>“Controller”</b>	shall have the same meaning as set out in the GDPR;
<b>“Correction Report”</b>	has the meaning given under Clause 24.8 of Schedule 1;
<b>“Data Protection Legislation”</b>	means (i) the Data Protection Act 1998 or, from the date it comes into force, the Data Protection Act 2018 to the extent that it relates to processing of personal data and privacy; (ii) the GDPR, the Law Enforcement Directive (Directive (EU) 2016/680) and any applicable national implementing Law as amended from time to time; and (iii) all applicable Law about the processing of personal data and privacy;
<b>“Data Protection Protocol”</b>	means any document of that name as provided to the Supplier by the Authority (as amended from time to time in accordance with its terms), which shall include, without limitation, any such document appended to Schedule 3 (Information and Data Provisions) of this Contract;

<b>“Defective Goods”</b>	has the meaning given under Clause 4.6 of Schedule 2;
<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 and/or Installation and Commissioning Services and/or Maintenance Services, 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 22 of Schedule 2 or, where Clause 22 of Schedule 1 of the Contract applies, the process for resolving Disputes as set out in Schedule 9. For the avoidance of doubt, the Dispute Resolution Procedure is subject to Clause 29.2.3 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>“Environmental Regulations”</b>	shall have the meaning given to the term in Clause 1.2 of Schedule 3;
<b>“eProcurement Guidance”</b>	means the NHS eProcurement Strategy available via: <a href="http://www.gov.uk/government/collections/nhs-procurement">http://www.gov.uk/government/collections/nhs-procurement</a> together with any further Guidance issued by the Department of Health in connection with it;
<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 and the Fixed-term Employees (Prevention of Less Favourable Treatment) Regulations 2002 (SI 2002/2034) and the Human Rights Act 1998;
<b>“FOIA”</b>	shall have the meaning given to the term in Clause 1.2 of Schedule 3;

<b>“Force Majeure Event”</b>	<p>means any event beyond the reasonable control of the Party in question to include, without limitation:</p> <ul style="list-style-type: none"> <li>(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;</li> <li>(b) acts of terrorism;</li> <li>(c) flood, storm or other natural disasters;</li> <li>(d) fire;</li> <li>(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;</li> <li>(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;</li> <li>(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;</li> <li>(h) industrial action which affects the ability of the Supplier to supply the Goods, but which is not confined to the workforce of the Supplier or the workforce of any Sub-contractor of the Supplier; and</li> <li>(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;</li> </ul> <p>but excluding, for the avoidance of doubt, the withdrawal of the United Kingdom from the European Union and any related circumstances, events, changes or requirements;</p>
<b>“Fraud”</b>	<p>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;</p>
<b>GDPR</b>	<p>means the General Data Protection Regulation (Regulation (EU) 2016/679);</p>
<b>“General Anti-Abuse Rule”</b>	<p>means</p> <ul style="list-style-type: none"> <li>(a) the legislation in Part 5 of the Finance Act 2013; and</li> <li>(b) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid national insurance contributions;</li> </ul>
<b>“Good Industry Practice”</b>	<p>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</p>

	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>“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 the Supplier’s response to these requirements);
<b>“Green Level”</b>	means the service standards identified as “green” in Annex A to Part II of Schedule 10;
<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 Department of Health, Monitor, NHS England, the Medicines and Healthcare Products Regulatory Agency, the European Medicine Agency the European Commission, 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>“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>“Invoice Price”</b>	means the sum of £[xxx] to be paid by Purchasing Authorities per pack of [xx] of the Goods supplied by the Supplier;
<b>“Key Provisions”</b>	means the key provisions set out in Schedule 1;
<b>“Key Performance Levels”</b>	mean those Performance Levels which attract Performance Credits as set out in Schedule 10;
<b>“Law”</b>	means any applicable legal requirements including, without limitation,: a) any applicable statute or proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument as applicable in England and Wales; b) any applicable European Union obligation, directive, regulation, decision, law or right (including any such obligations, directives, regulations, decisions, laws or rights that are incorporated into the law of England and Wales or given effect in England and Wales by any applicable statute, proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument); c) any enforceable community right within the meaning of section 2(1) European Communities Act 1972 (but only if and to the extent expressly retained or remaining in force pursuant to the Brexit Legislation);

	<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>“Minimum Quantity”</b>	has the meaning given under Clause 23.7 of Schedule 1;
<b>“NHS”</b>	means the National Health Service;
<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 is found on or after 1 April 2013 to be incorrect as a result of:</p> <p>(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;</p> <p>(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</p> <p>(b) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Effective Date or to a civil penalty for fraud or evasion;</p>
<b>“Party”</b>	means the Authority or the Supplier as appropriate and Parties means both the Authority and the Supplier;
<b>“Performance Credits”</b>	means the performance credits calculated in accordance with the mechanism described in Schedule 10;
<b>“Performance Levels”</b>	means the performance levels set out in Schedule 10;
<b>“Performance Monitoring System”</b>	means the performance monitoring system set out in in Schedule 10;
<b>“Performance Period”</b>	means a Quarter, save as expressly set out in Schedule 10;
<b>“Personal Data”</b>	shall have the same meaning as set out in the GDPR;
<b>“Policies”</b>	means the policies, rules and procedures of the Authority as notified to the Supplier from time to time;
<b>“Premises and Locations”</b>	means the Authority’s premises and locations where the Goods are to be installed, commissioned and located.

<b>“Process”</b>	shall have the same meaning as set out in the GDPR. Processing and Processed shall be construed accordingly;
<b>“Processor”</b>	shall have the same meaning as set out in the GDPR;
<b>“Procurement”</b>	means the procurement process leading up to the award of this Contract to the Supplier;
<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 20 of Schedule 2 for inclusion in the Authority's product catalogue from time to time;
<b>“Purchase Order”</b>	means the purchase order required by the Authority's financial systems, if a purchase order is referred to in the Key Provisions;
<b>“Purchasing Authority”</b>	means the following entities <a href="#">[insert link to CMU list]</a> and any successor bodies of the above
<b>“Quarter”</b>	means a period of three consecutive calendar months, ending on 31 March, 30 June, 30 September or 31 December save that the first quarter shall be calculated from the Commencement Date and the last quarter shall end on the last day of this Contract, and ‘Quarterly’ shall be interpreted accordingly;
<b>“Red Level”</b>	means the service standards identified as “red” in Annex A to Part II of Schedule 10;
<b>“Rejected Goods”</b>	has the meaning given under Clause 4.2 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 15.3 of Schedule 2;
<b>“Requirement to Recall”</b>	has the meaning given under 4.9 of Schedule 2;
<b>“Returned Goods”</b>	has the meaning given under Clause 23.8 of Schedule 1;
<b>“Returns Notice”</b>	has the meaning given under Clause 23.8 of Schedule 1;
<b>“Sales Report”</b>	has the meaning given under Clause 23.5 of Schedule 1;
<b>“Specification and Tender Response Document”</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>“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>“Supplier”</b>	means the supplier named on the form of Contract on the first page;
<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>“Term”</b>	means the term as set out in the Key Provisions;
<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 8.5 of Schedule 2; and
<b>“VAT”</b>	means value added tax chargeable under the Value Added Tax Act 1994 or any similar, replacement or extra tax.

- 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 References to any legal entity shall include any body that takes over responsibility for the functions of such entity.
- 1.4 References in this Contract to a “Schedule”, “Appendix”, “Paragraph” or to a “Clause” are to schedules, appendices, paragraphs and clauses of this Contract.
- 1.5 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.
- 1.6 Unless set out in the Commercial Schedule as a chargeable item and subject to Clause 30.6 of Schedule 2, the Supplier shall bear the cost of complying with its obligations under this Contract.
- 1.7 The headings are for convenience only and shall not affect the interpretation of this Contract.
- 1.8 Words denoting the singular shall include the plural and vice versa.
- 1.9 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.
- 1.10 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.
- 1.11 Where a document is required under this Contract, the Parties may agree in writing that this shall be in electronic format only.
- 1.12 Any guidance notes in grey text do not form part of this Contract.
- 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.

## **Schedule 5**

### **Specification and Tender Response Document**

**[To be inserted as part of the final Contract]**

#### **SPECIFICATION PART A**

##### **1. Delivery**

- The Suppliers shall maintain a 24 hour delivery service between Monday & Friday (orders placed after 17:00 on Thursday may be delivered on Monday) plus an emergency service to facilitate weekend or out of hours deliveries if required by the Purchasing Authority.
- Any Goods supplied by the Supplier shall have at least 12 months remaining shelf life at the date of delivery.

##### **2. Surety of Supply**

- The Suppliers shall maintain within the supply chain, sufficient capacity to satisfy 30 months of the anticipated demand in England, reflecting England's usage in comparison to the rest of the world.
- The Suppliers shall maintain physically within England, sufficient stock to satisfy at least 6 months of the anticipated demand in England.
- The Suppliers shall maintain supply capability and capacity to replenish stock in the England within 90 days of order placement.

##### **3. Supplier Commitments**

- The Supplier shall comply with the Supplier Commitments specified in Table 2 of Schedule 10.

##### **4. Reporting**

- The Supplier shall provide such reports and at such times as specified in Schedule 10.

## **SPECIFICATION PART B - Contract Technical Specification for Licensed Medicines for the NHS - April 2011**

### **5. General Requirements (Supplementary to Regulatory Requirements)**

#### **1.1 Critical information**

Critical information is defined as:

- ❖ The generic name of the medicine
  - ❖ The strength of the medicine
  - ❖ The form of the medicine
  - ❖ The route of administration
  - ❖ Posology
  - ❖ Warnings
- All critical information must be present and clear on both the label and packaging where appropriate (this includes small containers such as ampoules and vials)
  - The name of the medicine expressed on the packaging should be the same as registered in the summary of product characteristics (SPC). NB this will be the brand name for a proprietary product, but the generic name should also be clearly expressed. No Abbreviations
  - If the medicine contains more than one active ingredient, all generic names should be clearly stated on the pack. 'Co-' names should be as registered on the SPC and labelled as part of the name
  - Strengths should be clearly expressed and unambiguous
  - Base and salt strengths should be clearly defined where appropriate
  - The brand name should not be similar to another generic or brand name in either appearance or sound
  - For injections, the strength should be expressed both as total quantity per total volume and as amount per unit dose (e.g. milligrams per ml) where appropriate. Trailing zeros should not be used. Microgram doses should be spelt out rather than abbreviated. (**NB** pay special attention to different strengths/concentrations across injection product ranges).

#### **1.2 User Information**

- Only positive statements should be used on labels e.g. 'For intravenous use only'. Negative statements such as 'not for intrathecal use' should not be used
- All patient packs should include a patient information leaflet (PIL)
- The PIL should comply with current regulatory requirements.

#### **1.3 Pack Design**

- The pack design should comply with the principles of the "*MHRA Best Practice Guidance on Labelling and Packaging*" and the "*NPSA Guidelines on Packaging and Labelling*"
- The critical information should be given due prominence and located together in the same field of view where practicable (i.e. these items should not be broken up by additional information, logos, background texts or graphics)

- When the name of the medicine is a brand name, the generic name of the active ingredient should preferably be given prominence, but as a minimum standard be clear, easy to read and be in the same field of view as the critical information. There should be no intervening text
- The generic name and strength should appear on at least three non-opposing sides of pack (including “shelf” end)
- The batch number and expiry date should be present and legible, particularly when embossing is used rather than print. The expiry date should be unambiguously expressed (e.g. “use before” or if using “expires”, the full date of expiry should be expressed in day/month/year)
- Temperature storage conditions should be clearly stated on both the primary and secondary packaging
- Products that are sensitive to light should be labelled with “protect from light”. For these products, the primary packaging should be designed to protect the product from light (not just the secondary packaging), especially when the product is commonly removed from the secondary packaging and stored locally (e.g. vials in aseptic units and infusions in clinical areas)
- Colour should be used judiciously to aid identification of critical information
- Patient packs should have a space for placement of the dispensing label. This should be a blank white space in which there is no text, to aid legibility of the dispensing label. Where it is not possible to employ a blank space, the pack should be of a colour that will not interfere with the readability of the dispensing label.

#### **1.4 Corporate Livery**

- There should be good differentiation between different medicines within the corporate livery of the company. Consideration should be given to similar or look-alike names (INN and Brand) and potential problems associated with storage due to alphabetical location
- There should be good differentiation between strengths within the product range
- There should be good differentiation between dosage forms within product range
- There should be good differentiation between different formulations of the same product intended for different parenteral routes (e.g. intravenous and intrathecal).

#### **1.5 Dose Administration**

- Instructions for dosage manipulation should be clear and unambiguous (consideration should be given as to who will be administering the medicine)
- If complicated calculations are required to calculate the dose (e.g. dilutions, conversions from milligrams to millimols, mg/kg dosing in children etc.), unambiguous instructions, conversion tables and/or labelling should be provided
- If specific end user counselling is required, clear patient instructions should be provided to aid this process (e.g. inhalation devices used in asthma treatment)
- If additional devices are required to administer a dose, this should be supplied with the medicine along with clear instructions for its use
- Medicines should be in a ready to administer or use dosage form whenever possible. If reconstitution or serial dilution is required, instructions must be prominent, clear and unambiguous

- The SPC or sufficient technical information to ensure the safe administration of the medicine should be included in the packaging, especially where the medicine requires further manipulation by health professionals (e.g. fluid compatibility and infusion rates for injections).

## 1.6 Technical Data

- The recommended diluents should be clearly stated in the SPC and/or packaging
- The shelf life and specified storage conditions following opening or reconstitution should be clearly stated in the SPC and on the packaging
- For injectable medicines, where the formulation differs from the brand leader, this should be indicated and full formulation details provided, including a list of excipients
- Stability and compatibility data should be provided for injectable medicines commonly prepared as infusions in aseptic units. Data should be comparable to the brand leader and should include:
  - ❖ Physico-chemical compatibility with common diluents (sodium chloride 0.9%, glucose 5% etc)
  - ❖ Physico-chemical compatibility with common containers and packaging (polypropylene, glass, PVC etc)
  - ❖ Route of chemical degradation
  - ❖ Physico-chemical compatibility with other drugs
  - ❖ Degradation rate
  - ❖ Shelf life determination studies at 4°C and 25°C in line with the NHS guidance document "Standard Protocol for Deriving and Assessment of Stability Part 1 Aseptic Preparations (Small Molecules) Edition 2 2011 (see below)
  - ❖ Data relating to vial compatibility with common reconstitution devices should be provided where possible e.g. minibag plus, vial mate.

## 1.7 Product Quality

- The product must match the tender product description e.g. sugar free if stated; powders should not be substituted for liquids
- Pack closures should be tamper evident
- Patient packs should have child resistant closures
- Powders intended for dissolution should dissolve easily
- All packaging should be latex free.

## 1.8 Licensing

- The medicine must be licensed for use in the UK
- The licensed routes of administration should be clear and obvious

## 1.9 Robot Compatibility

- The pack integrity, dimensions, shape and layout should be compatible with automated dispensing systems
- As a minimum a unique EAN13 Bar code should be present on the pack and placed in line with GS1 guidance

- There should be no changes to the bar code during the product life.

### **1.10 Health and Safety Issues**

- The container should be free from external contamination. Preparations containing cytotoxic medicines or antibiotics should have been externally cleaned to remove contamination
- Containers containing cytotoxic medicines should be clearly labelled with a suitable warning on both primary and secondary packaging
- Cytotoxic products should be presented in fracture resistant containers.

## **2. Dose Form Specific Requirements**

### **2.1 Solid Oral Dosage forms**

- Should be provided in patient or blister packs or glass bottles
- Tablets /capsules in blister packs should be easily 'popped out' and the blister pack should have no sharp edges
- The name & strength of the medicine should be printed legibly over each blister or oriented repeatedly across strip
- Tablets and capsules should be marked for easy identification
- There should be no evidence of damage or lack of dose uniformity in tablets
- Scored tablets should be easily halved
- Data should be provided to demonstrate that all generic slow or modified release preparations conform to the bioavailability and release profile of the originator formulation.

### **2.2 Liquid Oral Dosage Forms**

- Oral liquid medicines should be sugar free when specified and alcohol free unless essential to the formulation. Where alcohol or sugar is present in the formulation, this should be clearly declared on the label. Where alcohol is present, the label should clearly state the alcohol content in weight per volume. NB non-cariogenic sugars that are suitable for diabetics are acceptable in sugar free formulations (e.g. liquid maltitol)
- The volume for reconstitution of oral liquids should be stated where applicable
- Suspensions and emulsions should re-suspend easily upon shaking
- The taste of liquid formulations should be acceptable for all patient groups and details of the flavour of the formulation should be provided
- Details of any excipients in the formulation should be provided (name & strength)
- The shelf life following reconstitution or opening should be clearly stated on the container where applicable
- If there is any reduction in the shelf life reduction following opening of the container, this should be clearly stated on the packaging.

### **2.3 Injectable Dosage forms**

- Injections should be in a ready to administer or use presentation wherever possible. Solutions should be offered rather than powders for reconstitution where formulation allows
- Ampoules should be labelled longitudinally
- A bar code should be present on the primary packaging
- There should be good differentiation between different formulations of the same product intended for different parenteral routes (e.g. intravenous and intrathecal)
- Displacement values should be provided for any injection requiring reconstitution
- Diluent compatibility data should be provided for any injectable dosage form that requires dilution or reconstitution prior to infusion
- Labels on vials/ampoules intended for use in aseptic units should be resistant to spraying and wiping with alcohol
- Primary packaging should be easy to disinfect and not provide “dust traps” e.g. some fracture resistant containers
- Vials intended for reconstitution must be of sufficient size to allow reconstitution in line with the SPC and with the volume of diluent commonly used in aseptic units (not just to allow bolus administration at ward level)
- Vials should be compatible with commonly used reconstitution and docking devices where appropriate.

#### **2.4 Crystalloid Intravenous Infusions**

- Compatible with the range of giving sets currently in use
- Able to be used with suitable pressure devices for intra-arterial infusions
- Compatible with most commonly used reconstitution devices
- Tamper evident port seal available
- Additive port design should minimise risk of microbial contamination
- Products should be double- wrapped and sterile within the outer wrap if commonly used in aseptic units
- Outer boxes should be robust and offer adequate protection to the inner products containers
- A user friendly product coding system should be available on the outer box
- Product identification labelling should be present on at least three non-opposing sides, including one face end of the outer container
- Data should be provided to demonstrate compatibility with a wide range of medicines commonly reconstituted in CIVA and cytotoxic preparation services
- Potassium containing solutions should be well differentiated from other products.

#### **2.5 Eye Preparations**

- Labelling should be as clear as possible to facilitate use by visually impaired patients

- Products should be preserved unless there is a clinical need for them not to be. The name and strength of the preservative should be clearly stated on the packaging.

## **Schedule 6**

### **Commercial Schedule**

#### **1 Payment for Goods**

1.1 Subject always to the Supplier's compliance with the terms of this Contract, the Authority shall:

1.1.1 by the end of the first Quarter, pay the Supplier 25% of the Contract Price less the value of Purchasing Authority purchases in the first Quarter; and

1.1.2 by the end of each subsequent Quarter, pay the Supplier 25% of the Contract Price, less the value of:

- (i) Purchasing Authority purchases in the applicable Quarter, and
- (ii) any deductions for Service Credits due for the applicable Quarter/s.

Where:

- the value of Purchasing Authority purchases is calculated in accordance with Clause 2.3 of this Schedule 6; and;
- the value of any deductions for Service Credits due under this Contract is calculated in accordance with Schedule 10.

#### **2 Purchasing Authority Purchases**

2.1 Purchasing Authorities may, from time to time, purchase the Goods from the Supplier (or via their respective supply route) at the Invoice Price.

2.2 Changes to the Invoice Price (if any) will be undertaken accordance with the Change Control Process set out in Schedule 11.

2.3 The value of Goods purchased by Purchasing Authorities each Quarter will be calculated as follows:

- Number of packs of Goods supplied for the applicable Quarter x the Invoice Price

2.4 The quantity of Goods supplied to Purchasing Authorities shall be determined and verified by reference to the information to be provided by the Parties to one another as set out in Annex B of Schedule 10.

#### **3 Extension of the Contract Term**

3.1 Notwithstanding any extension of the Term in accordance with Clause 15.2 of Schedule 2, the Contract Price shall in no circumstances exceed:

- (i) ten (10) million pounds sterling; or
- (ii) **[insert bid price]**

whichever is the lower.

#### **4 Invoicing**

4.1 The Supplier's shall invoice the Authority within 30 days of the end of each Quarter in printed and electronic form in any format reasonably requested by the Authority.

4.2 The invoices referred to in 4.1 of this Schedule 6:

4.2.1 shall be for a sum equal to 25% of the Contract Price less

- (i) the value of any Purchasing Authority purchases in the applicable Quarter,
- (ii) the value of any deductions for Service Credits due under this Contract for applicable Quarter/s.

Each invoice shall be supported by such information and be addressed to such individual as the Authority may inform the Supplier from time to time, including (but not limited to) the following information:

- (i) *25% of the Contract Price*
- (ii) *Purchasing Authority purchases*
- (iii) *Service Credits*

4.3 Without prejudice to Clause 9.7 of Schedule 2, where the quantity of Goods supplied to Purchasing Authorities cannot be agreed within 30 days of the end of each Quarter, the Supplier may submit an invoice in respect of the quantity of Goods supplied to Purchasing Authorities that is undisputed.

4.4 The Supplier shall invoice the Purchasing Authorities in respect of the Goods supplied in compliance with this Contract in accordance with the terms of the Purchase Orders issued by the Purchasing Authorities.

#### **5 Quarterly Reconciliation Report**

5.1 Following the end of each Quarter, the Authority shall provide a Quarterly Reconciliation Report (QRR) to the Supplier.

5.2 The QRR shall set out, as appropriate, for each Quarter and each Contract Year (as the case may be):

- a) The Contract Price payable to the Supplier;
- b) The income received by the Supplier from Purchasing Authority purchases;
- c) The value of any Service Credits due for the applicable Quarter/s;
- d) The quantum of any sum owed by one party to the other.

**Schedule 7**

**NOT USED**

**Schedule 8**

**NOT USED**

**Schedule 9**

**NOT USED**

## Schedule 10

### Performance Levels and Performance Credits

**DRAFTING NOTE:** The final form of this Schedule 10 is subject to the outcome and recommendations of the HTA. The final version of this Schedule 10 will be agreed between the Authority and Supplier in light of the HTA recommendations, however this version reflects the material principles and methodology agreed between the parties to date. The Parties agree that this Schedule 10 shall only be amended to the extent necessary to reflect the recommendations of the HTA

#### **Part I Performance Monitoring**

The Supplier acknowledges that accurate monitoring is an obligation of the Supplier under this Contract and any inaccuracy may constitute a material breach of this Contract. Annex A specifies the minimum monitoring requirements.

#### **Part II Performance Credits**

##### **1. Introduction**

##### **1.1 Key Performance Levels and Performance Credits:** This Part II:

1.1.1 identifies in Annex A the Key Performance Levels (as defined below) that the Authority views as fundamental and which, as a result, attract Performance Credits; and

1.1.2 sets out the mechanism for calculating Performance Credits.

1.2 **Other Performance Levels:** To the extent that the Supplier's obligations to supply the Goods (the "Performance Requirements") do not have an associated Key Performance Level, they shall remain an integral part of the Contract and the Supplier must meet the Performance Levels for each aspect of the Performance Requirements regardless of the fact that no Performance Credits apply in the event of failure to achieve the same. The fact that no Performance Credits apply to a Performance Level shall not prejudice the Authority's other rights and remedies under this Contract or at law in respect of failure by the Supplier to meet Performance Levels.

##### **2. Definitions**

2.1 **Key Performance Levels:** means the six (6) Performance Levels in Table 1, Annex A of this Schedule to which the Performance Credit regime outlined in this Schedule will be applied as at the Commencement Date,

##### **3 Performance Levels and Key Performance Levels**

##### **3.1 Not Used**

3.2 **Performance Levels:** Table 1, Annex A to this Schedule sets out the required Performance Levels for various aspects of this Contract.

3.3 **Warranty:** The Supplier warrants and undertakes that each report provided by the Supplier pursuant to (i) clause 24.3 of this Contract and (ii) Annex B of this Schedule 10 will be accurate in all material respects.

3.4 **Performance Bands:** Measured performance shall fall into three colour-coded bands, the colour coding of which is designed to help identify problem areas for management attention. Satisfactory performance will be categorised as "Green Level" and a failure to deliver an

element of the Performance Requirements will be classified as either “Amber Level or Red Level depending on the degree of failure.

3.5 **Performance Credits:** Performance Credits will be calculated and redeemable as set out at Clause 6 below.

#### 4. **Escalation**

4.1 **Escalation of problems:** The Quarterly Reports produced by the Supplier will be used as a management tool. Any problems causing any of the Performance Levels to be rated Red Level shall be considered worthy of serious management attention by the Authority and Supplier, but the Supplier will retain the primary obligation to rectify such problems.

5. **Correction reports:** The Supplier must prepare a Correction Report in the circumstances set out in clause 24.8 of Schedule 1 of this Contract.

#### 6. **Calculation of Performance Credits**

6.1 **Application of Performance Credits:** The parties agree that:

- i. Performance Credits are to be calculated on a Quarterly basis save for Performance Level number 2 (as specified in Table 1, Annex A to this Schedule), in respect of which Performance Credits are to be calculated on a monthly basis.
- ii. Performance Failure Points, as specified in Table 1, Annex A to this Schedule 10, will accrue for each Red Level status or Amber Level status achieved in a previous Performance Period.

6.2 **Amount of Performance Credit:** Further:

- i. a Red Level status will be applied to the Supplier's performance against any Performance Level which, calculated as an average over the relevant Performance Period, has been Amber Level for two or more consecutive Performance Periods.
- ii. the number of Performance Failure Points accrued by the Supplier during the relevant period shall be totalled for all of the Performance Levels to arrive at the number of points for the Performance Period. The total number of Performance Failure Points shall be converted into a monetary figure

6.3 **Value attributable to Performance Failure Points:** Each Performance Failure Point shall be worth 0.001 of the Contract Price.

6.4 **Redemption of Performance Credits:** Performance Credits shall be redeemed in accordance with the procedure set out in clause 24.6 of Schedule 1 of this Contract.

6.5 **Double Counting:** To the extent that the same event triggers Performance Credits under Performance Levels 3 and 4 or 5, 6 or 7, the Authority will only claim the largest Performance Credit.

6.6 **Authority right to waive:** Without having any obligation or creating any expectation that it will do so, the Authority may from time to time waive any entitlement to Performance Credits. To be valid, any such waiver shall be in writing expressly referring to the Performance Credits that have accrued.

### **Part III Data Queries and Resolution**

The proposed reporting cycle provides 10 days from receipt of reports for their contents to be queried and a further 10 days for the parties to resolve any queries. If queries are not resolved within these timescales, the remainder of the data/ information will be confirmed as agreed. The parties will then use all reasonable endeavours to resolve any remaining queries within the next 10 working days.

**Annex A of Schedule 10**

**Table 1: Performance Levels**

Ref	Performance Level	Performance Bands			Performance Failure Points		Key Performance Level	Report Frequency	Report Due Date <sup>1</sup>	Response Due Date <sup>2</sup>	Action Date <sup>3</sup>	Reporting Mechanism	
		Green Level	Amber Level	Red Level	Amber Level	Red Level							
<b>Delivery</b>													
1	Report the quantity of packs delivered to each Purchasing Authority and the delivery date <sup>4,5</sup>	N/A	N/A	N/A	N/A	N/A	N	Monthly	15	10	20	Supplier Monthly Activity Report <sup>10,11</sup>	
2	On Time In Full (OTIF): For X out of 100, deliver to Purchasing Authorities by the requested delivery date <sup>6</sup>	$X \geq 95$	$95 > X \geq 90$	$90 > X$	5	10	Y	Monthly	15	10	20	Supplier Monthly OTIF Report <sup>10,11</sup>	
<b>Surety of Supply</b>													
3	Maintain within the supply chain, sufficient capacity to satisfy X months of the anticipated demand in England. Supply chain capacity may include a combination of physical stock in England, manufactured product suitable for the UK and API. See insert for acceptable combinations. $X = Y + Z$ . Y may not be less than 6 months.	$X \geq 30$	$30 > X \geq 24$	$24 > X$	5	10	Y	Quarterly <sup>7</sup>	15	10	20	Forecast of annual usage to be provided to Authority by Commencement Date and then prior to the start of each Contract Year Quarterly Report <sup>11</sup> to include the actual stock holding in England (excluding Purchasing Authorities) for each month of reported quarter and average stock holding over quarter. Every second Quarterly Report to include the average quantity of manufactured product and API for each month during the period.	
		Performance Level subcomponents				Acceptable Green Level Combinations							
		Average quantity of stock physically in England equal to at least Y month's forecast usage in England				$Y \geq 24$	$Y \geq 18$	$Y \geq 12$					$Y \geq 6$
Average quantity of manufactured product (e.g. vials) and API inventory is sufficient to supply at least Z month's forecast usage in England and reflecting England's usage in comparison to the rest of the world.				$Z \geq 6$	$Z \geq 12$	$Z \geq 18$	$Z \geq 24$						
4	Maintain supply capability and capacity to replenish stock in England within X days of order placement	$X \leq 90$	$90 < X \leq 120$	$120 < X$	5	10	Y	Annually <sup>8</sup>	15	10	20	Self-Certification in each Quarterly Report. Each 4 <sup>th</sup> Quarterly Report to include evidence of compliance.	
<b>Stewardship, Manufacturing, Environmental &amp; Surveillance Commitments</b>													
5	Failure to comply with X of the stewardship commitments included in Table 2	$X = 0$	$X = 1$	$X \geq 2$	5	10	Y	Annually <sup>8</sup>	15	10	20	Each 4 <sup>th</sup> Quarterly Report <sup>10,11</sup> to include Self-Certification by the Supplier that the commitments have	

Ref	Performance Level	Performance Bands			Performance Failure Points		Key Performance Level	Report Frequency	Report Due Date <sup>1</sup>	Response Due Date <sup>2</sup>	Action Date <sup>3</sup>	Reporting Mechanism
		Green Level	Amber Level	Red Level	Amber Level	Red Level						
												been maintained together with any information required in Table 2
6	Failure to comply with X of the manufacturing or environmental commitments included in Table 2	X = 0	X = 1	X ≥ 2	5	10	Y	Annually <sup>8</sup>	15	10	20	Each 4 <sup>th</sup> Quarterly Report <sup>10,11</sup> to include Self-Certification by the Supplier that the commitments have been maintained together with any information required in Table 2
7	Failure to comply with X of the following surveillance commitments included in Table 2	X = 0	X = 1	X ≥ 2	5	10	Y	As per EMA <sup>8,9</sup>	15	10	20	Each 4 <sup>th</sup> Quarterly Report <sup>10,11</sup> to include Self-Certification by the Supplier that the commitments have been maintained together with any information required in Table 2

1. The day in the month immediately following the Performance Period, or the next working day if the due date falls on a weekend or bank holiday.
2. The number of working days after receipt of the report to respond or provide feedback.
3. The number of working days after receipt of the report within which the parties shall complete any actions unless mutually agreed otherwise.
4. Together with any other information reasonably requested by the Authority from time to time.
5. The Authority shall not be required to pay the Contract Price for any period unless the Monthly Activity Report for that period has been provided to the satisfaction of the Authority. Any delay to the submission of the Monthly Activity Report may result in an equivalent delay to payment of the Contract Price.
6. Suppliers shall maintain a 24 hour delivery service between Monday & Friday (orders placed after 17:00 on Thursday may be delivered on Monday) plus an emergency service to facilitate weekend or out of hours deliveries if required by the Purchasing Authority.
7. The physical stock holding in England to be reported each quarter, overall supply chain capacity to be reported at least every 6 months.
8. Any non-compliance with the Performance Level is to be reported immediately.
9. Every 6 months for the first 3 years after Marketing Authorisation, then annually unless otherwise directed by the MHRA/EMA.
10. The Authority may seek corroboration of the reported performance from data collated from other sources e.g. Purchasing Authorities
11. See Annex B of this Schedule 10 for minimum report requirements

**Table 2: Supplier Commitment**

Ref	Performance Level	Supplier Commitment	Additional Information
5	Stewardship <sup>1</sup>	1. To delink sales representative remuneration from the quantity of antimicrobial supplied in England and not to otherwise promote or encourage inappropriate use;	
		2. To act and behave in a manner consistent with the principles of good antimicrobial stewardship and to comply with any antimicrobial stewardship recommendations resulting from the HTA and / or PHE and/or published by NICE;	
		3. To support education of healthcare professionals regarding appropriate use of the antimicrobial consistent with good antimicrobial stewardship;	Provide a summary list of the educational events and activities undertaken in the prior 12-month period
6	Manufacturing and environmental practice <sup>2</sup>	1. A signatory to the AMR Industry Alliance Declaration;	Evidence of continued commitment and participation
		2. Compliance with the AMR Industry Alliance manufacturing standards;	Demonstrated compliance, via independent assessment, at each manufacturing site
		3. Compliance with good antimicrobial manufacturing practice throughout the supply chain;	Demonstrated compliance, via independent assessment, at each manufacturing site
		4. Compliance with environmental standards relevant to the manufacture of antimicrobials throughout the supply chain, including compliance with discharge limits at owned and/or supplier manufacturing sites and external wastewater treatment plants;	Demonstrated compliance, via independent assessment, at each manufacturing site
7	Surveillance	1. To monitor for emergence of resistance and to inform the Authority of any emergence of resistance as soon as it is identified (irrespective of where identified) and to share with the Authority any associated information and data;	Periodic Benefit Risk Evaluation Report (PBRER)
		2. To support surveillance efforts in England	To demonstrate participation in the BSAC Registry (if and when initiated) To demonstrate participation in other international surveillance programmes

- For the purpose of this Contract, promotional and educational activity has the meaning as set out in the MHRA Blue Book: advertising and promotion of medicines in the UK (<https://www.gov.uk/guidance/advertise-your-medicines>) and the ABPI Code of Practice (<https://www.abpi.org.uk/our-ethics/abpi-code-of-practice/>). For the duration of this contract, Product promotional and educational activity shall be limited not only to the requirements of the MHRA Blue Book and ABPI Code of Practice but, also to the recommendations and guidance of NICE or restrictions imposed by Purchasing Authorities, where such recommendations, guidance or restrictions have been made.
- Manufacturing site means any Approved Pharmaceutical Ingredient (API) manufacturing site, Drug Substance (DS) manufacturing site or Drug Product (DP) manufacturing site within the Supplier supply chain.

## **Annex B of Schedule 10**

### **Information Exchange**

The Supplier must supply to the Authority (in such format as may be prescribed by the Authority from time to time) the information set out below:

#### **1. Supplier Monthly Reporting Activity Report (Draft)**

The Supplier shall provide to the Authority by the due date specified in Table 1, a report including as a minimum:

- i. Purchasing Authority(ies)
- ii. Product Description & Presentation
- iii. Pack Quantity
- iv. Quantity of Packs Delivered
- v. Delivery Date
- vi. Shelf Life at Delivery

#### **2. Supplier Monthly OTIF Report (Draft)**

The Supplier shall provide to the Authority by the due date specified in Table 1, a report including as a minimum:

- i. Purchasing Authority(ies)
- ii. Product Description & Presentation
- iii. Requested Quantity
- iv. Requested Delivery Date
- v. Actual Quantity Delivered
- vi. Actual Delivery Date
- vii. OTIF (per line)
- viii. OTIF (overall for period)

#### **3. Supplier Quarterly Report (Draft)**

The Supplier shall provide to the Authority by the due date specified in Table 1, a report including as a minimum:

- i. Average quantity of stock physically in the UK;

#### **Additional information to be included in 2<sup>nd</sup> Quarterly Report of each Contract Year**

- i. Average quantity of manufactured product and API in the supply chain for each month and the whole period

#### Additional information to be included in 4th Quarterly Report of each Contract Year

- i. Self-certification that Performance Levels 4, 5, 6 & 7 achieved Green Level performance throughout the reporting period;
- ii. Evidence to support the self-certification.

Examples of acceptable evidence include:

- a. Performance Levels 4:
  - i. a report detailing the purchase order date, requested delivery date and actual delivery date of orders to replenish stock in the UK.

For any Performance Level that fell below the Green Level, the Supplier must provide further details regarding the Amber or Red Level performance, the root cause, how long it remained below Green Level and the corrective action taken and/or planned.

#### **4. Authority Quarterly Reporting (Draft)**

The Authority shall provide to the Supplier by the fifteenth day in the month immediately following the Performance Period, or the next working day if the due date falls on a weekend or bank holiday date, a report including as a minimum:

- i. Purchasing Authority(ies)
- ii. Product Description & Presentation
- iii. Quantity of Packs Delivered in the period (subject to confirming this data is available centrally)
- iv. Quantity of Packs dispensed in the period
- v. If available, why the product was dispensed (e.g. pathogen)

The Authority gives no warranty and makes no representation as to the accuracy of this information, and any failure on the part of the Authority to provide this information shall not be a breach of the Contract or otherwise give rise to any cause of action in favour of the Supplier (but without prejudice to the right of either Party to refer any issue relating to the calculation of the Contract Price to dispute resolution).

## Schedule 11

### Change Control Process

#### **1. General principles**

- 1.1 Where the Authority or the Supplier sees a need to change this Contract, the Authority may at any time request, and the Supplier may at any time recommend, such Change only in accordance with the Change Control Process set out in paragraph 2 of this Schedule 11.
- 1.2 Until such time as a Change is made in accordance with the Change Control Process, the Authority and the Supplier shall, unless otherwise agreed in writing, continue to perform this Contract in compliance with its terms before such Change.
- 1.3 Any discussions which may take place between the Authority and the Supplier in connection with a request or recommendation before the authorisation of a resultant Change shall be without prejudice to the rights of either party.

#### **2. Process**

- 2.1 Discussion between the Authority and the Supplier concerning a Change shall result in any one of the following:
- (a) no further action being taken; or
  - (b) a request to change this Contract by the Authority; or
  - (c) a recommendation to change this Contract by the Supplier.
- 2.2 Where a written request for a Change is received from the Authority, the Supplier shall, unless otherwise agreed, submit a Change Control Note signed by the Supplier to the Authority within three weeks of the date of the request.
- 2.3 The Supplier may reject a request for Change from the Authority pursuant to paragraph 2.2 only if, following a request for Change, it can demonstrate to the reasonable satisfaction of the Authority that the proposed Change:
- (a) requires this Contract to be performed in a way that infringes any Law; or
  - (b) would cause the Supplier to breach the terms of any licence or Consent necessary to supply the Goods; or
  - (c) is technically impossible.
- 2.4 A recommendation to amend this Contract by the Supplier shall be submitted directly to the Authority in the form of a Change Control Note signed by the Supplier at the time of such recommendation. The Authority shall give its response to the Change Control Note within three weeks.
- 2.5 Each Change Control Note shall contain:

- (a) the title of the Change;
- (b) the originator and date of the request or recommendation for the Change;
- (c) the reason for the Change;
- (d) full details of the Change, including any specifications;
- (e) the price, if any, of the Change;
- (f) a timetable for implementation, together with any proposals for acceptance of the Change;
- (g) details of the likely impact, if any, of the Change on other aspects of this Contract including:
  - (i) the timetable for the provision of the Change;
  - (ii) the Contract Price;
  - (iii) the documentation to be provided;
  - (iv) other contractual issues; and
  - (v) the date of expiry of validity of the Change Control Note;

2.6 For each Change Control Note submitted by the Supplier the Authority shall, within the period of the validity of the Change Control Note:

- (a) allocate a sequential number to the Change Control Note; and
- (b) evaluate the Change Control Note and, as appropriate:
  - (i) request further information;
  - (ii) accept the Change Control Note by arranging for the Change Control Note to be signed by or on behalf of the Authority and return a copy to the Supplier;  
or
  - (iii) notify the Supplier of the rejection of the Change Control Note.

2.7 A Change Control Note signed by the Authority and by the Supplier shall constitute an amendment to this Contract.